REGULATORY IMPACT ANALYSIS REPORT ON THE DRAFT ROYAL DECREE REGULATING *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

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EXECUTIVE SUMMARY

Proposing Ministry/Body	Ministry of Health (Spanish Agency of Medicines and Medical Devices)	**Date**	02/01/2025
Title of regulation	Draft Royal Decree regulating *in vitro* diagnostic medical devices.		
Report type	Normal ■ Abridged □		
SUITABILITY OF THE PROPOSAL			
Subject	On 26 May 2017, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU was published. This regulation is directly applicable from 26 May 2022. The transitional periods of this Regulation have subsequently been amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of the conditions applicable to devices manufactured and used exclusively in health institutions. The direct application of Regulation (EU) 2017/746 from 26 May 2022 requires the adaptation of the current rules on *in vitro* diagnostic medical devices, in order to repeal those provisions relating to matters that will be directly regulated by the provisions of that Regulation and, at the same time, to develop the necessary regulatory measures for those aspects in which, in accordance with Regulation (EU) 2017/746, Member States are required to lay down rules at national level.		
Objectives	This norm is necessary to: A) Establish the requirements for genetic information, counselling		

	and informed consent. B) Establish the requirements and procedures for the regulation of devices manufactured and used in a health institution (commonly referred to as 'in-house devices'). C) Establish the requirements for notification of *in vitro* diagnostic devices to the Marketing Register. D) Regulate the language rules. E) Establish the requirements for conducting performance evaluations in our country. F) Establish that, as regards Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices, the competent authority is the AEMPS regardless of the competences of other health authorities. The regulation has the following specific objectives regarding *in vitro* diagnostic medical devices: A) Repeal Royal Decree 1662/2000 of 29 September 2000 on *in vitro* diagnostic medical devices by direct application of Regulation (EU) 2017/746 as of 26 May 2022. B) Develop the necessary regulatory measures for those areas where the regulation has determined that it will be the Member States that will lay down the rules at national level. C) Adapt, adopt or maintain the measures required by national legislation.
Main alternatives considered	The possibility of adopting a rule amending the current legislation in the field (Royal Decree 1662/2000 of 29 September 2000), instead of replacing it, has been considered.
CONTENT AND LEGAL ANALYSIS	
Type of standard	Royal Decree
Structure of the regulation	The draft Royal Decree consists of a preamble, nine chapters, thirty-five articles, three additional provisions, nine transitional provisions, one repealing provision and three final provisions.
Reports compiled	•Consultative Committee of the National Health System (Article 67(2) of Law 16/2003 of 28 May 2003 on the Cohesion and Quality of the National Health System). •Interterritorial Council of the National Health System (Article 71 of Law

	16/2003 of 28 May 2003 on the Cohesion and Quality of the National Health System). •Report of the General Technical Secretariat of the Department (Article 26(5), fourth paragraph, of Law 50/1997, of 27 November 1997). •Ministerial Commission on Digital Administration. •Report of the Ministry of Defence (Article 26(5), first paragraph, of Law 50/1997 of 27 November 1997). •Report of the Ministry of Finance and Civil Service (Article 26(5), first paragraph, of Law 50/1997 of 27 November 1997). •Report of the Ministry of Industry, Trade and Tourism (Article 26(5), first paragraph, of Law 50/1997 of 27 November). •Report of the Ministry of Economic Affairs and Digital Transformation (Article 26(5), first paragraph, of Law 50/1997 of 27 November) •Report of the Ministry of Science and Innovation. Instituto de Salud Carlos III (Article 26(5), first paragraph, of Law 50/1997 of 27 November 1997) •Report of the Ministry of Consumer Affairs (Article 26(5), first paragraph, of Law 50/1997 of 27 November 1997). •Prior approval by the Minister for Digital Transformation and the Civil Service (Article 26(5), fifth paragraph, of Law 50/1997 of 27 November 1997). •Report of the Ministry of Territorial Policy on the adaptation of the draft to the order of distribution of powers between the State and the Autonomous Communities (Article 26(5), sixth paragraph, of Law 50/1997 of 27 November 1997). •Report of the Office for Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Courts (Article 26(9) of Law 50/1997, of 27 November 1997). •Report of the Spanish Data Protection Agency (Article 5.b of Royal Decree 428/1993 of 26 March approving the Statute of the Data Protection Agency). •Report of the National Markets and Competition Commission (Article 5.2 of Law 3/2013 of 4 June, establishing the National Commission for Markets and Competition). •Report of the Consumers and Users Council (Article 2 of Royal Decree 894/2005 of 22 July, regulating the Consumers and Users Council and Article 39.2 of the consolidated text of the General Law for the Protection of Consumers and Users and other complementary laws, approved by Royal Legislative Decree 1/2007 of 16 November). •Autonomous communities and cities of Ceuta and Melilla. • Notification to the European Commission pursuant to Royal Decree 1337/1999 of 31 July 1999 regulating the transmission of information in the field of technical standards and regulations and rules relating to information society services and Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services. •Opinion of the Council of State (Articles 22(2) and 22(3) of Organic Law 3/1980 of 22 April 1980, of the Council of State).

Public consultation process	The public consultation was carried out prior to the drafting of the text of the regulatory initiative, between 23 July 2021 and 8 September 2021, both inclusive. **Attached to this text is <u>ANNEX I, the list of entities consulted during that public consultation procedure.</u>**	
Hearing procedure/Public consultation	Once the text had been drafted, between 13 March and 3 April 2023, the public information procedure on the Department's website was completed, along with the hearing procedure for those associations or organisations that bring together or represent individuals whose rights or legitimate interests are affected by the regulation and whose purposes are directly related to its objective.	
IMPACT ANALYSIS		
COMPLIANCE WITH THE DISTRIBUTION OF POWERS	Article 149(1)(16) of the Spanish Constitution, which grants the State exclusive competence in matters of the foundations and general coordination of health, legislation on pharmaceutical products, except for Chapter VI, which is issued under the exclusive competence of the State in matters of external health.	
ECONOMIC AND BUDGETARY IMPACT	**Overall economic impact.**	
	With regard to competition	☐ The rule has no significant effects on competition. ■ The rule has positive effects on competition. ☐ The rule has negative effects on competition.

	From the point of view of administrative burdens.	☐ Implies a reduction in administrative burdens. Estimated quantification €_____ ■ Incorporates new administrative burdens Estimated quantification: €507,906 ☐ It does not affect administrative burdens
	With respect to budgets, the regulation ■ Affects the budgets of the General State Administration. ☐ Affects the budgets of other Territorial Administrations.	☐ Involves an expense: _____€. ■ Implies income
GENDER IMPACT	The law has a gender impact that is	Negative ☐ Neutral ■ Positive ☐
IMPACT ON CHILDREN AND ADOLESCENTS	No impact is expected.	
IMPACT ON FAMILIES	Having assessed the impact that the regulation could have with respect to the protection of the family, according to the tenth additional provision of Law 40/2003, of 18 November 2003, on the Protection of Large Families, it is considered to have no impact.	
CLIMATE CHANGE IMPACT	Regarding the impact of this regulation on climate change, it is considered to have a positive impact.	
OTHER IMPACTS CONSIDERED	The standard has a positive health impact	
EX POST	Due to the punctual and complementary nature of the modifications	

EVALUATION	undertaken, which constitute only a partial modification of the material area regulated, no *ex post* evaluation is considered necessary.

CONTENTS

This report has been drawn up pursuant to the provisions of Royal Decree 931/2017, of 27 October 2017, regulating the Regulatory Impact Analysis Report.

2. Budgetary impact.
3. Analysis of administrative burdens.
4. Gender impact.
5. Impact on children and adolescents.
6. Impact on the family.
7. Climate change impact.
8. Other impacts.

VII.- *EX POST* EVALUATION

I.- DESIRABILITY OF THE PROPOSAL

1. Rationale.

On 26 May 2017, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU was published. This regulation is directly applicable from 26 May 2022. The transitional periods have subsequently been amended by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022, amending Regulation (EU) 2017/746 as regards the transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of the conditions applicable to devices manufactured and used exclusively in health institutions.

The direct application of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as of 26 May 2022, requires the adaptation of the current national legislation on *in vitro* diagnostic medical devices, in order to repeal those areas relating to matters that will be directly regulated by the provisions of the Regulation and, at the same time, to develop the necessary regulatory measures for aspects where, in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, Member States should establish a regulation at national level.

2. Objectives.

This norm is necessary to:

- Establish the requirements for genetic information, counselling and informed consent.
- Establish the requirements and procedures for the regulation of devices manufactured and used in a health institution (commonly referred to as “in-house devices”)
- Establish the requirements for notification of *in vitro* diagnostic devices to the Marketing Register.
- Regulate the language rules.
- Establish the requirements for conducting performance evaluations in our country.
- Establish that, with respect to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices, the competent authority is the Spanish Agency of Medicines and Medical Devices regardless of the competences of other health authorities.

The norm has the following specific objectives regarding medical devices:

- Repeal, in general, Royal Decree 1662/2000 of 29 September 2000 on *in vitro* diagnostic medical devices – with the exception of Articles 9, 10, 11, 12, 18 (paragraphs 5 and 6), 20, 25, 26 and 27 – in view of the direct application of Regulation

(EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 as from 26 May 2022.

- Develop the necessary regulatory measures for those areas where the Regulation has determined that it will be the Member States that will lay down the rules at national level.

- Adapt, adopt or maintain the measures required by national legislation.

3. Alternatives.

The direct application of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as of 26 May 2022, requires the adaptation of the current national legislation on *in vitro* diagnostic medical devices, in order to repeal those precepts relating to matters that will be directly regulated by the provisions of the cited Regulation and, at the same time, to develop the necessary regulatory measures for aspects where, in accordance with that Regulation, Member States are required to establish regulations at a national level.

This dual need to, on the one hand, repeal and adapt previous national legislation to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and, on the other hand, lay down rules for the implementation of aspects that the Regulation leaves down to the Member States, means it is essential to have recourse to a regulatory solution, with non-regulatory alternatives being excluded, as is the alternative of doing nothing.

Among the possible regulatory solutions, the drafting of a regulation amending Royal Decree 1662/2000 of 29 September 2000, which regulates *in vitro* diagnostic medical devices, was considered as an alternative, as was its repeal in general and the drafting of a new regulation containing the provisions of both Royal Decrees that should remain in force, with the appropriate adaptations to the new European legislation. This second option has been chosen, considering that it offers greater clarity and regulatory consistency.

4. Adherence to the principles of sound regulation.

Article 129 of Law 39/2015 of 1 October, on the Common Administrative Procedure for Public Administrations, lays down the principles of good regulation with which the exercise of legislative action and regulatory power must comply.

The draft Royal Decree complies with the principles of necessity and effectiveness, since it is justified on grounds of general interest, in pursuing the aims and objectives set out in the previous paragraph, and is the most appropriate instrument for ensuring the achievement of the proposed goals, as will be explained later in the analysis of alternatives.

As regards compliance with the principle of proportionality, it should be noted that the proposed rule contains the rules required to meet the identified needs, so that, in order to achieve the objectives set, there are no other measures that are less restrictive of rights or impose fewer obligations on the subject persons. In addition, any limitations on rights and obligations imposed by the rule are proportionate to the aims pursued and are

justified by the mandatory nature of compliance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017; and, at national level, by Law 14/1986 of 25 April 1986, on General Health, and by the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015.

At the same time, the necessary adaptation of the national legislation applicable to *in vitro* diagnostic medical devices to European Union standards results in greater legal certainty, providing consistency and stability to the regulatory framework in this area.

In compliance with the principle of efficiency, the draft Royal Decree introduces only those administrative burdens necessary to adapt the regulation of *in vitro* diagnostic medical devices for human use and their accessories subject to marketing authorisation or registration, while ensuring the achievement of the general interest it pursues. Likewise, and in this sense, the draft Royal Decree does not introduce or establish additional or different procedures to those contemplated in Law 39/2015, of 1 October 2015. This rule, as a basic and common law in matters of administrative procedure, is of complementary and supplementary application to the European Regulation concerning the procedures provided for therein, to which this Royal Decree refers.

As part of the procedure for drawing up the text submitted, the active participation of the persons potentially subject to the regulation has been encouraged through the procedures of prior public consultation and public hearing and information, taking their comments into account.

5. Annual regulatory plan.

This draft Royal Decree is included in the Annual Regulatory Plan, regulated by Law 50/1997, of 27 November 1997, on the Government.

6. Linking the rule to the application of the recovery fund.

This rule is not linked to the implementation of the Recovery, Transformation and Resilience Fund.

II.- CONTENT

1. Structure.

This draft is structured as a preamble, nine chapters, thirty-five articles, three additional provisions, nine transitional provisions, one repealing provision and three final provisions.

2. Content.

- Chapter I, ‘General provisions’, consists of six articles — Articles 1 to 6 — and includes the subject-matter of the Royal Decree, the definitions and the scope of application, establishes the competent authority in this field and the health guarantees to be complied with by devices, and contains provisions on administrative cooperation between the Spanish Agency of Medicines and Medical Devices and the Autonomous Communities.

- Chapter II, ‘Facilities’, consists of three articles – from Article 7 to 9 – and establishes the activities carried out with devices that are subject to a prior operating licence for facilities, the requirements for the granting of the prior operating licence, and the specific aspects for the manufacture of devices by health institutions for their exclusive use by the institution itself. This Chapter II develops the provisions of Article 100 of Law 14/1986, of 25 April 1986, on General Health, maintaining the prior licensing regime required by law, regulated until now in Royal Decree 1662/2000, of 29 September 2000, regulating *in vitro* diagnostic medical devices, and extending it to cover new activities.

  As regards the manufacture by health institutions of devices for their own exclusive use, the Royal Decree establishes the obligation to notify the start of activities and the declaration provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 to the Spanish Agency of Medicines and Medical Devices. This type of manufacture and exclusive use in health institutions is not aimed at subsequent commercialisation or economic benefit and is in the direct interest of a specific group of patients for whom there are no alternatives on the market, so it requires the corresponding agility and flexibility, in the interests of patients, always ensuring the proper functioning and safety of the devices.

  In addition, a paragraph has been included (Article 9(3)) according to which laboratories in health institutions, for manufacturing purposes, must comply with ISO 15189 in accordance with the periods laid down in the eighth transitional provision. This provision is considered necessary, given that it implies an explicit recognition of the standards in force in this field at international level.

- Chapter III, ‘Genetic testing, genetic information and counselling. Reference laboratories’ consists of three articles. Articles 10 and 11 lay down the obligation for health institutions and professionals to provide persons subject to genetic testing with genetic information and appropriate counselling, as well as to obtain their express consent. The last Article of this Chapter III, Article 12, on European reference laboratories, establishes the national authority that will carry out the validation and verification of the applicant laboratories at national level prior to their referral to the Commission for possible designation.

- Chapter IV, ‘Notified bodies’, consists of two articles — 13 and 14 — and establishes the authority responsible for notified bodies and the obligations of those notified bodies.

- Chapter V, ‘Placing on the market and putting into service’, consists of seven articles – from Article 15 to 21 – and sets out the aspects for the creation of the Marketing Register, the content of the notification to the Marketing Register and the traceability requirements for persons placing medical devices on the market in Spain; the means necessary for compliance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 as regards relabelling, repackaging and translation activities; the obligations of economic operators; the requirements for the distribution and sale of devices, including the new concept of devices subject to prescription and the aspects relating to exhibitions. It also establishes the role of the Spanish Agency of Medicines and Medical Devices based on Article 3(5) of the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Article 7(29) of Royal Decree 1275/2011, of 16 September 2011, which creates the State Agency ‘Spanish Agency of Medicines and Medical Devices’ and approves its Statute, to establish, for reasons of public health, specific conditions for mail-order sales to the public, without prejudice to the powers and functions of other administrations.

- Chapter VI, ‘Trade on the European Union market and on the external market’, consists of two articles – 22 and 23 – and sets out the aspects relating to Community movement and import, the requirements for devices intended for export and the possibility of issuing free sale and export certificates.

- Chapter VII, ‘Performance studies’, consists of six articles – from Article 24 to 29 – and sets out the aspects to be complied with for the performance of interventional clinical performance studies and other performance studies involving risks for the subjects referred to in Article 58(1) and (2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, and the procedure to be followed for their authorisation, the aspects relating to compensation for damages, and the liability regime. It also determines the requirements for the conduct of interventional clinical performance studies and other performance studies involving risks for the test subjects conducted with CE-marked devices and, finally, refers to other performance studies.

- Chapter VIII, ‘Surveillance system’, consists of one article –30– and sets out the aspects relating to the surveillance system in Spain and to the reporting of serious incidents by health professionals and authorities and the role of the head of surveillance.

- Chapter IX, ‘Market control activities and health protection measures’, consists of five articles — Articles 31 to 35 — and establishes the aspects for the coordination of the market control activities, the inspection activities by the health administrations, the health protection measures, the particular health control measures and the hearing of the interested party and appeals.

- The three additional provisions regulate the application of the fees of the recast text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015, of 24 July, in its version in force after the entry into force of the sixth final provision of Law 38/2022 of 27 December, for the establishment of temporary energy taxes and temporary tax on credit institutions and

financial credit establishments and creating the temporary solidarity tax on large fortunes, and amending certain tax rules, to the procedures regulated in the rule, the application of the Royal Decree to the cities of Ceuta and Melilla and application within the scope of the Ministry of Defence.

- The nine transitional provisions specify the regime applicable to issues such as the temporary exemption from a prior operating licence for the full manufacture of devices for third parties; the system to which the renewal and modification of licences already granted will be subject; the regime applicable to performance studies that have already been initiated; the specific provisions on the European Database on Medical Devices (EUDAMED); the transitional regime for the new Marketing Register and the legal regime for medical devices covered by the provisions of Article 110(3) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (known as *legacy devices*); the validity of the authorisation, certification and notification procedures carried out in accordance with the previous regulations, the accreditation to ISO 15189 by the laboratories of the health institutions and the transitional legal regime for the manufacture of devices by health institutions for their exclusive use by the institution itself.

- The sole repealing provision repeals Royal Decree 1662/2000 of 23 September 2000, with the exception of the articles relating to information concerning the notification of placing on the market and putting into service, the register of persons responsible for placing on the market, performance evaluation studies, certificate notifications and surveillance. This provision is made on the basis of the repeal of Directive 98/79/EC and Commission Decision 2010/227/EU laid down in Article 112 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and also taking into account Article 110(3) and (4) on the transitional legal regime for the devices of that Regulation and subsequent Regulations.

  On the other hand, and until the development of its specific legislation, the articles of the Royal Decree are exempted from repeal regarding certain points related to the procedure of the notified body, as well as to the publicity, promotion, incentives and sponsorship of scientific meetings. With the exception of advertising, the Royal Decree on devices for self-testing for the detection of HIV and the Royal Decree on devices for self-testing for COVID-19 are also repealed. Finally, as a general rule, all provisions of equal or lower rank are repealed in case of any discrepancy with the provisions of the proposed standard.

- The final provisions contain provisions relating to powers, structured around the exclusive competence of the State in matters of legislation on pharmaceutical devices and external health, as recognised in Article 149(1)(16) of the Constitution; to the implementing powers, which are conferred on the Ministry of Health; and entry into force. In this regard, it should be noted that the entry into force of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on 26 May 2022 means that the national legislation on *in vitro* diagnostic medical devices must be adapted immediately, justifying its entry into force on the day following its publication in the

Official State Gazette, pursuant to the second paragraph of Article 23 of Law 50/1997 of 27 November on the Government.

III.- LEGAL ANALYSIS

1. Legal basis and regulatory status

Article 40 of Law 14/1986 of 25 April, on General Health, provides that the General State Administration must develop the regulations for the authorisation and registration or approval, as appropriate, of medical devices, as well as the regulation and authorisation of the activities of natural or legal persons engaged in the manufacture of these devices.

By virtue of the above, it is understood that the regulatory status of the draft is that of a Royal Decree, pursuant to the provisions of the aforementioned legal bases.

2. Consistency with the Spanish legal system.

See previous section.

3. Consistency with European Union law.

One of the main purposes of this reform project is to adapt the Spanish legal system to the new situation resulting from the entry into force of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, thereby contributing to its consistency with European Union law.

4. Repeal of regulations.

By means of the draft Royal Decree, all norms of equal or lower rank are repealed insofar as they contradict or oppose its provisions and, expressly:

- Royal Decree 1662/2000 of 23 September, with the exception of Articles 9, 10, 11, 12, 18 (paragraphs 5 and 6), 20, 25, 26 and 27.

The repealing provision is drafted as follows, on the basis of the provisions of Regulation 2017/746:

Sole repealing provision. Repeal of regulations.

However, notwithstanding the provisions of Article 110(3) and (4) concerning the transitional legal regime for devices, and considering the repeal of Directive 98/79/EC and Commission Decision 2010/227/EU as laid down in Article 112 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, Royal Decree 1662/2000 of 29 September on *in vitro* diagnostic medical devices is repealed, with the exception of:

1.º Article 20 and the obligations relating to surveillance and performance evaluation studies set out in the relevant Annexes, which are repealed with effect from the later date of those referred to in Article 113(3)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.

2.º Article 18(5) and (6), Articles 9, 10, 11 and 12, and the notification of certificates provided for in the relevant Annexes, which are repealed, as appropriate, with effect from the later date of those referred to in Article 113(3)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.

3.º Articles 25, 26 and 27 relating to advertising, promotion, incentives and sponsorship of scientific meetings shall remain in force until the development of their specific legislation.

The specific dates of repeal are not determined as these transitional periods are being extended by the European Commission. In addition, these dates are subject to, and vary according to, the type of device and its risk classification, so there is no single date to indicate regarding the validity of these articles.

5. Entry into force and validity.

The entry into force of the proposed legislation shall take place on the day following its publication in the Official State Gazette, with the exception of Article 1, which shall enter into force three months after its publication in the Official State Gazette. This period of 3 months is considered necessary and sufficient for companies to adapt.

IV.- ADAPTATION OF THE REGULATION TO THE ORDER OF DISTRIBUTION OF POWERS

1. Titles of competence: identification of the prevailing title.

The prevailing title of competence under which this Royal Decree is issued is the exclusive competence that, in matters of the foundations and general coordination of health and legislation on pharmaceutical devices, is assigned to the State by Article 149(1)(16) of the Spanish Constitution, except for Chapter VI, which is issued based on the exclusive competence of the State to regulate external health, in accordance with the same article of the Constitution.

2. The most relevant competence issues raised by the draft Royal Decree.

There are no issues of a competence-related nature.

3. Regional and local participation in the development of the project.

During the drafting process, the Autonomous Communities and the cities of Ceuta and Melilla have been consulted.

V.- DESCRIPTION OF THE PROCEDURE

In regard to the processing of the draft, the provisions established in Article 26 of Law 50/1997 of 27 November 1997 on Government have been followed.

Pursuant to the provisions of Article 26 of Law 50/1997 of 27 November on Government, a prior public consultation has been held to seek the views of those potentially affected by the future regulation; this period lasted from 23 July 2021 to 8 September 2021, both inclusive, with comments received from the following persons and entities:

- Association for Health Self-care (ANEFP)
- General Council of the Official Colleges of Pharmacists (CGCOF)
- Federation of Spanish Pharmacists (FEFE)
- Spanish Federation of Healthcare Technology Companies (FENIN)
- Spanish Society of Electromedicine and Clinical Engineering (SEEIC)

The contributions received concerned issues relating to the language regime, prior operating licences, devices manufactured and used in health institutions, obligations of economic operators, marketing registration, distribution and sales requirements, prescription devices, performance studies, monitoring and control activities, electronic instructions, technical assistance for electro-medical equipment and advertising.

The contributions received during the prior public consultation procedure were assessed pursuant to the provisions of Annex I to this report.

The draft has been prepared by this Spanish Agency of Medicines and Medical Devices, pursuant to the provisions of Article 14(2)(g) of the By-laws of the Spanish Agency of Medicines and Medical Devices approved by Royal Decree 1275/2011 of 16 September, which sets out the duties of the Director: “g) to coordinate the preparation of draft general provisions, technical guidelines, circulars and instructions”.

In turn and within the framework of the Public Administrations, pursuant to Article 26 of Law 50/1997 of 27 November 1997, the following reports have been collected:

- Advisory Committee of the National Health System (Article 67(2) of Law 16/2003 of 28 May 2003 on the cohesion and quality of the National Health System) (held on 13 June 2023).
- Interterritorial Council of the National Health System (Article 71 of Law 16/2003 of 28 May 2003 on the cohesion and quality of the National Health System) (held on 23 June 2023).

- Report of the General Technical Secretariat of the Department (Article 26(5), fourth paragraph, of Law 50/1997, of 27 November 1997) (dated 22 October 2024).
- Report of the Technical Cabinet of the Undersecretariat of the Department (Article 26(5)(1) of Law 50/1997 of 27 November) (dated 13 March 2023).
- Report of the Cabinet of the General Secretariat of Digital Health, Information and Innovation of the National Health System (Article 26(5)(1) of Law 50/1997, of 27 November) (dated 21 and 22 March 2023).
- Ministerial Commission on Digital Administration (of 16 March 2023).
- Report of the Ministry of Defence (Article 26(5)(1) of Law 50/1997 of 27 November) (dated 29 March 2023).
- Report of the Ministry of Finance (Article 26(5)(1) of Law 50/1997 of 27 November) (dated 4 April 2023).
- Report of the Ministry of Industry, Trade and Tourism (Article 26(5)(1) of Law 50/1997 of 27 November 1997) (dated 10 May 2023).
- Report of the Ministry of Economic Affairs and Digital Transformation (Article 26(5) (1) of Law 50/1997 of 27 November 1997) (dated 25 April 2023).
- Report of the Ministry of Science and Innovation. Instituto de Salud Carlos III (Article 26(5)(1) of Law 50/1997 of 27 November) (dated 4 April 2023).
- Report by the Ministry of Consumer Affairs (Article 26(5)(1) of Law 50/1997 of 27 November) (dated 28 March 2023).
- Prior approval by the Minister for Digital Transformation and the Civil Service (Article 26(5)(5) of Law 50/1997 of 27 November).
- Report of the Ministry of Territorial Policy on the adaptation of the draft to the order of distribution of powers between the State and the Autonomous Communities (Article 26(5), sixth paragraph of Law 50/1997, of 27 November 1997) (dated 17 March 2023).
- Report of the Office for Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Courts (Article 26(9) of Law 50/1997, of 27 November 1997). Not received.
- Report of the Spanish Data Protection Agency (Article 5(b) of Royal Decree 428/1993 of 26 March 1993 approving the Statute of the Data Protection Agency) (dated 16 June 2023).
- Report of the National Markets and Competition Commission (Article 5(2) of Law 3/2013 of 4 June 2013 establishing the National Markets and Competition Commission) (dated 16 May 2023).
- Report of the Consumers and Users Council (Article 2 of Royal Decree 894/2005 of 22 July, regulating the Consumers and Users Council and Article 39(2) of the consolidated text of the General Law for the Protection of Consumers and Users and other complementary laws, approved by Royal Legislative Decree 1/2007 of 16 November) (dated 28 March 2023).

- Autonomous Communities and cities of Ceuta and Melilla.
- Notification to the European Commission pursuant to Royal Decree 1337/1999 of 31 July 1999 regulating the transmission of information in the field of technical standards and regulations and rules relating to information society services and Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services.
- Opinion of the Council of State (Articles 22(2) and 22(3) of Organic Law 3/1980 of 22 April 1980, of the Council of State).

VI.- IMPACT ANALYSIS

1. Economic impact.

(a) General impact on the economy

From a general perspective, the draft is considered as having a limited but positive impact on the overall economy. On the one hand, its provisions can be considered as having a positive impact on the economy by extending the eligible qualification requirements for the position of the technical manager to include other types of qualifications and the experience gained in medical devices in the process of choosing the technical manager, which will encourage job creation by making these jobs accessible to a greater number of people.

Likewise, the draft Royal Decree establishes the requirements for the manufacture of devices in health institutions, which will encourage the development of alternatives to the devices available on the market, will enhance the research and development of devices by the health institutions themselves, having a direct impact on patients. Furthermore, the draft Royal Decree provides for the possibility of manufacturing the necessary devices at the health institutions themselves in the event of a health crisis.

On the other hand, stemming from the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, the Royal Decree includes national provisions relating to performance studies, aimed mainly at promoting the conduct of safe studies with *in vitro* diagnostic medical devices.

(b) Impact on market competition

The draft Royal Decree will develop the new regulatory measures required for the areas in which, based on the Regulation, Member States are required to establish rules at a national level.

This Royal Decree maintains the requirements established by Law 14/1986, of 25 April 1986, on General Health, regarding prior operating licences for manufacturing, import, and sterilisation activities.

Maintaining this requirement for a prior operating licence ensures that the facilities where these devices are manufactured and the activities they are carrying out are appropriate and do not compromise the safety of the devices, nor pose an additional risk to patients or users of the devices. This requirement prior to the start of the activities allows for the identification of possible non-conformities in the facilities, means, procedures, and personnel, and thus limits the possible risks or failures that could occur as a result of the activity in question (manufacture, import, and sterilisation). Prior monitoring of facilities limits the number of suspensions of activity, withdrawals or cessations of use in relation to devices available on the market resulting from inadequate performance.

Furthermore, having a licence allows the Agency to quickly validate manufacturers in EUDAMED, as well as to assign the single registration number (SRN) required in the Regulation. This also benefits companies, as they are able to obtain this number for their regulation-related activities without delay.

As regards the manufacture by health institutions of devices for their own exclusive use, the Royal Decree establishes the obligation to notify the start of activities and the declaration provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 to the Spanish Agency of Medicines and Medical Devices. This type of manufacture and exclusive use in health institutions is not aimed at subsequent commercialisation or economic benefit and is in the direct interest of a specific group of patients for whom there are no alternatives on the market, so it requires the corresponding agility and flexibility, in the interests of patients, always ensuring the proper functioning and safety of the devices.

The conditions and requirements for manufacturing in health institutions, due to the specific characteristics of the institutions and their facilities, differ from those required by legislation for manufacturers. Manufacturing in health institutions, for example, does not involve an audit of its facility and critical subcontractors by a notified body. Therefore, in order to ensure the maximum control of the manufacturing by the institution itself and that this exceptional manufacturing provides the greatest guarantees for the patients with whom the devices are used, the possibility of subcontracting the activity to a third party is restricted.

This mode of manufacture, as it involves situations in which there are no alternative devices on the market, does not directly affect competition.

Finally, the Royal Decree establishes the possibility of issuing export certificates to economic operators in Spain, in addition to those included in the Regulation for manufacturers and authorised representatives, which greatly enables Spanish companies to export and sell their devices in third countries, which require this document, as opposed to the distribution of devices from other European manufacturers, which may constitute an incentive for competition.

(c) Impact on market unity

In relation to the possible impact this draft will have, once approved, in relation to the matters set out in Law 20/2013 of 9 December 2013, on the guarantee of market unity, it should be

noted that the draft does not contain conditions or requirements that directly or indirectly discriminate based on the establishment or residence of an economic operator.

2. Budgetary impact.

The impact of the draft on the income and expense budgets of the Government Agencies is analysed below.

With regard to the revenue budget of the General State Administration, it should first be noted that the application of this Royal Decree does not imply the creation of any new charge or public price, which will be those established in the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July, in its version in force after the entry into force of the sixth final provision of Law 38/2022 of 27 December, for the establishment of temporary energy taxes and temporary tax on credit institutions and financial credit establishments and creating the temporary solidarity tax on large fortunes, and amending certain tax rules.

On the one hand, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 includes new activities such as the manufacture of devices in health institutions. This new activity will require prior notification of activity, to which the following fees provided for in Article 123(1) of the recast text of the Law on guarantees and rational use of medicinal products and medical devices, in its version in force after the entry into force of the sixth final provision of Law 38/2022 of 27 December, for the establishment of temporary energy taxes and temporary tax on credit institutions and financial credit establishments and creating the temporary solidarity tax on large fortunes, and amending certain tax rules:

For the prior notification of activity, the fee provided for in heading 5.17 shall be applied for a unit amount of EUR 983.85.

For modifications or revalidations that include inspection of facilities, the fee provided for in heading 5.19 will be applied for a unit amount of EUR 983.85.

Amendments that do not include the inspection of facilities shall be subject to the fee provided for in heading 5.21 at a unit price of EUR 245.96.

In the case of the manufacture of *in vitro* diagnostic medical devices in health institutions for their own and exclusive use within the institution, for which a prior notification will be made before the commencement of the activity, the fee will be the same as that for manufacturing. This assessment of the documentation shall also be accompanied by the corresponding inspection. The initial notification must be updated by the institution in the event of any modification of the activities, throughout the years of conducting the manufacturing activity, including the corresponding fee for the modification. The AEMPS will review these updates and modifications, which may again require an inspection. As this is a new activity that has not been regulated until now, it is impossible to accurately calculate the number of health institutions that will carry out this activity. However, since it is an activity commonly carried out in the laboratories of health institutions, it is estimated that a large percentage of them will carry out this activity in accordance with the Regulation and the Royal Decree. Consequently, to estimate the future income derived from the application of the aforementioned rates, we will take into

account that 50 % of hospitals could carry out these activities and that this activity would be increased with the rest of the laboratories in other health institutions. If we consider that of the total of 866 public and private hospitals in Spain listed in the Catalogue of the Ministry of Health, 50 % carried out manufacturing for their own and exclusive use in the hospital, we would have a total of 433 hospitals (more than three times the activity compared to the total of *in vitro* diagnostic manufacturers) that would have to carry out the notification of the activity. At the time of the review and inspection, AEMPS would ask these hospitals for the documentation and the payment of the corresponding fee.

From the estimated total of 433 hospitals that would need to communicate the manufacture of medical devices at hospitals for their own and exclusive use in the hospital; this would lead to a minimum initial fee income (at fee rate 5.17) of EUR 426 007.

In addition, the draft regulation extends the licensing requirement to manufacturers of devices for third parties under the Regulation, to which the same fees mentioned above will apply for new licensing, modification, and revalidation. The number of manufacturers in this situation is unknown, so the impact of this measure on the income budget of Government Agencies cannot be quantified either. As these are new activities that have not been regulated up until now, it is impossible to accurately calculate the number of companies that will carry out this activity. Consequently, to estimate the future income derived from the application of the aforementioned fees, a preliminary estimate is made based on the total number of companies in Spain manufacturing *in vitro* diagnostic devices for third parties.

With regard to third-party manufacturing, around 136 companies are currently listed in the AEMPS register as being subcontracted for third-party manufacturing of *in vitro* diagnostic devices, of which 6 perform full device manufacturing. According to the new Royal Decree, these 6 companies will require the prior licensing of their manufacturing activities. Considering that the number of companies manufacturing *in vitro* diagnostic devices in Spain in 2022 is 142, this activity would represent an increase of 4.22 % over current activity.

From the estimate of a total of 6 companies that would require a manufacturing licence; this would lead to a minimum initial fee income (at fee rate 5.17) of EUR 5 903.10

On the other hand, Article 18 of the draft Royal Decree establishes the creation of a new Marketing Register for all types of devices, regardless of their risk class. The purpose of this register is to have public information on all devices marketed in Spain; this will make it possible, inter alia, to carry out the market surveillance and control functions required from the authorities under the Regulation.

There is currently a register for *in vitro* diagnostic devices in lists A and B and devices for self-testing to which the fee provided for in heading 8.3 of Article 123(1) of the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices applies, for an amount of EUR 105.10, and for its amendments, the fee provided for in heading 8.33, amounting to EUR 63.06. With the recent amendment of the aforementioned recast text, the new fee 5.1 will apply after its entry into force. With the entry into force of this Royal Decree, and until the EUDAMED database and the Marketing Register are fully operational, the aforementioned fees will continue to apply to class B, C, D devices and devices for self-testing. Class A devices from manufacturers located in Spain will continue to be notified to the register of responsible parties with no associated fee. Once the Marketing Register becomes operational, the fees will be modified to apply to all classes of devices (A, B, C, and D) by UDI-

DI, not by a set or category of devices as is currently done. The fee shall be calculated on the basis of different tranches based on the number of UDI-DI marketed in Spain by the economic operator. This fee will be paid when the device is first marketed in Spain and must be renewed annually based on the number of UDI-DIs that the economic operator continues to market in Spain. With regard to this modification of the fee, it is currently unknown how manufacturers will allocate the UDI-DIs, or the number of Class A devices available on the market, so it is not possible to estimate the exact amount of fee revenue involved.

Currently, a total of 1,858 notifications of devices from lists A and B and of devices for self-testing are registered in the Communication of Placing on the Market application. In the calculations currently being carried out for the revision of the AEMPS rates, an estimate has been made of at least an increase of 10,000 notifications for Class A, B, C, D, and new devices. When this Royal Decree comes into force, and provided that the EUDAMED database is fully operational, an initial unit rate estimated at EUR 99.71 will be applied, and tranches will be established depending on the number of UDI-DI, with the corresponding discounts for companies with a greater number of notifications up to a maximum established.

The tranches according to the number of UDI-DIs shall be as follows:

Number of UDI-DIs	Discount
From 2 to 9 notifications.	8 %
From 10 to 19 notifications.	16 %
From 20-29 notifications.	20 %
From 30 to 99 notifications.	24 %
100 to 150 notifications.	28 %
More than 150 notifications.	100 %

Based on these estimates, this register could represent a maximum increase of up to EUR 997,000 if we consider a unitary notification by UDI-DI.

Remaining on the register is subject to an annual fee equivalent to 60 % of the total amount based on the number of UDI-DIs that the company will keep on the market.

The new Regulation on *in vitro* diagnostic medical devices establishes a procedure for the authorisation of interventional clinical performance studies and other performance studies involving risks for subjects, along similar lines to those established in Regulation 2017/745 on

medical devices, with respect to clinical investigations. Therefore, the same fees will be applied to these studies as to clinical investigations in accordance with the provisions of Article 123(1) of the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, in its version in force after the entry into force of the sixth final provision of Law 38/2022, of 27 December. Fee category 5.22 (Authorisation of clinical investigations with medical devices), with a unit amount of EUR 1 553.51.

Due to the fact that these are new activities not regulated so far, no precise calculation can be made of the number of researchers who will carry out these performance studies. Consequently, in order to estimate the future income derived from the application of the aforementioned fees, a preliminary estimate is made based on the total number of clinical investigations authorised in Spain in 2021. During 2021, 78 clinical investigations were authorised in Spain and it is estimated that for performance studies referred to in Article 58(1) and (2) of Regulation (EU) 2017/746, authorisation will be requested for around 39 performance studies (50 % of the total number of clinical investigations in 2021).

From the estimate of a total of 39 studies that would require authorisation, this would entail a minimum initial income on fees (Fee category 5.22) of EUR 60 586.89

With regard to the expenditure budget, and as indicated above, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 recognises the possibility of carrying out new activities such as the manufacture of devices in health institutions for their exclusive use. This activity will require prior notification of commencement of activity. As part of the process for reviewing this communication and the accompanying documentation, an inspection by the functional health areas of the Government Delegations will be included. Likewise, third-party manufacturers will need a licence and, prior to its granting, an inspection must be carried out by the functional health areas of the Government Delegations.

According to preliminary estimates, both the number of actions taken by the Agency regarding prior operating licences for third-party manufacturers and the prior notification of manufacturing activity in health institutions, as well as the inspection activities of the functional areas of the Government Delegations, could rise. Specifically, an increase in manufacturing activity for exclusive use by health institutions has been estimated at more than three times compared to current manufacturers of *in vitro* diagnostic devices, and the manufacture of devices for third parties by 4.22 %.

While this estimate would imply a significant increase in activity, mainly in manufacturing in health institutions, it should be taken into account that some of the companies carrying out third-party manufacturing activities of devices will be entities for which, to some extent, an assessment has already been made by the Agency for other activities (e.g. subcontracting) and, therefore, the issuance of the licence might require a lower investment of human and material resources. Likewise, notifications of manufacturing in health institutions will be reviewed following specific criteria based on the type and risk of devices being manufactured.

On the other hand, and as mentioned above, Regulation 2017/746 establishes a procedure for the authorisation of interventional clinical performance studies and other performance studies involving risks for subjects, following similar lines to those established in Regulation 2017/745

on medical devices with respect to clinical investigations. It has been estimated that there will be a 50 % increase in activity in the area of clinical investigations.

Furthermore, other IT applications compatible with the European EUDAMED database will be developed, which will facilitate and speed up the implementation of these new activities, as well as market surveillance and control actions, allowing for the automation of work that is currently mainly performed manually and that consumes a large volume of staff resources.

In any case, the workload resulting from the obligations established by the Royal Decree will be borne by the current staff assigned to both the Spanish Agency of Medicines and Medical Devices and the functional areas of the Government Delegations. The Agency shall be responsible for the redeployment of necessary human resources, in particular from the Surveillance Area to other areas. This redeployment of staff shall be sufficient to meet the new requirements of the regulation and the Royal Decree. Therefore, the draft does not entail an increase in staff costs.

3. Analysis of administrative burdens.

The proposed regulation creates new administrative burdens not provided for in the previous legislation. On the one hand, and as indicated above, some of these burdens correspond to new activities that the previous regulations did not specifically regulate, such as the manufacture of devices in health institutions, which will require prior notification of the start of activities. These new requirements make it possible to regulate and establish the conditions for activities that may currently be taking place despite not being regulated. Likewise, a prior operating licence will be required for third-party manufacturers. The requirement to hold a prior operating licence ensures that the facilities where these devices are manufactured are appropriate and do not compromise the safety of the devices, nor pose an additional risk to patients or users of the devices.

This obligation to obtain the prior operating licence entails different administrative burdens for each applicant. First, the submission of the application online, the estimated unit cost of which is EUR 5[1], and an additional EUR 4 for each of the requirements that, in each case, must be proven pursuant to Article 8 of the proposed Royal Decree and the specific requirements of each licence. Finally, the obligation to have a document archiving system available to the competent authorities is an obligation that is comparable to keeping books, with an estimated cost of EUR 150 in electronic form, and to keeping documents, with an estimated unit price of EUR 20. Having identified these unit costs, and based on the estimates made above, it is expected that at least 6 entities among the third-party manufacturing companies will require a prior operating licence.

Likewise, according to the previous estimates, it is expected that 433 hospitals will notify the AEMPS online of manufacturing activities in hospitals of devices for use by the hospital. This

[1] The calculations in this section have been made pursuant to the Table for the measurement of the direct cost of administrative burdens in the Methodological Guide for the preparation of the Regulatory Impact Analysis Report.

entails an administrative burden to be assumed by the filer of the online application, the estimated unit cost of which is EUR 5, and an additional EUR 4 for each of the requirements that, in each case, must be proven pursuant to Article 9 of the proposed Royal Decree and the specific requirements of each licence.

On the other hand, it includes the obligation to notify the Marketing Register of devices in classes A, B, and C, in addition to new class D and devices for self-testing for which this obligation already exists. The creation of a new public Marketing Register will make it possible to know which devices are available in the Spanish market, which will increase transparency in the medical devices sector in Spain, which lacks a similar public register. Compliance with these new communication obligations for their registration entails an administrative burden with a unit cost of EUR 50 and registration will be performed online. As explained above, based on the estimates and forecasts made in the previous sections, it is expected that at least 10 000 additional notifications of devices of classes A, B, C and new devices could be received.

The register referred to in Article 10(3) and Article 21 is an existing register and therefore does not generate a new administrative burden.

With regard to performance studies, the new regulation establishes the obligation to authorise certain studies, in line with the obligations already established for clinical investigations. The proposed regulation therefore also creates new administrative burdens not provided for in the previous legislation.

Based on the above estimates, it is expected that 39 applications for authorisation of performance studies may be submitted electronically to the AEMPS. This implies an administrative burden on the communicant for the electronic submission of the application, whose unit cost is estimated at EUR 5 and an additional EUR 4 for each of the requirements that in each case must be accredited in accordance with the provisions of Articles 24 and 27, as well as EUR 20 for the obligation to keep documents.

Name of the administrative burden (numbering as per Annex V of the methodological guide)	**Unit cost of the burden (EUR)**	**Frequency**	**Entities concerned**	**Total per burden (EUR)**
2. Submit an online application Article 7	5	1	6	30
7. Online submission of documents, invoices or requirements Article 8.a)	4	1	6	24

Article 8(b)	4	1	6	24
Article 8(c)	4	1	6	24
Article 8(e)	4	1	6	24
14. Book keeping Article 8.d)	150	1	6	900
11. Obligation to keep documents Article 8.d)	20	1	6	120
2. Submit an online application Article 9(7)	5	1	433	2 165
7. Online submission of documents Article 9.7.b)	4	1	433	1 732
7. Online submission of documents Article 9.7.c)	4	1	433	1 732
13. Online inscription in a register Article 18	50	1	10,000	500,000
2. Submit an online application Articles 24 and 28	5	1	39	195
7. Online submission of documents, invoices or requirements Articles 24 and 28	4	1	39	156
11. Obligation to keep documents Article 24(6) and Article 28	20	1	39	780
TOTAL administrative burden (EUR)				**€507 906**

4. Gender impact.

Pursuant to Article 19 of Organic Law 3/2007 of 22 March 2007 on the effective equality of women and men, and Article 26(3)(f) of Law 50/1997 of 27 November 1997, the gender impact of this draft has been assessed and it has been concluded that the draft has no impact on this area, since no previous gender inequalities have been identified in the area regulated by the regulation.

5. Impact on children and adolescents.

This impact has been assessed pursuant to Article 22 quinquies of Organic Law 1/1996 of 15 January, on the Legal Protection of Minors, partially amending the Civil Code and the Civil Procedure Act. No impact is expected whatsoever, since the purpose of the draft legislation does not specifically address these groups.

6. Impact on the family.

In turn, an assessment of the impact that the regulation could have on the protection of the family, as provided for in the tenth additional provision of Law 40/2003 of 18 November 2003 on the Protection of Large Families, is considered null and void for the same reasons as set out in the previous paragraph, since the proposed regulation does not affect the subjects under the scope of Law 40/2003 of 18 November 2003.

7. Climate change impact.

Regarding the impact of this regulation on climate change, it is considered to have a positive impact. As indicated above, the proposed regulation reduces administrative burdens in some areas compared to the previous legislation and increases communication to electronic registers, which would mean a decrease in the use of paper. This reduction in administrative burdens could also reduce the number of trips to offices to carry out advertising authorisation procedures, for example by reducing fuel consumption or gas emissions.

8. Other impacts.

The rule has a positive health impact, as it maintains the prior operating licence requirements for manufacturing, import, or sterilisation activities. This requirement ensures that the activities and their facilities are adequate and do not compromise the safety of the devices, nor pose an additional risk to patients or users thereof, and limits the number of withdrawals or cessations of use of devices available on the market resulting from inadequate installation.

With regard to the manufacture by health institutions for their exclusive use within the institutions, the Royal Decree establishes the requirement to make a prior notification of the start of activity to the Spanish Agency of Medicines and Medical Devices, instead of the prior operating licence in accordance with the provisions of Article 100 of Law 14/1986, of 25 April, on General Health. This requirement can be attributed to the exceptional nature of this type of manufacturing, which is not aimed at subsequent commercialisation and has no economic benefit, and which is in the direct interest of a specific group of patients for whom there are no alternatives on the market. This type of manufacturing entails the corresponding speed and flexibility requirements, in the interest of patients, always ensuring the proper functioning and safety of the devices. This mode of manufacturing, being designed for situations where there are no alternative devices on the market, does not directly affect competition.

In this same sense, the establishment of requirements for the manufacture of devices in health institutions will encourage the development of alternatives to the devices available on the

market and will enhance the research and development of devices by the health institutions themselves, with a direct impact on patients. Furthermore, the draft Royal Decree provides for the possibility of manufacturing the necessary devices at the health institutions themselves in the event of a health crisis.

In terms of ensuring adequate public information, this rule has a major health impact by establishing an obligation for health institutions and professionals to provide persons subject to genetic testing with the necessary information and appropriate advice, as well as to seek their express consent.

Regarding the establishment of the procedure and requirements for the authorisation in Spain of interventional clinical performance studies and other performance studies involving risks for subjects, innovation and research with *in vitro* diagnostic medical devices is promoted.

There is also a positive impact on health as the standard includes the obligation for healthcare professionals to report serious incidents, making it possible to quickly identify signs of failure in a device and the adoption of the necessary measures. Furthermore, pursuant to the recommendations of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, the procedure for reporting serious incidents by patients and users is enabled.

As far as transparency is concerned, the regulation also has a positive impact and is a continuation of the lines laid down in the Regulation to this end. An example of this is the creation of a public Marketing Register that brings together all medical devices marketed in Spain.

Furthermore, as regards the above-mentioned Marketing Register, by extending the communication to all types of medical devices, regardless of their classification, a positive impact is also evident since the authorities are enabled with the tools to verify that the devices that are on the market, as well as their instructions and labelling, comply with the applicable rules. Likewise, the register, that will be enabled to notify the devices that are going to be relabelled or repackaged, will ensure that these devices comply with these standards and do not pose a risk to users and patients.

Finally, as regards foreign trade, the regulation has a positive impact as it enables the of issue free-sale certificates to other economic operators whose registered offices are located in Spain, in addition to those set out in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.

VII.- ***EX POST*** **EVALUATION**

This norm is not among those for which an evaluation is planned to analyse the results of its application.

ANNEX I. CONTRIBUTIONS RECEIVED IN THE PRELIMINARY PUBLIC CONSULTATION PROCEDURE FOR THE DRAFT.

Pursuant to the provisions of Article 26 of Law 50/1997 of 27 November on Government, a prior public consultation has been held to seek the views of the subjects potentially affected by the future regulation; this period lasted from 23 July 2021 to 8 September 2021, both inclusive, with comments received from the following persons and entities:

- Association for Health Self-care (ANEFP)
- General Council of the Official Colleges of Pharmacists (CGCOF)
- Federation of Spanish Pharmacists (FEFE)
- Spanish Federation of Healthcare Technology Companies (FENIN)
- Spanish Society of Electromedicine and Clinical Engineering (SEEIC)

As part of the preparation of this Royal Decree, the following comments and observations made as part of the prior public consultation have been assessed:

- With regard to the **language rules**, the Royal Decree establishes that the official language with reference to the information to be provided with the device for the purposes of marketing in Spain shall be in Spanish as a minimum. It also establishes the that documentation to be submitted to the Spanish Agency of Medicines and Medical Devices, shall be in Spanish as a minimum.

- In relation to the **operating licences** and in particular with regard to questions concerning the role of the technical manager, this role will continue to be required for activities requiring a licence, such as manufacturing, sterilisation and import.

  The functions of the technical manager are different from the functions of the person responsible for regulatory compliance, as defined in Article 15 of Regulation 746/2017. However, a person who meets the requirements set out in both the new Royal Decree and the Regulation could hold both positions.

  The specific information included in the licence document is not regulated in this Royal Decree. Specific instructions for the operating licence procedure will be developed at a later stage.

  In relation to the requirement for a health licence for natural and legal persons who carry out the complete manufacture of devices for third parties, it is a requirement contained in Article 100 of Law 14/1986, of 25 April, on General Health.

- In relation to the **manufacture of devices in health institutions** (commonly referred to as *in-house*), the text of the Royal Decree establishes that they must comply with the general safety and performance requirements set out in Annex I to Regulation 746/2017, as well as the conditions set out in Article 5(5) of the Regulation itself, such as '*that the*

health institution justifies in its documentation that the specific needs of the patient group for which the devices are intended cannot be met, or cannot be met at the appropriate level of performance, by another equivalent device placed on the market'. Therefore, the manufacture of these devices would not place manufacturers at a competitive disadvantage.

Moreover, to ensure that these devices comply with health guarantees, the new Royal Decree provides that health institutions, in order to carry out this manufacturing activity, must make a prior notification of the start of activity to the Spanish Agency of Medicines and Medical Devices, which will provide the necessary means to comply with this obligation, including inspections, controls, and the adoption of measures where appropriate.

Regarding the possible incompatibility between prescriber and manufacturer established in Royal Legislative Decree 1/2015, the Regulation contemplates the possibility for health institutions as entities to manufacture medical devices; therefore, the health institution is authorised by the Regulation to carry out such manufacturing of devices. The incompatibility is regulated in Royal Legislative Decree 1/2015 and for this incompatibility to exist, it should be established that the personnel at the service of the health institution that manufactures the devices may have direct economic interests in that manufacture, which is not regulated in this Royal Decree. However, these aspects may be clarified in the guides and instructions to be developed for this purpose.

In relation to the consideration of equivalent device available on the market, European guidelines are being developed where the scope of this term will be clarified in detail, as well as the different aspects necessary for the implementation of Article 5(5). If necessary, the AEMPS would develop additional instructions.

In relation to the software device manufactured by a health institution, the comments received from various associations will be taken into account for the development of the instructions for these devices mentioned above. With regard to the existence of a national register of *in-house* software devices, the notification by health institutions of the manufacturing activity shall be recorded in an AEMPS database, part of which may be made public.

- Regarding **the obligations of economic operators,** the Regulation clarifies the responsibilities of economic operators, and it is the responsibility of each of them to establish the procedures for their compliance, which is not the subject of this Royal Decree.

  With regard to the obligations of the **importer** and the physical importer, both as defined in the Regulation, the Regulation and the draft Royal Decree, together with the question-and-answer documents drawn up in the Medical Devices Coordination Group (MDCG), cover the comments submitted.

  With regard to the **Marketing Register of medical devices**, the current draft Royal Decree establishes the creation of a Marketing Register in which any economic operator distributing a medical device in Spanish territory must make a notification to the Spanish Agency of Medicines and Medical Devices. The Spanish Agency of Medicines and Medical Devices will maintain the register with notifications. The Agency is designing and developing the register based on the connection to EUDAMED. It is also envisaged that part of this register will be public.

In relation to the duplication of information in the national register when EUDAMED is available, the current draft of the Royal Decree establishes a register that will download from the European database the necessary data through the unique device identifier (hereinafter UDI-DI), to which certain data that are not available in EUDAMED will be added, for example the identification data of the economic operator making the notification, labelling and instructions for use with which the device is to be marketed in Spain and the date on which marketing begins in Spain.

The comments received regarding the high volume of references to be registered has been taken into account in the development of the registration design, as well as in the modification of the applicable rates.

- The **distribution and sales** requirements will continue to be regulated by the Royal Decree. Distribution and sale activities shall take place at establishments that ensure the appropriate storage and preservation of the devices and shall continue to be subject to monitoring and inspection by the health authorities of the Autonomous Community in question. These establishments shall also inform the health authorities of the Autonomous Community when they start their activities.

- The draft Royal Decree exempts pharmacies from being required to report the start of their activities to the health authorities of the Autonomous Community, unless they undertake distribution activities.

- The proposals made regarding a common form and awareness campaigns aimed at points of sale to the public and pharmacies on the regulation of medical devices will be taken into account in the future actions to be carried out in collaboration with the Autonomous Communities in the framework of the Technical Inspection Committee (CTI).

- In relation to **sale to the public, distance selling and prescription,** the draft Royal Decree covers devices subject to prescription. For devices for self-testing, only human genetic tests will require a prescription.

  As for the sale to the public of devices for self-testing, the obligation of exclusive sale through pharmacies or through the pharmacy's own website remains.

  The intervention of the pharmacist is considered essential, as during the dispensation, they can inform the patient about the correct handling of the test and the sample, as well as the interpretation of the result, advising the user when it is necessary to contact the health service. In addition, the community pharmacy, as a health establishment, ensures appropriate preservation conditions. On the other hand, if market surveillance and control measures are necessary, the traceability of the devices in the pharmaceutical channel is guaranteed.

  In relation to the observation regarding Royal Decree 870/2013 on the distance dispensing of medicines not subject to medical prescription, although the inclusion of these terms in the draft Royal Decree is not contemplated, the subsequent legislative development adapted to the field of medical devices will be evaluated.

- As for the **carrying out of self-testing tests** by the pharmacist, the Royal Decree provides that '*Products may only be placed on the market, made available on the market and/or put into service if they comply with the requirements laid down in*

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in this Royal Decree, when duly supplied, properly installed and maintained in accordance with the manufacturer's instructions, and ***are used in accordance with their intended purpose****, without compromising the safety or health of patients, users or, where appropriate, third parties*'. The intended purpose of the manufacturer provides that these tests can be carried out by users.

However, the new Royal Decree establishes that the Spanish Agency of Medicines and Medical Devices, in order to guarantee the protection of human health, safety, or compliance with public health rules, may adopt all necessary and transitional measures that are justified in respect of a device, category, or specific group of devices, may issue provisions on conditions of use thereof or on special monitoring measures, and include the necessary warnings to avoid health risks in its use.

With regard to the translation into Spanish of the '*device for self-testing*' as 'producto para auto-test', the official translation of Regulation 2017/746 is used in the Royal Decree.

- With regard to the **electronic instructions**, they are regulated in Regulation (EU) 2017/746 and the corresponding implementing acts, and the new Royal Decree does not establish additional requirements.

- With regard to the **performance studies** and its language regime, the new Royal Decree on *in vitro* diagnostic medical devices, which is currently under development, will require certain documentation to be presented, at least, in Spanish. However, in order to facilitate and promote research in Spain, and provided that the Research Ethics Committee on Medicinal Products (CEIm) has no objection to this, the performance study plan and the investigator's manual could be accepted in English. However, the AEMPS shall always retain the authority to request a translation of these documents, as well as any other document in the submission.

  The new Royal Decree on *in vitro* diagnostic medical devices will establish the national requirements applicable to performance studies, which must also comply with the provisions of Regulation 2017/746 on *in vitro* diagnostic medical devices.

  Likewise, and in relation to the procedures for making notifications to the AEMPS according to the different obligations established in the Regulation, the Royal Decree establishes the general principles. These procedures will be detailed in future instructions, including the process in the absence of the *EUDAMED* database. Currently, there is information published on the AEMPS website that clarifies the procedure to be followed for the application for authorisation of performance studies.

- In relation to the **surveillance of *in vitro* diagnostic medical devices**, the new Royal Decree, following the same line as the previous one, maintains the obligation for health institutions to appoint a surveillance officer for the procedures arising from the implementation of the surveillance system. The appointment shall be communicated to the health authorities of the relevant Autonomous Community and to the Spanish Agency of Medicines and Medical Devices. Additionally, it establishes the possibility for the AEMPS to set up an electronic register for such communications and, in that case, health institutions will be obliged to communicate the required data to the aforementioned register.
  In the implementation phase, consideration will be given to initiating some method of awareness-raising aimed at health institutions with the objective of highlighting the need

for their collaboration in the implementation of corrective safety actions and to improve the effectiveness of the surveillance system.

In relation to the notification of corrective safety actions by manufacturers, the obligation is established to inform the AEMPS about such action before it is carried out (in accordance with the provisions of Articles 87(1) and 87(8) of Regulation 746/2017). It is specified that the safety note intended for communication to users or customers must be in Spanish and be sent to the AEMPS before its dissemination.

In addition, the obligation that other communications intended for users or customers about any other warning, preventive measure or other corrective actions related to devices marketed being in Spanish has been included. In these cases, the Spanish Agency of Medicines and Medical Devices may require that this information is submitted.

- In relation to contributions/queries received on **advertising or incentives** relating to medical devices, a new Royal Decree is being developed that will specifically regulate the advertising of medical devices, meaning it is not subject to this new Royal Decree. This Royal Decree on advertising complies with the principles established in Royal Legislative Decree 1/2015.

- The regulation of the **technical assistance** of electrical medical equipment does not fall within the scope of the new Royal Decree. Circular No. 3/2012 contains recommendations addressed to all persons involved in the installation and maintenance of equipment at health centres, whether manufacturers or companies acting on their behalf, services contracted by health centres or health centres themselves. It regulates the qualification of staff, means, security checks and controls, documentation and registration, as well as incident reporting.

Once the new Royal Decrees on medical devices have been published, the AEMPS will also review the implementing legislation that requires an update.

ANNEX II. TABLE OF OBSERVATIONS MADE TO THE DRAFT ROYAL DECREE REGULATING *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

MINISTERIAL DEPARTMENTS

- MINISTRY OF SCIENCE AND INNOVATION GENERAL TECHNICAL SECRETARIAT
- MINISTRY OF HEALTH. GENERAL TECHNICAL SECRETARIAT
- MINISTRY OF HEALTH - GENERAL SECRETARIAT FOR DIGITAL HEALTH, INFORMATION AND INNOVATION OF THE SNS (SGSDII)
- MINISTRY OF FINANCE AND CIVIL SERVICE. GENERAL TECHNICAL SECRETARIAT.
- MINISTRY OF ECONOMIC AFFAIRS AND DIGITAL TRANSFORMATION GENERAL TECHNICAL SECRETARIAT
- MINISTRY OF INDUSTRY, COMMERCE AND TOURISM — GENERAL TECHNICAL SECRETARIAT
- MINISTRY OF DEFENCE - GENERAL TECHNICAL SECRETARIAT

BODIES

- SPANISH DATA PROTECTION AGENCY (AEPD)
- NATIONAL COMMISSION FOR MARKETS AND COMPETITION (CNMC)

AUTONOMOUS COMMUNITIES

- ANDALUSIA
- CATALONIA
- MADRID

INSTITUTIONS

- A3Z ADVANCED
- ASSOCIATION OF TESTING, CALIBRATION AND ANALYSIS ENTITIES (FELAB)

- SPANISH BIOINDUSTRY ASSOCIATION (ASEBIO)
- SPANISH ASSOCIATION OF PHARMACISTS IN INDUSTRY (AEFI)
- SPANISH ASSOCIATION OF INDEPENDENT LABORATORIES (AELI)
- SPANISH ASSOCIATION FOR THE DIGITAL ECONOMY (ADIGITAL)
- SPANISH ASSOCIATION OF TESTING, CALIBRATION AND ANALYSIS LABORATORIES (EUROLAB)
- THE BIOMEDICAL DIAGNOSTIC CENTER OF THE HOSPITAL CLINIC OF BARCELONA
- OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA
- GENERAL COUNCIL OF THE OFFICIAL COLLEGES OF PHARMACISTS (CGCOF)
- FEDERATION OF SPANISH PHARMACISTS (FEFE)
- HEFAME GROUP
- SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)
- SPANISH SOCIETY OF PRIMARY CARE PHARMACISTS (SEFAP)
- SPANISH SOCIETY FOR IMMUNOLOGY (SEI)
- ASSOCIATION FOR HEALTH SELF-CARE (ANEFP)
- SPANISH FEDERATION OF HEALTHCARE TECHNOLOGY COMPANIES (FENIN)

INDIVIDUALS

LEGISLATIVE TEXT	REMARK	REASONED DECISION	INSTITUTION
GENERAL	• The date contained therein should be updated as the project progresses. • In the section 'Title of the regulation', it should read 'Draft Royal Decree regulating *in vitro* diagnostic medical devices'. • In the section 'Reports received', it is recommended to include the mandatory		GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	procedure of notification to the European Commission under Royal Decree 1337/1999 of 31 July 1999 regulating the transmission of information in the field of technical standards and regulations and regulations relating to information society services and under Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules relating to information society services. • In the section 'Prior public consultation and public information procedures', these procedures should be separated into two columns, on the one hand 'Public consultation procedure' and on the other hand 'Hearing procedure/public information'. • 'Impact on children and adolescents', 'Impact on the family' and 'Climate change impact' should be reflected in separate sections.	Accepted. The changes to the Regulatory Impact Analysis Report are made	
GENERAL	In line with the structure previously proposed for the executive summary, the body of the report should follow the following model. Model indicated	Accepted and updated	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
GENERAL	In section I.A. Purposes and objectives pursued, it is recommended that the error in the quotation of Royal Decree 1662/2000, of 29 September be corrected in the Spanish text, **sobre** productos sanitarios **para** *diagnóstico in vitro.*	Accepted	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	•In section I.B. Adaptation of the draft Royal Decree to the principles of good regulation, as noted regarding the preamble of the draft, the compliance of the norm to the principle of efficiency must be justified.	Accepted and amended as follows: In compliance with the principle of efficiency, the draft Royal Decree introduces only those administrative burdens necessary to adapt the regulation of *in vitro* diagnostic medical devices for human use and their accessories subject to marketing authorisation or registration, while ensuring the achievement of the general interest it pursues. Likewise, and in this sense, the draft Royal Decree does not introduce or establish additional or different procedures to those contemplated in Law 39/2015, of 1 October 2015. This rule, as a basic and common law in matters of administrative procedure, is of complementary and supplementary application to the European Regulation concerning the procedures provided for therein, to which this Royal Decree refers.	
	• In section II.A. Legal basis and rank of the draft, the first paragraph refers to the empowerment and should therefore be deleted from this section	Accepted and removed	

	• In section III.B. Processing, in the second paragraph there is a typographical error, in the Spanish draft text ‘potencialmentete’.	Accepted	
	• In section III.A. Content, the second paragraph on page 12 regarding exceptions to the derogation until the development of the specific legislation should be revised, as this does not seem to be the case for the notified body procedure.	Accepted and amended	
	• Reference is also made to the repeal of the Royal Decree on devices for self-testing for the detection of HIV and the Royal Decree on devices for self-testing for COVID-19. It seems that this should refer to Royal Decree 588/2021 of 20 July, amending Royal Decree 1662/2000 of 29 September, on *in vitro* diagnostic medical devices, to regulate the sale to the public and advertising of COVID-19 devices for self-testing, and Royal Decree 1083/2017 of 29 December, amending Royal Decree 1662/2000 of 29 September, on *in vitro* diagnostic medical devices, to regulate the sale to the public and advertising of devices for self-testing for HIV detection. However, since these are amending royal decrees, it is not appropriate to provide for their express repeal and, therefore, these royal decrees do not appear in the repealing provision, and it is therefore recommended that the reference to these repeals be deleted from the report.	Accepted. The repeal was included in a previous version of the draft that was deleted.	

	• In section III.B. Processing, reports from internal bodies or units of the Department are mentioned and as the Directorate-General for the Basic Portfolio of National Health System and Pharmacy Services, the Office of the Secretary of State for Health and the National Transplant Organisation have not issued a report, it is recommended that the reference to them be deleted. • In Section VI. List of rules that are repealed, it is recommended that the content of the repealing provision of the draft be explained and when the provisions that remain in force should be understood as repealed. • On the other hand, although the repeal is indicated of all rules of equal or lower rank in so far as they contradict or oppose the provisions of the Royal Decree, this provision has not been established in the repealing provision.	Accepted and removed Not accepted. The repeal is carried out in line with that of the regulation itself. The specific dates of repeal are not determined as these transitional periods are being extended by the European Commission. In addition, these dates are subject to, and vary according to, the type of device and its risk classification, so there is no single date to indicate regarding the validity of these articles. Accepted and added	
GENERAL	In accordance with guideline 80 of the	Accepted and corrected accordingly.	MINISTRY OF INDUSTRY,

	Guidelines on Legislative Drafting, approved by the Agreement of the Council of Ministers of 22 July 2005, the first citation of norms, both in the explanatory part and in the enacting terms, must be complete and may be abbreviated on other occasions by indicating only type, number and year, if any, and date. Thus, the first normative reference that appears in the antepenultimate paragraph of the explanatory part and the normative reference that appears in the first additional provision must be cited in full.		TRADE AND TOURISM
GENERAL	OBSERVATION 1 - Headings of the Articles, additional provisions, transitional provisions, single repealing provision and final provisions. The titles or headings of the aforementioned provisions must comply with the criteria on numbering, composition, and format of the articles and provisions established in the Guidelines on Legislative Drafting numbers 27, 29, and 37 approved by the Agreement of the Council of Ministers of 22 July 2005 (BOE No 180, of 29/07/2005). JUSTIFICATION: Reference should be made to the aforementioned Guidelines on Legislative Drafting, numbers 27, 29 and 37 approved by the Agreement of the Council of Ministers of 22 July 2005.	Accepted and corrected accordingly.	MINISTERIAL COMMISSION FOR DIGITAL ADMINISTRATION
GENERAL	Generally speaking, the draft regulates multiple aspects of the production and distribution of medicinal products and medical devices. However, it would be appropriate to include a	Not accepted. The text only refers to *in vitro* diagnostic medical devices and not to medicinal products. Regulation 2017/746 on *in vitro*	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH

	provision on the storage conditions of the devices.	diagnostic medical devices already lays down the requirements and conditions for the storage of the devices, so it is not considered necessary to include any additional requirements in this text.	MADRID
GENERAL	The regulatory impact analysis report will include any other point that may be relevant at the discretion of the proposing body, paying special attention to social and environmental impacts, the impact on equal opportunities, non-discrimination, and universal accessibility for persons with disabilities and the impact that the development or use of the means and services of the digital administration will have for citizens and the Administration. The said risk analysis or the DPIA has not been carried out by the proposing body of the draft RD, nor does the Regulatory Impact Analysis Report refer, in its Impact Analysis section, to impacts due to the protection of personal data. This AEPD suggests that this DPIA be carried out and incorporated into the Regulatory Impact Analysis Report so that the risk/impact posed to the interested parties by the processing of personal data in the regulated matter can be established in the file, and the necessary organisational or security measures etc. can be foreseen to reduce the risks derived from such	Accepted. Regulatory Impact Analysis Report is revised. Environmental and climate change matters have been incorporated in the Regulatory Impact Analysis Report. In terms of data protection, the report from the DPO of the AEMPS has been issued and incorporated into the file. A general reference to the project's compliance with the general data protection regulations has been included.	SPANISH DATA PROTECTION AGENCY

	processing. However, and as this AEPD has also maintained, at the time when a legal norm is applied to regulate processing, controllers or processors will be obliged to apply that norm, so it will be necessary to first determine that it is in accordance with the regulations on the protection of personal data. Carrying out the aforementioned Risk Analysis, and where appropriate the DPIA, would allow controllers or processors not to have the obligation to carry out such an impact assessment of personal data (DPIA) prescribed in Article 35(1) GDPR (and which the Royal Decree on the National Security Framework has also considered mandatory) precisely because it has already been carried out within the process of developing the general rule.		
GENERAL	It is understood that due to the proliferation of 'kits for self-sampling', and based on ensuring that medical devices do not pose risks to health and safety, ensuring their use in accordance with the intended purpose by the manufacturers, something should be regulated in this new Royal Decree where necessary requirements are contemplated.	Not accepted. Regulation 2017/746 and the wording of this Royal Decree already establish that devices must be used in accordance with the intended use of the manufacturer. The health authorities shall be responsible for enforcing those requirements in the context of market surveillance.	ANDALUSIA
GENERAL	In accordance with section V. Appendices to the guidelines on legislative drafting regarding the use of acronyms, which '(...) may be justified within a provision, in order to avoid	Not accepted. It is correct to use the full name of the Agency.	MADRID

	cumbersome formulations and tiresome repetitions, provided that it is explained, when they appear for the first time (outside the title and the explanatory part), by their inclusion in parentheses or commas preceded by the expression 'hereinafter' and written in capital letters without full stops or spaces of separation.', it is suggested that the acronym AEMPS be used in the text of the draft Royal Decree.		
GENERAL	As set out in Annex I, entitled 'Contributions received in the process of prior public consultation of the draft' of the Regulatory Impact Analysis Report on the draft Royal Decree regulating *in vitro* diagnostic medical devices, this Federation made submissions to the prior consultation, which included the following comments from the regulator: 'With regard to self-testing by the pharmacist, the Royal Decree provides that 'Products may only be placed on the market, marketed and/or put into service if they comply with the requirements laid down in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in this Royal Decree, when they have been duly supplied, are correctly installed and maintained in accordance with the manufacturer's instructions, and are used in accordance with their intended purpose, without compromising the safety or health of patients, users or, where appropriate, third parties'. The intended purpose of the manufacturer provides that these tests can be carried out by users.	Not accepted. Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices provides in Article 5(1). A device may only be placed on the market or put into service if it complies with this Regulation, provided that it is properly supplied and installed, maintained, and used in accordance with its intended purpose. Likewise, the Regulation itself already establishes specific requirements for devices for self-testing to ensure proper use and interpretation of the results by lay users, which is why it is not considered necessary. In this sense, the current text of the draft Royal Decree does not limit in any way the ability of the patient or user to ask the pharmacist for advice and information regarding the performance of a self-testing test at the time of its acquisition. On the other hand,	FEDERATION OF SPANISH PHARMACISTS - FEFE

	‘However, the new Royal Decree provides that the Spanish Agency of Medicines and Medical Devices, in order to ensure the protection of human health, safety, or compliance with public health rules, may adopt all necessary and transitional measures that are justified in respect of a device, category, or specific group of devices, may lay down provisions on the conditions of use thereof or on special monitoring measures, and include the warnings necessary to avoid health risks in their use.’ From this Federation, it is considered that the regulator has not fully understood the request or claim made by this Federation regarding the performance of self-testing tests by the pharmacist, as it is not a matter of substituting or replacing the patient, much less in a general way of impairing their ability to perform such tests. Furthermore, it is certainly not FEFE's intention to amend or contravene what is established by the manufacturer of these medical devices, which classify them as ‘medical devices for self-testing’. FEFE’s claim was and still is, as we will reiterate in this submission, that a provision should be issued whereby, as with the Personalised Dosing Systems, it is expressly recognised that once the ‘medical device for self-testing’ had been dispensed and at the patient’s request, the pharmacist can help the patient to carry out the test, interpret the result and, where appropriate, also at the patient’s request, certify the result to them. The professional capacity of the pharmacists is	regulating the option of authorising pharmacies to carry out the self-testing test together with the patient in the establishment itself is not the purpose of this Royal Decree, but rather of the activities that can be carried out in health establishments.	

	beyond doubt, as is the fact that they are qualified to do so; the need for such a rule is simply for reasons of legal certainty. In compliance with the provisions of Article 5(3) of the draft text: 'In order to ensure the correct use of the devices, the professionals who use them must be properly qualified and trained.' It should be borne in mind that the regulator itself in Annex I, entitled 'Contributions received in the process of prior public consultation of the project' of the Report on the Regulatory Impact Analysis of the draft Royal Decree regulating *in vitro* diagnostic medical devices, when dealing with the subject of sale to the public, distance selling and prescription, indicates: '[…] 'With regard to the sale to the public of devices for self-testing, the obligation of exclusive sale through pharmacies or through the website of the pharmacy itself remains. It is considered that the intervention of the pharmacist is essential, as during the dispensing, they can inform the patient about the correct handling of the test and the sample, as well as the interpretation of the result, indicating to the user, if necessary, when they should contact the health service. In addition, the community pharmacy, as a health establishment, ensures appropriate preservation conditions. Furthermore, if the adoption of market surveillance and control measures is necessary, the traceability of the devices in the pharmaceutical channel is		

	guaranteed'. FEFE expressly wishes to reiterate that the proposed norm includes a specific provision recognising the pharmacist's ability to assist the patient in carrying out self-testing, either in the collection of the samples themselves, or at any other stage of the self-testing process, including the reading, verification and, where appropriate, certification of the test result, all with the patient's prior consent and once the medical device has been dispensed.		
PREAMBLE	In accordance with the provisions of guideline 15 of the Guidelines on Legislative Drafting, approved by the Agreement of the Council of Ministers of 22 July 2005 (hereinafter, Guidelines on Legislative Drafting), 'if the explanatory part of the provision is long, it may be divided into sections, which shall be identified by Roman numerals centred on the text.' Therefore, due to its length, it is recommended that the preamble be divided into sections, the first (I) relating to European legislation, comprising the first to sixth paragraphs; the second, (II) on the content of the draft, which would comprise paragraphs seven to twenty; and the third, which would	Accepted and amended accordingly	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	begin with the twenty-first paragraph. • In paragraph 25, it is recommended that explicit reference be made to the principle of transparency. • On the other hand, the justification of the rule in relation to the principle of efficiency which means avoiding unnecessary or ancillary administrative burdens and streamlining, in its implementation, the management of public resources, is missing.	This comment is accepted and added. Accepted and added with the same previous text in relation to administrative burdens.	
PREAMBLE	As regards the explanatory part: In the seventh paragraph of page 4, in accordance with the Guidelines on Legislative Drafting numbers 73 and 80, approved by the Agreement of the Council of Ministers of 22 July 2005 (hereinafter guidelines), it is suggested that the full title of Royal Decree 1337/1999, of 31 July be included.	Accepted.	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID
PREAMBLE	Analysis of competence 1. As for the title of competence that empowers the Government for its approval, the explanatory part provides that this draft Royal Decree is issued under the exclusive competence of Article 149(1) (16) of the Spanish Constitution which attributes to the State in matters of legislation on pharmaceutical devices, with the exception of Chapter VI, which is issued under the exclusive competence that this same article attributes to	Not accepted. The regulation of this matter by the State legislature by means of a rule of lower rank than the law is clearly covered in the 3rd Additional Provision of the TRLGURM. Notwithstanding the foregoing, it should be noted that it is not a question here of a regulatory development of a law, but of the accommodation of the	CATALONIA

	the State in matters of external health. The judgement of the Constitutional Court No 98/2004 of 25 May 2004 has established that the jurisdictional title relating to the legislation on pharmaceutical devices covers (exclusively) those rules which have as their object the organisation of medicinal devices as 'substances', the manufacture and marketing of which is subject - through the corresponding evaluation, registration, authorisation, inspection and surveillance activities - to the control by public authorities, in order to guarantee the rights of patients and users who use them. Moreover, as stated in the explanatory memorandum, the draft is also supported by Article 100(1) of Law 14/1986 of 25 April 1986, the General Health Law, of a basic nature, in relation to the granting of the prior operating licence to companies that carry out activities of manufacture, grouping, sterilisation and import of *in vitro* diagnostic medical devices, as well as the manufacture of this type of devices by health institutions for their exclusive use by the institution itself. In fact, the Government of Catalonia has issued regulatory standards in areas of regulation contained in this draft Royal Decree, developing basic legal precepts, such as Decree 265/2005 of 13 December 2005, which lays down the requirements for the granting of operating	national legal framework in the matter to the provisions of the European standard — Regulation (EU) 2017/746 — which has the status of a law, and the supranational nature of which justifies *per se* a State regulatory action, as opposed to the Autonomous Community. Given that the purpose of this draft Royal Decree is to bring the current national legislation on *in vitro* diagnostic medical devices into line with the provisions of Regulation (EU) 2017/746, which has been in force since 26 May 2022, this regulation, first, is tasked with repealing the provisions relating to matters directly governed by the provisions of the Regulation and, secondly, with developing the necessary regulatory measures in respect of those aspects in which the Member States are required, pursuant to that Regulation, to establish nationwide rules. In this context, it is the responsibility of the State not only to establish the basic legislation applicable throughout its territory, but also to coordinate the various actions to be carried out by the regional administrations in general, which involves the prior determination of basic criteria and parameters for administrative action in this field.	

	health authorisation to manufacturers of custom-made orthoprosthetic medical devices and, more recently, Decree 159/2016 of 2 February 2016 laying down the technical requirements for the manufacture and marketing of dental prostheses and other customised dental health devices. In any case, we believe that the draft must clearly identify which precepts correspond to one or the other title, and in that identification, it must be aligned with the laws and the interpretation of the Constitutional Court. The granting of this consideration is important. In accordance with Article 111 of the Statute of Autonomy of Catalonia, in the shared competences, the Generalitat holds the legislative power, the regulatory power, and the executive function, within the framework of the bases that the State establishes as principles or minimum common normative standards in norms with the rank of law, except in the cases determined in accordance with the Constitution and this Statute. The current Statute has affirmed a well-established jurisprudential doctrine, proclaiming the general rule that state bases must be established by laws and must be minimum common denominator normative principles, and the use of instruments of lower rank than the law for the fixing of bases constitutes an exception. This statutory provision binds the		

	State legislature and the General State Administration, as the holder of regulatory power. In this case, however, recourse to regulatory power with general effectiveness for the entire State is expressly established in the third additional provision of the consolidated text of the Law on Guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015, a rule that was not challenged before the Constitutional Court at the time. With regard to State competence in the area of legislation on pharmaceutical devices, the Generalitat has executive competence, which includes, as provided for in Article 112 of the Statute, regulatory power and executive function.		
PREAMBLE	At European level, it has been considered necessary to establish a new robust, transparent, predictable and sustainable regulatory framework for *in vitro* diagnostic medical devices, ensuring the highest level of effectiveness, safety and health protection for patients and users. Point 1 of Annex I to Regulation 2017/746 ensures compliance with efficacy and safety to guarantee that the benefit-risk balance is not adversely affected.	Not accepted. The wording of the preamble follows that of Regulation 2017/746, as the main guarantees.	FENIN
PREAMBLE	This Regulation harmonises the rules	Not accepted. The wording of the	FENIN

	applicable to the placing on the market and putting into service *in vitro* diagnostic medical devices and their accessories in the European Union, thus allowing them to benefit from the principle of free movement of goods, and, in addition, ensuring a high level of protection, so that the devices in circulation do not present risks to the health of patients, users or third parties and achieve the performance intended by the manufacturer, when used under the conditions laid down. his Regulation harmonises the rules applicable to the placing on the market and putting into service *in vitro* diagnostic medical devices and their accessories in the European Union, thus allowing them to benefit from the principle of free movement of goods, and, in addition, ensuring a high level of protection, so that the devices in circulation do not present risks to the health of patients, users or third parties and achieve the performance intended by the manufacturer, when used under the conditions laid down, all under objective criteria of evidence. JUSTIFICATION: Point 1 of Annex I to Regulation 2017/746 ensures compliance with efficacy and safety to guarantee that the benefit-risk balance is not adversely affected. In this regard, clinical trials are divided into three levels based on the scientific validity, analytical	preamble follows that of Regulation 2017/746, as the main guarantees.	

	performance, and clinical performance of the device.		
PREAMBLE	Page 2 introduction This type of manufacture and exclusive use in health institutions is not aimed at subsequent marketing or obtaining economic benefit, and it is in the direct interest of a specific group of patients for whom there are no alternatives on the market, so it requires the corresponding agility and flexibility, in the interests of patients, always ensuring the proper functioning and safety of the devices. Perhaps add 'or that these are inferior to those developed by the health institution' after 'for which there are no alternatives on the market'. Include reference to the alternatives being inferior to those developed by the health institution.	Not accepted. Regulation 2017/746 clearly indicates the conditions for considering it as in-house manufacture in a health institution. This regulation already provides that this manufacture will be carried out *where the specific needs of the patient group for which the devices are intended cannot be met, or cannot be met at the appropriate level of performance, by another equivalent device placed on the market;* The inclusion of the wording 'or that the alternatives are inferior to those developed by the health institution' would mean including requirements in national legislation that are different from those established in the regulation.	SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)
PREAMBLE	The explanatory part of the draft states that 'although Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 is directly applicable in the countries of the European Union, it is necessary to regulate at national level the aspects that the European norm leaves to the regulation of each Member State. To this end, this Royal Decree is adopted, which specifies issues such as the determination of the competent authority for the purposes of Regulation (EU) 2017/746 of the	Not accepted. This requirement is not new; it has existed since at least Royal Decree 414/1996 of 1 March 1996. Both Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 and Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market	SPANISH SOCIETY OF MICROBIOLOGY

	European Parliament and of the Council of 5 April 2017, the health guarantees for devices, the establishment of the language regime, and the regulation of procedures for the manufacture of devices for use in the health institution itself (...)' The rules governing external trade in the medical devices covered by the draft are set out in Articles 22 and 23 of the draft. In this regard, in relation to importation, Article 22 seems to establish a system of pre-import control by the 'Spanish Agency of Medicines and Medical Devices, through the services of pharmaceutical inspection of the functional areas of health and social policy of the Government Delegations', so that compliance with certain requirements will be verified before importation and, in the event of non-compliance, the goods will be rejected. However, there is no mention of whether such intervention affects the authorisation of the customs procedure by the customs authority. In this regard, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 does not provide for a system of pre-import control and, therefore, it could be contrary to it to make the release for free circulation of the goods subject to the prior intervention of the	surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 lay down in their articles the obligation of the Member States to control the external borders to ensure that they only introduce products which comply with the Community rules applicable to them and products which do not pose a risk to health. Customs authorities shall cooperate with the competent sectoral authorities. The objective of this prior control is therefore to ensure the entry into Spain and the EU of devices that comply with the legislation on medical devices.	

	pharmaceutical inspection services		
Article 1	In order to delimit the scope of the proposed regulation and enhance understanding of it, the following wording is proposed for the first paragraph: 'The purpose of this Royal Decree is to lay down detailed rules for the application to *in vitro* diagnostic medical devices for human use and their accessories, complementary to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, and in particular:' Paragraph (c) should therefore contain the short citation of the regulation and also the short citation of the Article: '(c) Genetic testing as an *in vitro* diagnostic medical device for human use included in the definition in ~~paragraph 2 of~~ Article 2(2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.'	Not accepted. It is proposed that the text be maintained in the same form as in Royal Decree 192/2023 of 21 March to align both Royal Decrees, which must be completely consistent, and to avoid discrepancies in interpretation. On the other hand, the proposed wording that mentions 'complementary' might not refer in its entirety to the subject matter of the Royal Decree. The amendment to include 2(2) instead of paragraph is accepted.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
Article 1	This Royal Decree aims to regulate '*in vitro* diagnostic medical devices for human use and their accessories, and in particular:' Listed below are a number of elements that can	Not accepted because it is implicitly understood that regulating *in vitro* diagnostic medical devices for human use and their accessories does not involve only the device but the entire	MINISTRY OF INDUSTRY, TRADE AND TOURISM

	hardly be considered as '*in vitro* diagnostic medical devices for human use' or 'accessories' thereof, (a) The competent authority and health guarantees. (b) Procedures for the granting of licences prior to operation of facilities. (d) Reference laboratories. (f) Placing on the market and putting into service in Spain. It is therefore recommended that the wording of paragraph 1 be revised.	scope it covers.	
Article 1	For the purposes of this Royal Decree, the definitions set out in Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in the acts adopted for its implementation shall apply. JUSTIFICATION: We propose amending the text to use the same wording as in Royal Decree 192/2023 on medical devices.	Accepted	FENIN
Article 1	Article 1. *Purpose.* This Royal Decree aims to regulate diagnostic medical devices *in vitro* for human use and their accessories, and in particular: a. The competent authority and the health guarantees. b. The procedures for the granting of prior operating licences for facilities c. Genetic tests considered as *in vitro* diagnostic medical devices for human use as defined in Article 2(2) of	Not accepted. No clarification is considered necessary. Both the object and scope of Regulation 201/746 and the draft Royal Decree regulate devices that are considered *in vitro* diagnostic devices and their accessories. This is why Article 1(c) expressly mentions that the Royal Decree regulates genetic tests that are considered to be *in vitro* diagnostic	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. d. Reference laboratories. e. The requirements and actions of notified bodies. f. Placing on the market and putting into service in Spain. g. Intra-Community and external trade. h. Performance studies. i. The surveillance system. j. Market inspection and control and health protection measures. It needs to be clarified whether there are genetic tests that expressly fall outside Article 2(2) and are therefore not considered an *in vitro* diagnostic medical device.	medical devices for human use included in the definition contained in Article 2(2) of the Regulation, leaving other types of devices outside the scope.	
Article 2	ONE. - ON THE CHANGE OF NAME OF DEVICES FOR SELF-TESTING (Article 2). Article 2 of the draft Royal Decree expressly provides that 'for the purposes of this Royal Decree, the definitions set out in Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in the provisions adopted for its implementation shall apply.' The text of the draft Royal Decree does not exactly comply with the requirements of this EU Regulation, since it refers to these devices as 'productos de autodiagnóstico'. However, the original English	Not accepted. The definition of 'autodiagnóstico' is set out in Article 2(5) of Regulation (EU) 2017/746, in the official Spanish version. REGLAMENTO (UE) 2017/ 746 DEL PARLAMENTO EUROPEO Y DEL CONSEJO - de 5 de abril de 2017 - sobre los productos sanitarios para diagnóstico in vitro y por el que se derogan la Directiva 98/ 79/ CE y la	ANEFP

	text of Regulation 2017/746, of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, includes in Article 2(5) the term 'device for self-testing' to refer to these devices. The most appropriate translation into Spanish for this expression should be 'producto para autotest', which is much more in line with the purpose of these devices than is currently the case under Spanish legislation. We would remind that this type of device is intended to allow the layperson to determine certain biochemical parameters, detect certain physiological states, infections, food intolerances, allergic processes, and pathologies, mainly. Its purpose is not, therefore, to diagnose diseases. In addition, it should be borne in mind that, according to the RAE, the word 'test' may be used in Spanish as a synonym for 'prueba' or 'examen'. Therefore, ANEFP proposes that the translation of the expression 'device for self-testing' be changed to 'producto de auto-test', to be included in the text of the draft Royal Decree regulating *in vitro* diagnostic medical devices.	Decisión 2010/ 227/ UE de la Comisión (boe.es)	
Article 2	It states, 'For the purposes of this Royal Decree, the definitions set out in Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in the provisions adopted for its implementation shall apply...'. Devices for self-testing are defined as any device intended by the manufacturer to be used	Not accepted. Subparagraph (a) The concept of the information society is already contained in Article 6(1) of the Regulation *1. A device offered through information society services as defined*	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI

	by lay persons, including devices used for self-testing services offered to lay persons by means of information society services. The concept of the information society and the types of devices for self-testing offered through this channel should be clarified. (b) The Royal Decree should use the term "productos de auto test" instead of 'autodiagnóstico' because it is more faithful to the concept used in English and to avoid errors of interpretation regarding the ability of a layperson to diagnose themselves through the use of one of these tests.	*in point (b) of Article 1(1) of Directive (EU) 2015/1535.* Subparagraph (b). The definition of a 'test de autodiagnóstico' is included in Article 2(5) of Regulation (EU) 2017/746, in the official Spanish version. REGLAMENTO (UE) 2017/ 746 DEL PARLAMENTO EUROPEO Y DEL CONSEJO - de 5 de abril de 2017 - sobre los productos sanitarios para diagnóstico in vitro y por el que se derogan la Directiva 98/ 79/ CE y la Decisión 2010/ 227/ UE de la Comisión (boe.es)	
Article 2	'For the purposes of this Royal Decree, the definitions set out in Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in the provisions adopted for its implementation shall apply.' Regarding the scope of application, Article 1(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 provides: '6. Devices which are also machinery within the meaning of Article 2(2)(a) of Directive 2006/42/EC of the European Parliament and of the Council shall, where a hazard exists within the meaning of that	Not accepted. The Royal Decree does not mention that rule; it is Regulation 2017/746, so this Royal Decree cannot modify what is indicated in a Regulation.	MINISTRY OF INDUSTRY, TRADE AND TOURISM

	Directive, also comply with the essential health and safety requirements set out in Annex I to that Directive, in so far as those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.' The aforementioned Directive could be replaced by a new regulation shortly (COM(2021) 202 - Proposal for a Regulation of the European Parliament and of the Council on machinery products), with the essential health and safety requirements identified in Annex III to the same (COM(2021) 202 ANNEX - Annex to the Proposal for a Regulation of the European Parliament and of the Council on machinery products). For this reason, it is suggested that, before the final approval of the draft Royal Decree, it should be verified whether this new EU regulation has been published and, if necessary, the references to the regulation should be amended.		
Article 3	Like Article 1, in the same vein, reference could be made to Article 3 concerning the scope of application, as it concerns only medical devices. It is therefore recommended that the wording of paragraph 3 be revised.	Not accepted because it is implicitly understood that regulating *in vitro* diagnostic medical devices for human use and their accessories does not involve only the device but the entire scope it covers.	MINISTRY OF INDUSTRY, TRADE AND TOURISM
Article 3	Article 3(1), second paragraph, refers to the designation, for the purposes of the Royal Decree, of *in vitro* diagnostic medical devices; however, such clarification could be better accommodated by mentioning the referred	Not accepted. It is considered more appropriate to include the reference to a device in general once the definition of an *in vitro* diagnostic medical device	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID

	devices for the first time.	has been stated. Also, in line with Royal Decree 192/2023	
Article 3	(a) Point 2. It states that 'Medical devices whose conformity has been determined in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 do not fall under Royal Decree 186/2016 of 6 May regulating the electromagnetic compatibility of electrical and electronic equipment...'. The reason why Royal Decree 186/2016 is not applicable should be clarified, as well as what happens with electrical tests	Not accepted. The justification is set out in recital 14 of the Regulation itself and in footnote 1. This legislation does not apply to them because the safety aspects of it are already included in the general safety and operational requirements of Annex I to Regulation 201/746. That is why compliance with Regulation 2017/746 directly implies compliance with the electromagnetic compatibility regulation of electrical and electronic equipment.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
Art. 3	Article 3. Scope. 1. This Royal Decree shall apply to devices falling within the scope of Article 1 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. For the purposes of this Royal Decree, *in vitro* diagnostic medical devices and accessories for *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'. It is necessary to clarify whether it follows from this that genetic tests are hereinafter also referred to as 'devices'.	Not accepted. As indicated in ASEBIO's claim against Article 1, paragraph (c) expressly mentions that the Royal Decree regulates genetic tests that are considered to be *in vitro* diagnostic medical devices for human use included in the definition contained in Article 2(2) of the Regulation, leaving other types of devices outside the scope. These tests are therefore *in vitro* diagnostic medical devices and are therefore included in the general name 'devices' used throughout the Royal Decree. It should also be noted that this general designation also	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

		applies in Regulation (EU) 2017/746, Article 1(2).	
Article 3	Article 3(3) i.e. the third paragraph of Article 3. 'Scope'. Proposed wording: '3. This provision shall not affect the application of Royal Decree 601/2019 of 18 October 2019 on the justification and optimisation of the use of ionising radiation for the radiation protection of persons during medical exposure; nor of ~~Royal Decree 783/2001 of 6 July approving the Regulation on health protection against ionising radiation~~ **Royal Decree 1029/2022 of 20 December 2022 approving the Regulation on the protection of health against the risks arising from exposure to ionising radiation**; nor Royal Decree 1836/1999 of 3 December approving the Regulation on nuclear and radioactive facilities; nor Royal Decree 1085/2009 of 3 July 2009 approving the Regulation on the installation and use of X-ray devices for medical diagnostic purposes.' ▪ Justification: Article 3 of the draft Royal Decree regulates the scope of application of the legislation, noting that it will not affect the application of the Regulation on health protection against ionising radiation, approved, as indicated, by Royal Decree 738/2001 of 6 July 2001. However, that reference is outdated, in so far as that Royal Decree was expressly repealed	Accepted. The reference to Royal Decree 738/2001 of 6 July 2001 is replaced by Royal Decree 1029/2022 of 20 December 2022.	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN (CGCOF)

	by the sole repealing provision of Royal Decree 1029/2022 of 20 December 2022 adopting the Regulation on the protection of health against the risks arising from exposure to ionising radiation. We therefore propose that Article 3(3) update the reference to refer to the currently applicable Royal Decree.		
Article 3	Art 3.3. This provision shall not affect the application of Royal Decree 601/2019 of 18 October 2019 on the justification and optimisation of the use of ionising radiation for the radiation protection of persons during medical exposure; neither Royal Decree 1029/2022 of 20 December approving the Regulation on health protection against risks arising from exposure to ionising radiation; nor Royal Decree 1836/1999 of 3 December 1999 approving the Regulation on nuclear and radioactive facilities; nor Royal Decree 1085/2009 of 3 July 2009 approving the Regulation on the installation and use of X-ray devices for medical diagnostic purposes. JUSTIFICATION: There is an error in the reference of the Royal Decree on ionising radiation, the Royal Decree in force is Royal Decree 1029/2022 of 20 December approving the Regulation on the protection of health against risks arising from exposure to ionising radiation.	Accepted	FENIN
Article 4	In paragraph 1 it is also recommended to indicate that the Spanish Agency of Medicines and Medical Devices is responsible for the implementation of the above-mentioned	Not accepted. It is proposed that the text be maintained in the same form as in Royal Decree 192/2023 of 21 March	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	Regulation.	to align both Royal Decrees, which must be completely consistent, and to avoid discrepancies in interpretation. The Article refers to Article 96 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, which concerns the competent authority for the purposes of this Regulation. However, there are other national health authorities, such as the Autonomous Communities, which have competences and are also co-responsible for activities under the Regulation, such as market control.	
Article 4	Article 4.1 It is requested that the wording in the draft '...regardless of the powers of other health authorities' be replaced by 'as well as the health authorities of the Autonomous Communities within the scope of their powers'. Justification: In accordance with current legislation (Article 108 of the consolidated text of the Law on Guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015), the health authorities of the Autonomous Communities are competent to carry out the corresponding inspection and control actions to ensure compliance with that Law. Therefore, and taking into account the European regulatory	Not accepted. The text is not limited solely to the powers of the health authorities of the Autonomous Communities, but extends this to include additional health authorities (city councils, town councils, peripheral pharmaceutical services)	CATALONIA

	framework, these powers extend to actions to ensure compliance with the provisions of Regulation (EU) 2017/746, in order to comply with what is established in Article 101.		
Art. 4	Article 4.2. The Spanish Agency of Medicines and Medical Devices shall decide on the application to a device of the definitions and classification criteria in accordance with Articles 2 and 47(2) and Annex VIII to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. Prior to this decision, and if necessary, the Spanish Agency for Medicinal Products and Medical Devices may consult the Committee on Medical Devices, regulated by article 28 bis of Royal Decree 1275/2011 of 16 September, establishing the State Agency 'Spanish Agency for Medicines and Medical Devices' and approving its Statute, as well as experts in the field. JUSTIFICATION: We propose amending the text to use the same wording as in Royal Decree 192/2023 on medical devices.	Accepted	FENIN
Article 5	• The second and fourth subparagraphs of paragraph 3 refer to professionals or personnel duly qualified or trained for the use or maintenance of the devices, however, this required training or qualification is not specified.	Not accepted. Based on the wide variety of *in vitro* diagnostic medical devices (software, analysers, reagents, calibrators, sample collection kits, etc.), it is not possible to specify the training or qualification, as it will depend on the type of device in question.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	• It is recommended that the wording drafted in the third subparagraph of paragraph 3 be revised since the intended meaning is not clear, since Article 6(2) of the cited Regulation refers to a device not placed on the market but used to provide a diagnostic or therapeutic service through information society services or by other means, but nothing is inferred about this in the aforementioned paragraph, where, moreover, it does not appear to be syntactically correct when it states 'Para las pruebas diagnósticas (…) solo podrán ser utilizadas (…). • On the other hand, in accordance with guideline 68 of the Guidelines on Legislative Drafting, articles must be cited correctly in a concise and descending manner. It is therefore recommended to replace the reference to paragraph 2 of Article 6 by 'Article 2.6 of Regulation (EU) 2017/746'.	Not accepted. The wording of the third paragraph of Article 5 refers to point 2.6 of the Regulation, not point 6.2; we do not know if it is an error. On the other hand, point 2.6 refers to diagnoses made at the patient's care site (i.e. at the patient's bedside or those made in pharmacies by the pharmacist) and point 6.2 refers to distance sales, which is not the same concept. The revision of the syntactic correction is accepted Accepted Accepted and amended	
Article 5	In the third subparagraph of Article 5.3, in accordance with guideline 68, it is suggested	Not accepted, it is already the short citation.	GENERAL TECHNICAL SECRETARIAT

	that the short and descending citation from the article of the above-mentioned Regulation be used.		DEPARTMENT OF HEALTH MADRID
Article 5	It states that 'In order to ensure the correct use of the devices, the professionals who use them must be properly qualified and trained.' It is understood that the term 'properly' is not sufficient, and this qualification and training should be specified.	Not accepted. It is not considered the purpose of this Royal Decree to specifically provide for the qualification and training of professionals using *in vitro* diagnostic medical devices. The wide variety of techniques used in the use of *in vitro* diagnostic medical devices implies that the qualification and training must be related to the technique in question.	ANDALUSIA
Article 5	Article 5.2. Replace '..., at least in Spanish,...' with '..., at least in Spanish and in the other co-official languages of the Spanish State,...' Justification: In accordance with Law 22/2010 of the Consumer Code of Catalonia (Article 128-1), consumers in Catalonia have the right to receive in Catalan the information necessary for the proper consumption, use and handling of goods and services, according to their characteristics, regardless of the medium, format or medium used, and, especially, the mandatory data directly related to the safeguarding of health and safety. This is the case of the information contained in the labelling of the devices regulated in this draft Royal Decree.	Not accepted. On the basis of Article 15 of Law 39/2015 of 1 October, reference is made to Spanish, with the constitutional provision of Article 3 implementing the naming of Spanish as the official language of the State. Therefore, it is understood that the denomination, for internal coherence and in order not to break the co-officiality, also proper to the legal system, where it is covered by the regulatory rule — the statute of autonomy — is that of 'Spanish'. Account should also be taken of Article 10(14) of the said Regulation (EU) on the obligation of the manufacturer to	CATALONIA

		cooperate with the relevant authority by providing information and documentation of the device in an official language of the Union (Spanish since 1986, as a language unanimously approved by the Council).	
Article 5	Art 5.3. In order to ensure the correct use of the devices, the professionals who use them must be properly qualified and trained. The validation of the results generated by these devices must be carried out by specialists responsible for the execution and analysis of the technique or test. For diagnostic devices for near-patient testing, in accordance with Article 2(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, they may only be used by users with the level of training, qualification, or experience established by the manufacturer in the instructions for use of the device.	Not accepted; it is a general provision. It is not the purpose of this Royal Decree, nor is it within the competence of the Agency to establish the types of professionals who will use the devices regulated therein. In addition, given the wide variety of devices on the market, depending on the type of device, they will be specialists of one type or another.	SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)
Article 5	1. Devices may be placed on the market, marketed and/or put into service only if they comply with the requirements laid down in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in this Royal Decree, provided that these are duly supplied, correctly installed and maintained according to the manufacturer's instructions, and are used in accordance with their intended purpose, without compromising the clinical effectiveness in diagnosis, safety or health of patients, users or, where applicable, third parties.	Not accepted. Annex I of the Regulation already sets out the general safety and performance requirements. Article 5(1), when indicating compromise, focuses on safety and health. Likewise, for consistency, the wording of Royal Decree 192/2023 is followed.	FENIN

	JUSTIFICATION: Regulation 2017/746, in point 1 of Annex I, ensures compliance with both efficacy and safety to guarantee the benefit-risk balance. This benefit-risk balance is of fundamental importance, for example, in the case of those medical devices that have the explicit objective of serving as therapeutic decision-making tools regarding the use of drugs or other interventions, or when they modify usual clinical practice.		
Article 5	5.2. At the time of entry into service in Spain, the devices must include the data and information contained in paragraph 20 of Annex I to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 at least in Spanish so as to make it possible to have effective, truthful and sufficient information on their essential characteristics in a certain and objective manner. For genetic tests, it is not clear how the data and information contained in paragraph 20 of Annex I to Regulation (EU) 2017/746 should be included.	Not accepted. As indicated above, genetic tests considered as *in vitro* diagnostic medical devices for human use, as defined in Article 2(2) of Regulation (EU) 2017/746, are *in vitro* diagnostic medical devices for all purposes and must therefore comply with all the provisions of Regulation 2017/746 and the provisions of the future RD on *in vitro* diagnostic devices.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 5	Concerning paragraph 3 of Article 5. 'Health guarantees of devices'. ▪ Proposed wording: '3. Only devices that comply with the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and this Royal Decree may be used in Spain, under the conditions and according to the	Partly accepted. The word 'users' is replaced by 'health professionals' As regards the AEMPS being the body to establish the level of training, qualification or experience of health professionals using these devices, it is not for that Agency to establish these	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	purposes foreseen by the manufacturer thereof. In order to ensure the correct use of the devices, the health professionals who use them must be properly qualified and trained. For diagnostic devices for near-patient testing, in accordance with Article 2(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, they may only be used by ~~users~~ **health professionals** with the level of training, qualification, or experience established by **the Spanish Agency of Medicines and Medical Devices** ~~the manufacturer in the instructions for use of the device.~~ Devices must be properly maintained by suitably qualified personnel in such a way as to ensure that, during their period of use, they retain the safety and performance intended by their manufacturer.' ▪ Justification: Article 5 of the draft Royal Decree establishes the health guarantees applicable to medical devices. Among these, the third paragraph regulates the use of the devices, requiring that they be used in accordance with the conditions and purposes provided for by the manufacturer and that they are used by professionals with the appropriate training and qualifications. In this regard, it is striking that it is not specified that the professionals who will use the medical devices are, precisely, health professionals or those in the health sector, figures legally	requirements. It is the manufacturer who designs the device and defines the intended purpose and the user who can perform the test. The Regulation itself establishes in its Annex I section 20(4)(1)(e) the need to include in the instructions for use the intended user, as appropriate (e.g. devices for self-testing or diagnostic devices for near-patient testing and professional use in laboratories, health professionals) On the other hand, at national level, the level of training, qualification or experience of health professionals for the use of the devices will be regulated by the provisions of Law 44/2003, of 21 November, on the organisation of the health professions ('LOPS') and in Royal Decree 1277/2003, of 10 October, laying down the general rules on the authorisation of health institutions, services and establishments and their legislative development at Autonomous Community level.	

	regulated in Law 44/2003, of 21 November, on the organisation of the health professions ('LOPS'). When defining these devices, Article 2 of the Regulation provides that they must be used for the study of samples from the human body with the sole or main purpose of providing information on one or more of the following: ▪ a physiological or pathological process or state; ▪ congenital physical or mental impairments; ▪ predisposition to a medical condition or disease; ▪ to determine safety and compatibility with potential recipients; ▪ to predict the response or reaction to treatment; ▪ to define or monitor therapeutic measures. As can be seen, all the purposes provided for by the Regulation are related to health care, so that, under the LOPS itself and the rest of the sectoral legislation, they must be provided by health professionals. Therefore, it does not make sense to refer to a generic formula such as 'professionals', when these devices will have to be used professionally by a well-defined category of professionals in our system such as health professionals. Moreover, it makes even less sense not to specify this issue if it is taken into account that, in the same paragraph, these professionals are required to use the devices with appropriate training, which only health professionals can have, and thus ensure health, safety, and the		

	correct interpretation and management of the results obtained during their use. On the other hand, Article 5(3) regulates use of diagnostic devices for near-patient testing, indicating that they must be used by users with the level of training, qualification, and experience established by the manufacturer; so it will be up to the manufacturer to determine who can carry out these tests and under what circumstances. Referring to the Regulation, which introduced this practice, it defines it in the following terms: '"diagnostic devices for near-patient testing" means any device not intended for self-testing but for testing outside the laboratory, usually near the patient or at the patient's bedside, **by a health professional**;' [emphasis added]. As can be seen, the Regulation—which is a harmonising rule with direct effect in the Member States—establishes that this type of practice must be carried out by a health professional, without it being possible for it to be used by another professional or 'user' (as the draft Royal Decree states). That being so, it makes no sense for the draft Royal Decree, a rule subsequent to the Regulation, not to be in line with it, and to introduce divergent wording which, read in isolation, may imply that such tests may be carried out by any non-health professional, which may entail risks to the health and safety of the patient, in so far as both the performance		

	of those tests and the management and interpretation of their results require the intervention of a health professional. Finally, Article 5(3) stipulates that the qualification required of the user who carries it out shall be determined by the manufacturer, who will include it in their conditions of use. In our view, this is an ill-advised option, since it involves, in practice, conferring on an agent interested in the widest possible marketing of the device the competence to determine who will be able to use it. Thus, there is a clear incentive for the manufacturer to include as little training as possible so that it can be used by as many users as possible, something that clearly undermines the independence that must govern this type of decision, which clearly and directly affects the safety of patients. In the same way, this may mean that, for different commercial brands of a similar device, there are different requirements depending on who manufactures them, something that lacks all logic and could cause a confusing situation for professionals and patients. For all these reasons, we consider it essential that the AEMPS, as the regulatory body for these devices at the national level, establishes the training requirements for carrying out the practice with each type of device, to ensure that the professional who performs it possesses the training and skills necessary for its safe and effective execution throughout the national territory, regardless of the manufacturer's		

	interests.		
Article 5	Article 5(3) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices, in Article 2(6), provides: '"diagnostic device for near-patient testing" means any device not intended for self-testing but for testing outside the laboratory, usually close to the patient or at the patient's bedside, by a health professional.' However, Article 5(3) of the draft text provides: 'For diagnostic devices for near-patient testing, in accordance with Article 2(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, they may only be used by users with the level of training, qualification, or experience established by the manufacturer in the instructions for use of the device.' We understand that this wording may cause confusion for the interpreter of the norm. We start from the premise that the reference to 'Article 2(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017' in the proposed standard must be understood as referring to those diagnostic services based on the information society, i.e., remotely, with the Spanish authorities limiting unlimited or indiscriminate access to these diagnostic tests and restricting their use to users with skills higher than common. We commend this limitation, as it contributes to the guarantee regime inherent in Spanish health regulations.	Not accepted. As set out in Article 2(6) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, '"diagnostic device for near-patient testing" means any device not intended for self-testing but for testing outside the laboratory, usually close to the patient or at the patient's bedside, by a health professional.' Therefore, this type of device is intended to be used near the patient or at the patient's bedside, with no place for its use as part of diagnostic or therapeutic services offered through information society systems regulated in Article 6(2) of the Regulation. A) The reference to Article 2(6) which sets out the definition of diagnostic devices for near-patient testing is considered sufficient to ensure that these devices are used by the health professionals indicated by the manufacturer in the instructions for use. B) However, the wording has been redrafted to replace 'user' with 'health professional'.	FEDERATION OF SPANISH PHARMACISTS - FEFE

	We are aware of the difficulty of drafting the rule, but we consider that a simple reference to the article of the Regulation is not sufficient, especially since it refers to a rule which refers again to another article of another legislative provision. We must assume that the classification as 'diagnostic devices for near-patient testing' in the information society systems will ensure, when it is not a matter of acquiring the medical devices themselves, the presence of the health professional and that they possess the required professional qualifications.		
Article 5	Art 5.3. To ensure the correct use of the devices, the professionals using them, as well as those validating or interpreting the results, must be properly qualified and trained. (...) may only be used by users with the level of training, qualification, or experience established by the competent health authorities in the matter. JUSTIFICATION: we consider it inappropriate for the manufacturer to set the personnel requirements	Not accepted. It is the manufacturer who, based on their conformity assessment procedure, establishes which professionals should use the device, and in no case is it the responsibility of the health authorities. This is a requirement already established by Regulation 2017/746.	SPANISH SOCIETY FOR IMMUNOLOGY SEI
Article 5	ONE. Concerning Article 5(3). The second paragraph says, 'To ensure the correct use of the devices, the professionals who use them must be properly qualified and trained'. This should be amended as follows: 'To ensure the correct use of the devices, except in the case of devices for self-testing, health professionals who use them must be properly qualified and trained to do so,	Not accepted. It is not considered necessary to clarify that the text does not include self-testing, since the wording refers to the qualification of professionals and self-testing kits are for lay users. On the other hand, it is not the purpose of this Royal Decree or within the competence of the Agency to	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA

	in accordance with current legislation.' The rationale for this proposal stems from the legislation. *In vitro* diagnostic medical devices (not devices for self-testing) can only be used by the health professionals referred to in Law 44/2003 of 21 November 2003 on the organisation of the health professions and, among them, only by those who are qualified to do so. To do otherwise would be to violate all health and education legislation, as well as the curriculum guidelines for these professions. With the wording submitted for us to study, this regulatory norm would be null and void as it violates a norm with the rank of law (Article 47(2) of Law 39/2015 of 1 October 2015); see Article 2 in conjunction with Article 6(3) of Law 44/2003 and Order SCO/3369/2006 of 9 October 2006 approving and publishing the training programme for the speciality of Clinical Analysis, Order SCO/3252/2006 of 2 October 2006 approving and publishing the training programme for the speciality of Clinical Biochemistry, Order SCO/3255/2006 of October 2006 approving and publishing the training programme for the speciality of Immunology, and Order SCO/3256/2006 of 2 October 2006 approving and publishing the training programme for the speciality of Microbiology and Parasitology. Law 16/2003, on Cohesion and Quality of the National Health System, is also violated, as it	determine what type of professionals can use *in vitro* diagnostic tests. It is the manufacturer who, based on their conformity assessment procedure, establishes which professionals should use the device, and in no case is it the responsibility of the health authorities. This is a requirement already established by Regulation 2017/746	

	organises the healthcare services around the activities of prevention, diagnosis, treatment, and rehabilitation that are carried out in health or socio-sanitary centres, in such a way that none of these activities can be performed by non-health personnel, as is intended in this case through the incorporation of other professionals and laypeople in the matter. Do not forget that only the designated professionals can provide this service, which requires the use of *in vitro* diagnostic medical devices, ensuring the appropriate professional, specialised, and quality care for the patient, a contributor to the National Health System. The current wording of the draft also unquestionably violates Article 43 of the Spanish Constitution. That wording, when referring to professionals, may refer to all types of such and it certainly cannot be accepted that in a health regulation the use of *in vitro* diagnostic medical devices is referring to any professional, not even to health professionals, since those who can use such devices and in a healthcare context for the interpretation of the results obtained in relation to the clinical situation of the patient are perfectly identified by the legislation, making this information available to clinicians. (c) Communication and discussion, with other specialists, about the meaning of the information obtained, among many other activities specific to such a discipline (paragraph 3b) of the Annex to Order SCO/3369/2006, of 9 October 2006.		

	These devices, regulated by this draft, are for *in vitro* diagnosis; therefore, only health professionals who can perform them, study and analyse the results, report them, and provide care to the patient and the multidisciplinary team for diagnosis are authorised to do so. The regulation must be drawn up by dedicating the precise and necessary time to allow the study of the situation, and in its wording, it is detected that it has not been carried out in this way. Later, we will see how a non-existent figure in the field is introduced as 'any other points of sale exclusively serving the public' in several provisions resulting from a carry-over of another regulation relating to medical devices, but not to *in vitro* diagnostic devices. Special mention must be made of the extraction or taking of samples; of course, the competent professional specialist for conducting the precise analyses using the devices regulated by this draft decree is also competent for such extraction. This is a phase within the process. For this phase, other health professionals, such as nursing staff, are authorised, but so far, they lack competence for any activity other than taking samples, since the analytical process corresponds to a specialist as referred to in Articles 2 and 6(3) of Law 44/2003, and this is categorical; it is not open to any interpretation. And this must be clear, without a doubt or interpretations, given that the superior legislation by virtue of the principle of normative		

	hierarchy clearly establishes the functional delimitation and the powers attributed in the matter, so that this draft must be limited in this matter to referring to the superior and specific legislation, such as Law 44/2003, of 21 November and the Orders cited, among others. We also propose adding a paragraph to Article 5(3) after the third paragraph: **'And regarding devices for self-testing, which are exclusively dispensed in pharmacies, pharmaceutical professionals will inform the user/patient of everything necessary for their use, and may offer their administration within the healthcare establishment itself'**. The wording we propose would be the most in line with the current social reality and with comparative law, as demanded by patients (evidenced during the health crisis caused by Covid-19, when self-testing kits were marketed), and it would be illogical that, if users request that they be conducted in this healthcare establishment, subject to administrative authorisation, surveillance, inspection, and control by the health authorities, it cannot be carried out on-site by these professionals in this matter of self-testing that can be performed by the patient. And its non-permission constitutes discrimination against the reality experienced daily in primary care centres and hospitals, where these self-testing tests are conducted in these facilities not by the	Not accepted. Article 2(5) of Regulation 2017/746 on *in vitro* diagnostic medical devices sets out the definition of 'device for self-testing' '(5) "device for self-testing": *any device intended by the manufacturer to be used by lay persons, including devices used for self-testing services offered to lay persons by means of information society services'*. Furthermore, Article 5(1) of this Royal Decree provides that 'A device may only be placed on the market... *is used*	

	user but by the personnel of said healthcare services. Concerning the third paragraph, which reads: For diagnostic devices for near-patient testing in accordance with Article 2(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, they may only be used by users with the level of training, qualification, or experience specified by the manufacturer in the instructions for use of the device, the proposal is to delete it. The reason is that it infringes the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, in the guidelines for health professionals' own studies and specialised health training, which it attributes to specialists in the health sciences who can make clinical determinations. In this way, it is intended that 'any person' can use these *in vitro* diagnostic medical devices, which are not for self-testing. Precisely these tests are defined in Article 2 (6) of the oft-repeated Regulation (EU) 2017/746 as: 'Any device not intended for self-testing but for testing outside the laboratory, usually near the patient or at the patient's bedside, by a health professional'; (the bold text and underlining are ours). Health professionals are those referred to in Articles 2 and 6(3) of Law 44/2003 of 21 November 2003 on the organisation of the health professions. Therefore, the reason is	*correctly in accordance with its intended purpose.*' Likewise, the Regulation itself already establishes specific requirements for devices for self-testing to ensure proper use and interpretation of the results by lay users, so it is not considered necessary. In this sense, the current text of the draft Royal Decree does not limit in any way the ability of the patient or user to ask the pharmacist for advice and information regarding the performance of a self-testing test at the time of its acquisition. On the other hand, regulating the option of authorising pharmacies to carry out the self-testing test together with the patient in the establishment itself is not the purpose of this Royal Decree, but rather of the activities that can be carried out in health establishments.	

	clear: it goes against the very Regulation that it intends to develop, and all the legislation cited with respect to our amendment to the second subparagraph of Article 5(3), which we are not repeating for reasons of procedural economy. For diagnostic devices for near-patient testing, in accordance with Article 2(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, they may only be used by a health professional. We repeat, either nothing is said, bearing in mind that the provisions of the Regulation apply, or if it is said, it should be drafted in accordance with the aforementioned EU law and not as it has been drafted. But it also violates the provisions of Article 2 of the draft submitted for our consideration, which expressly states 'Definitions. For the purposes of this Royal Decree, the definitions set out in Article 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and the provisions adopted for its implementation shall apply.' It is therefore clear that the above-mentioned paragraph 3 of Article 5(3) should be deleted from the text. For the sake of completeness, the definition of diagnostic devices for near-patient testing is clearly set out in Article 2(6) of the Regulation, so that these devices, which are not for self-testing and therefore not intended for use by lay		

	persons, must be administered by a health professional at the patient's home, in the health institution, in the ambulance, or in the socio-health centre where they are located, but, as stated, by a health professional. And that health professional cannot be just any health professional, but must be one who is qualified for this task, as we have already seen, namely the specialists in the clinics indicated through specialised health training (clinical analysis, immunology, clinical biochemistry and microbiology, and parasitology). Another thing is that, as we have indicated, the phase of sample extraction, in addition to the specialists ('who can do the most, can do the least'), can be carried out by other professionals such as nurses. But the extraction of samples cannot be confused with the use of all *in vitro* diagnostic medical devices and the process of analysis, study, and determination that leads to the results of the specialist's activity. Since this is who determines the diagnosis alone, with the specialist or together with the multidisciplinary team treating the patient. It seems that the wording of the rule overlooks the fact that the regulation's ultimate goal is safety and quality in patient care. And logically, both amendments adhere to the true safety and quality of patient care, on the one hand, and in accordance with the regulations that, as we have seen in the wording of the third subparagraph of Article 5(3), are violated by minimising with that wording the true qualification that must be held		

	by the health professional who uses this medical device for the exclusive benefit of the patient, whether for diagnosis, control, care in collaboration with the doctor treating the patient, etc. And in the same provision, the second subparagraph of Article 5(3) should have mentioned the devices for self-testing, which, however much training the instructions provide for the user, are indeed devices for self-testing and the requirement for a prescription is eliminated, except for genetic tests. Realistically, if the user wishes to obtain them for self-administration, and if performing them in the pharmacy is not permitted, no amount of information provided by the pharmaceutical professional guarantees, at least under this rule, that it is done for the benefit of the patient.		
Article 7	•In order to improve comprehension, it is recommended that the order of the clauses be altered in paragraph 1, this will also align its content with the provisions of paragraph 2, which clarifies that the prior operating licence is unique to the activity and to the facility: '1. Natural and legal persons engaged in the manufacture, import or sterilisation of medical devices and the facilities where such activities are carried out shall require a prior operating licence, granted by the	Not accepted. Consistency with Royal Decree 192/2023 of 21 March is considered key in processes that, with the exception of the device, are exactly the same. The modification of the wording for *in vitro* diagnostic medical devices compared to the previous wording that has just been published may create problems due to different interpretation. In addition, these processes with similar wordings also originate from the previous Royal	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	Spanish Agency of Medicines and Medical Devices, in accordance with the provisions of the Article 100 of Law 14/1986 of 25 April, on General Health, which shall cover the facilities and the activities carried out therein, both own and contracted.’	Decrees of 1996 and 2009.	
	• With regard to the latter phrase, the question arises as to whether the agreement relates to activities or facilities and, if so, whether it is appropriate to alter the order of the sentence as follows: ‘manufacturing, importing or sterilising activities and the facilities where they are carried out, both own and contracted.’	Not accepted. For the sake of consistency with Royal Decree 192/2023 of 21 March 2023, the agreement can also be made for both the activity and the facility.	
	• As the prior operating licence concerns both the activity and the facility, it is recommended to reconsider whether the term ‘facilities’ should be retained in the title of the article.	Not accepted. Consistency with Royal Decree 192/2023 of 21 March is considered key in processes that, with the exception of the device, are exactly the same. The modification of the wording for *in vitro* diagnostic medical devices compared to the previous wording that has just been published may create problems due to different interpretation.	
	• In addition, it is suggested that in the second subparagraph of paragraph 1, the licence which is referred to be indicated as the ‘prior	Not accepted. For the sake of consistency with Royal Decree 192/2023 of 21 March, as	

	operating licence for import activity'. • Similarly, in paragraph 3, instead of using the term 'authorisations', it is recommended to refer to prior operating licences. • In paragraph 4, in accordance with the provisions of Royal Decree 942/2010, of 23 July, regarding the restructuring of various functional areas integrated into the Government Delegations, it is recommended to refer to the Health and Social Policy Areas with capital initial letters. This observation extends to the other occasions when these areas are cited in the draft. • Paragraph 6 mentions the inspection reports, but it is not clear whether it intends to refer to the reports provided for in paragraph 4.	these are processes that have been implemented for a long time and the activities subject to a prior operating licence are listed in the previous paragraph. Not accepted. For the sake of consistency with Royal Decree 192/2023 of 21 March and considering that the licences are an authorisation document of the AEMPS, the terms are considered synonymous. Accepted. Not accepted. For the sake of consistency with Royal Decree 192/2023 of 21 March. Similarly, since only the inspection referred to in paragraph 4 is mentioned, and no reference is made to any other type of inspection, the reference to this paragraph is not considered necessary.	
Article 7	First. - Article 7 of the draft royal decree regulates the prior operating license that the	Not accepted. Natural and legal persons, with regard to the application	MINISTRY OF FINANCE

	Spanish Agency for Medicines and Health Products must grant to natural and legal persons engaged in the manufacture, import, or sterilization of medical devices and the facilities in which these activities are carried out. Paragraph 1 of this Article states that '(...) natural and legal persons engaged in the manufacture, import or sterilisation of medical devices and the facilities in which such activities are carried out shall require a prior operating licence, granted by the Spanish Agency of Medicines and Medical Devices.' Subsequently, it states: 'The authorisations referred to in paragraph 1 shall be requested by electronic means from the Spanish Agency of Medicines and Medical Devices, which shall examine the documentation submitted (...)'. In this regard, it is recalled that Article 14(1) of Law 39/2015, of 1 October 2015, on the Common Administrative Procedure of Public Administrations, determines that natural persons may choose at any time whether to communicate with Public Administrations through electronic means or not. Article 14(3) also provides for the possibility for administrations to establish the obligation to interact through electronic means for certain procedures and for certain groups of natural persons who, due to their economic, technical, or other reasons, are proven to have access to electronic means. It should therefore be provided that natural persons may interact with the Agency by non-	for the operating licence for activities involving the manufacture, import, or sterilisation of medical devices and facilities, are obliged to interact with the administration through electronic means.	AND CIVIL SERVICE

	electronic means, or, if the possibility provided for in Article 14(3) is to be used, this option must be justified in the preamble to the draft and in the Regulatory Impact Analysis Report. In addition, paragraph 3 provides that the decision shall be issued within three months from the date on which the application was entered in the website of the Spanish Agency of Medicines and Medical Devices authorised for this purpose. It is suggested, firstly, to bring the wording into line with the provisions of Article 21(3)(b) of Law 39/2015, 1 October, according to which the period must run from the time the application has been entered in the electronic register of the Administration or body competent for processing it. Secondly, it would be considered appropriate to refer to the system of appeals against the decisions of the Spanish Agency of Medicines and Medical Devices that put an end to the administrative procedure, establishing that, against the prior licence authorisation decision, an appeal may be filed, optionally, before the body that issued it, within one month, if the resolution is express, in accordance with the provisions of Articles 123 and 124 of Law 39/2015, of 1 October 2015, on the Common Administrative Procedure of Public Administrations. Without prejudice to the foregoing, an administrative appeal may be lodged against the decision authorising the licence before the Administrative Litigation Chamber of the	Not accepted. The application must reach the Agency in order to validate the application and determine whether it is a medical device and the activity to which it relates. Not accepted. It is implicit when it is indicated that the administrative procedure applies.	

	National High Court within two months, if the decision is express, or six months if it is not, in accordance with the provisions of Article 11(1) (a) of Law 29/1998 of 13 July, regulating Administrative Justice.		
Article 7	The claim proposes the removal of the licence: The licence aims to strengthen the safety of medical devices, through the control over the capacity of the human and material elements involved in the different phases of the manufacturing and placing on the market processes. It should be borne in mind that this control is in addition to the mechanisms provided for in the EU Regulation with the same purpose: control of medical devices before they are placed on the market, the obligation for importers to be registered, and the possibilities for prohibition and withdrawal from the market of a medical device by the health authorities. Thus, other countries around us do not require prior licensing of manufacturers, importers and sterilisers of medical devices. The justification, in accordance with the principles of necessity and proportionality, for the requirement of a prior licence must therefore focus on assessing what that requirement adds to the control mechanisms already provided for in EU legislation. The justification offered by the Regulatory Impact Analysis Report in this regard emphasises, in summary, that the control of	Not accepted. The Law on General Health lays down this requirement for the manufacturing of medical devices in Spain, without exempting manufacturers from this obligation to third parties. It also establishes this requirement for import activity. On the other hand this process has already been maintained in Royal Decree 192/2023 on medical devices, which entered into force last March, so for consistency, this activity should be maintained in the current text. Finally, other countries have other requirements for the control of manufacturing activities in their territory. As regards the placing on the market in Spain of medical devices that have already been placed on the market in other EU countries, this activity is not	NATIONAL COMMISSION FOR MARKETS AND COMPETITION

	operator access facilitates and strengthens the effectiveness of the control over devices and operators provided for in the EU Regulation, by ensuring a certain quality of their facilities, means, procedures and personnel. However, this general explanation, which seems reasonable, does not result in the extension of the control obligations to two activities that until now were not subject to prior licensing: the placing on the market in Spain of medical devices that have already been placed on the market in other EU countries (an activity that for the purposes of the EU Regulation does not constitute 'importation') and the complete manufacture of devices for third parties who place them on the market. In the first case, it should be borne in mind that this is a prior check on persons introducing medical devices into Spain that have been produced or sterilised in another Member State or imported into the EU by A company established in another Member State. Thus, the draft Royal Decree should justify why the control carried out in the EU country where the manufacturer, steriliser or importer is established is not sufficient and needs to be supplemented by a new control in Spain. In the second case (manufacturing for third parties), the identity of the third party may render the control redundant. If the third party is itself a manufacturer, it shall be subject to a	subject to a licence and is not indicated in the draft Royal Decree. Whether the activity of acting as an importer of devices entering Spain from third countries is subject to licensing. If the device enters Spain from the EU, it is not subject to pharmaceutical inspection at the border. In addition, medical devices that have already been placed on the market in another EU country are considered to comply with the requirements of the regulation since it is applicable to them because they are within the EU (principle of free movement within the EU). Not accepted. For third-party manufacturers, if the company already has a manufacturer's licence and it covers all the devices it manufactures	

	licence; if it is not a manufacturer (e.g. a 'distributor'), then the person who manufactures for this distributor will be considered a manufacturer and will be subject to control. Thus, the draft Royal Decree should justify what benefits for public health the prior control over the manufacturer that manufactures for third parties adds, when there is already public control over these. Moreover, the complete revalidation of the process every five years introduces a significant administrative and economic burden on companies for their access to the market. It is advised that, in cases where the licence is maintained, its revalidation is facilitated by a responsible declaration and not by a new full authorisation process. In summary, it is considered that the draft Royal Decree should provide a specific justification for the two new scenarios to which the facilities licence requirement is extended and facilitate the renewal of licences through a responsible declaration instead of a new full authorisation process.	on its own behalf or for third parties, it must modify the licence to include the activity 'third-party manufacturing', but it is not reassessed or inspected unless any changes are made to their initial licence. There would be no redundancy. In the case set out in the claim, there is no concept of a manufacturer manufacturing for a distributor, as one of the two will have to be the legal manufacturer of the device. It is this manufacturer, if it is located in Spain, that must have an activity licence issued by the AEMPS. Finally, the manufacturing conditions and facilities vary greatly, so it is considered necessary to review them again within a period of 5 years. These revalidations focus on the processes that have been modified.	

Article 7	(a) The second subparagraph of paragraph 1. It states that an import licence shall be required for 'natural and legal persons who, without being importers in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, carry out the physical importation of a device into Spain', without it being clear what this refers to, as it does not coincide with the definition of 'importer' given in the European Regulation, nor does the Royal Decree define what 'physical importation' means. (b) Paragraph 2. It provides that 'A single prior operating licence shall be granted covering the facilities and the activities to be carried out there, both own and subcontracted', without making it clear whether it is a single licence per facility or per manufacturer, nor whether the subcontracted activities (the term of which must be defined in order to avoid interpretations) also refer to those which are subcontracted for complete manufacture. (c) Paragraph 9 states that 'the agreement regarding activities by the authorised entities does not relieve them of ultimate responsibility for any breaches by subcontractors'. In this regard, it should be made clear what is meant by authorised entities, which should be specified, understanding that it refers to manufacturers. On the other hand, it is understood that, if the	Not accepted. This is the activity per se of importing and will be referred to as the physical importer. This figure may or may not coincide with the figure of the legal importer as indicated in the Regulation. A question-and-answer document and working instructions have been created further detailing this concept Not accepted. The text of the previous Royal Decree is maintained, and it is also the same as the new Royal Decree 192/2023 on medical devices. However, there is an instruction document as well as a question-and-answer document that clarify more specific situations regarding medical device facilities. Not accepted. The text of the previous royal decree using the term entity in its most general form is maintained; to date, it has not raised queries as to its clarity. In addition, the draft also includes other activities such as importation.	ANDALUSIA

	subcontractor is licensed because they carry out the complete manufacture for third parties, the manufacturer who subcontracts that complete manufacture would be liable for any breaches by the subcontractors, since, although they are licensed, by acting as a subcontractor they cannot place these devices on the market. This should be made clear in the text, as referring to "agreement of activities" is an ambiguous term that can be interpreted in different ways.	In relation to the last comment, the company that applies for and obtains the licence, regardless of whether it subcontracts the activity, is ultimately responsible for the manufacture.	
Article 7	In the second paragraph of Article 7(1), it is suggested to use the subjunctive mood 'introduzcan' instead of the indicative 'introducen'. In Article 7(3), it is suggested that reference be made to Royal Decree 1275/2011 of 16 September 2011, which establishes the 'Spanish Agency of Medicines and Medical Devices' and approves its Statute, as this is the regulation that stipulates that the decisions of this public body bring administrative procedures to an end.	Not accepted.	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID
Article 7	2. With regard to the executive function concerning the granting of the prior licence for facilities in relation to companies involved in the manufacture of medical devices, we must point out that the Government of Catalonia has been calling for the transfer of the authorisation functions for facilities where proprietary pharmaceuticals, medical devices and cosmetics are manufactured. This claim is now reinforced as this draft Royal	Not accepted. The competence relating to the regulation of import, processing, manufacturing, distribution or export activities corresponds to the General State Administration in accordance with the provisions of Article 100 of Law 14/1986, of 25 April, on General Health. These powers concern the activities to be conducted independently of the establishment	CATALONIA

	Decree provides that, on the basis of Article 100(1) of Law 14/1986 of 25 April 1986 on General Health, health institutions carrying out the manufacture of *in vitro* diagnostic medical devices for exclusive use by the institution itself must inform the Spanish Agency of Medicines and Medical Devices of the start of the activity, and subsequent amendments, when these health institutions, in accordance with the legislation in force (Royal Decree 1277/2003 of 10 October 2003 laying down the general rules on the authorisation of health institutions, services and establishments), have had to be authorised in advance by the Generalitat de Catalunya, through this Department of Health, and which, in many cases, are the exclusive property of this Department or the latter forms part of their governing and management bodies. This obligation of notification to the Spanish Agency of Medicines and Medical Devices prior to the start of the activity can be understood as a mechanism of intervention by the administration in line with the requirement of prior authorisation, although of a lower intensity. Article 100(1) of the General Health Law establishes, as a basic requirement, that a prior licence shall be required of natural and legal persons engaged in the import, manufacture, distribution, or export of medicines and other medical devices, as well as of their laboratories and establishments. Under Article 40(6) of the same Law, it is the responsibility of the State Administration to	where they are carried out, as well as the authorisations of health establishments issued by the Autonomous Communities. As regards the reference made in the claim concerning the authorisation of the manufacture of medical devices as currently carried out by the Autonomous Communities, Royal Decree 437/2002 of 10 May establishing the criteria for granting operating licences to manufacturers of custom-made medical devices, in its preamble states: “Article 100(1) of Law 14/1986 of 25 April, on General Health, empowers the State Administration to require prior authorisation for natural and legal persons engaged in the import, production, manufacture, distribution or export of medicines and other medical devices and their laboratories and establishments. That provision also states that such a licence must be revalidated on a regular basis. Article 76 of Law 55/1999 of 29 December, on fiscal, administrative and social measures, adds a subparagraph to the section on safeguarding the powers of the Autonomous Communities in relation to the establishments and activities of natural or legal persons engaged in the	

	authorise the activities of natural or legal persons engaged in the preparation, production and manufacture of the devices referred to in paragraph 5 of the same Article, namely medicinal products for human and veterinary use, other medical devices and devices that may pose a risk to persons. Pursuant to Law 55/1999 of 29 December on fiscal, administrative and social measures, a new paragraph was added to article 100(1), cited above, which reads as follows: “The above shall be without prejudice to the powers of the Autonomous Communities in relation to the establishments and activities of natural or legal persons engaged in the manufacture of custom-made medical devices. In any case, the criteria for granting the prior licence shall be drawn up by the Ministry of Health and Consumer Affairs.’ Furthermore, Article 108 of the consolidated text of the Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July, provides in paragraph 1 that it is for the health authorities, within the scope of their powers, to carry out the necessary inspections to ensure compliance. Paragraph 2 of that provision defines the scope of the inspection function reserved for the Government Agencies. The legal and regulatory framework (currently Royal Decree 1662/2000 of 29 September 2000 on *in vitro* diagnostic medical devices, which the draft Royal Decree will repeal) establishes a concurrent inspection model in some areas –	manufacture of custom-made medical devices, while retaining, in any case, the power of the Ministry of Health and Consumer Affairs to draw up the criteria for granting the prior licence for the operation of such establishments and for the development of such activities. Article 76 also provides that, pending the publication of the rule governing those criteria, the procedure applicable before the entry into force of Law 55/1999 is to be maintained.” The wording confirms that the activity of the Autonomous Communities with regard to manufacturing licences relates only to the manufacture of custom-made medical devices.	

	and therefore potentially generating duplicate actions – and not always clearly defined. Thus, reasons of effectiveness and efficiency, while taking into account the powers that the Catalan regional government has in the field of control and inspection related to the industrial manufacture of medicines, medical devices and cosmetics, determine the need for the transfer of the requested functions, including inspection and control actions prior to their operation. There are no legal arguments to differentiate the control and surveillance actions of these facilities, depending on whether they are prior to their authorisation or associated with their subsequent operation. In contrast, according to the applicable constitutionality block, these ex-ante control functions — authorisation — were to be attributed to the Autonomous Communities. On the other hand, the Constitutional Court, despite having accepted State actions of an executive nature in the field of health, under the protection of the titles of competence recognised in Article 149(1)(16) of the Spanish Constitution, when required by the very nature of the functions - due to their interdependence throughout the state territory and their impact on the foundations of the regulatory system - and due to the necessary guarantee of supra-community interests (STC 32/1983, of 28 April 1983), has reaffirmed the principle of autonomous ownership of the powers of health execution. In Judgement 54/1990 of 28 March 1990,		

	concerning the challenge by the Government of Galicia to Circular 14/1985 of the Ministry of Health and Consumer Affairs, where the competence to carry out inspections aimed at verifying compliance with the legislation in force on the distribution and dispensing of narcotic drugs and psychotropic substances by warehouses, pharmacies, and pharmaceutical services was disputed, the Court held that the inspection and control of distribution fell under the responsibility of the Autonomous Community, 'as it is an ordinary action that in no way affects the regulatory system and is implemented in a series of typical enforcement measures strictly regulated and aimed at ensuring the application of the current legislation on medicines, which is of a State nature.' The prior authorisation of the entities and undertakings that manufacture certain devices provided for in Article 40 of the General Health Law as a preventive system to guarantee compliance with the legislation in force should belong to the regional administrations because it is an 'implementation' activity in the 'matter of pharmaceutical products' or 'internal health'. This recognition of competence would not mean introducing a factor of inequality that would affect the basic conditions of health protection: with regard to medicinal products and other pharmaceutical products in any case since the regulatory power in this field is exclusively vested in the General State Administration and it would be for the Autonomous Communities to		

	verify its application; as regards medical devices and cosmetics, the cohesion of the system would be ensured, where appropriate, with the possibility of establishing a minimum common denominator of basic standards. This recognition of competence in favour of the Autonomous Communities would affect the wording of Articles 7 and 9 of the draft Royal Decree.		
Art. 7	Article 7(5) In order to give legal certainty to applicants, we consider that the documentation that can replace the inspection reports should be detailed when issuing the operating licence for companies that carry out manufacturing, assembly, sterilisation or storage activities at facilities located outside Spanish territory.	Not accepted. The documentation that can be submitted to demonstrate compliance with the requirements of these subcontracted companies can be varied and should be assessed meaning that it is not appropriate to include it in a legislative document. The basic documentation is currently included in the Licence Instruction Document.	CATALONIA
Art. 7	Article 7(6) The Spanish Agency of Medicines and Medical Devices shall refuse, suspend or revoke operating licences if the documentation provided or the inspection reports relating thereto do not guarantee that adequate facilities, means, procedures and personnel are available to carry out the respective activities or when the conditions under which the licence, its modifications or revalidations were granted are not maintained. Quality controls, which I assume are included in procedures, are not discussed at any time.	Not accepted. This point 6 refers to the actions of the AEMPS for the suspension, refusal or revocation of licences and the causes that would lead to these decisions. As the claim indicates, the details of the procedures are included in the Article dedicated to them: Article 8. *Requirements for the granting of a prior operating licence* and described in more detail in the instructions for obtaining the licence.	SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)

	However, I believe it is sufficiently important to be recorded. Although it is already explicit in Article 8 later on.		
Article 7	Delete: the prior operating licence shall also be required for those natural and legal persons who carry out the complete manufacture of the devices for third parties. Justification: Article 8(e) lays down the requirements for subcontracted activities: Such subcontracted activities may only be carried out by entities that meet the requirements set out in subparagraphs (a) and (b) of this Article, referring to the following: (a) Availability of a quality management system capable of guaranteeing the quality of the devices and the execution of the appropriate procedures and controls. (b) Availability of adequate facilities, procedures, equipment and personnel according to the activities and devices in question. Compliance with these requirements by the subcontracted companies is verified by the AEMPS, prior to the granting of the prior licence requested by the manufacturer and can be subsequently monitored at any time during its validity, by the AEMPS's own inspection authority. For this reason, we consider that the manufacturing of a device as a subcontractor (whether manufacturing in whole or in part) should be excluded from the scope of licences and should only apply to legal manufacturers. The imposition of this requirement on third-party manufacturers established in Spain, which is not required in any other Member State, could constitute a competitive disadvantage for the	Not accepted. The Law on General Health lays down this requirement for the manufacturing of medical devices in Spain, without exempting third-party manufacturers from this obligation. It also establishes this requirement for import activity. On the other hand, this process has already been maintained in Royal Decree 192/2023 on medical devices, which entered into force last March, so for consistency, this activity should be maintained in the current text. In addition, the licence instruction document and the question-and-answer documents detail the concept of full manufacturing.	FENIN

	development of this activity in Spain, as it is not possible to impose this same requirement on complete subcontracting from third countries or from the European Union itself. Legal manufacturers could use third-party manufacturers established outside Spain, penalising Spanish companies that currently carry out this activity. If this requirement is maintained, it should be defined what is meant by complete manufacture and whether it applies to both natural and legal persons.		
Article 7	Article 7. Prior operating licence for facilities. 1. In accordance with Article 100 of General Health Law 14/1986 of 25 April 1986, natural and legal persons engaged in the manufacture, import, grouping or sterilisation of medical devices and the facilities in which such activities are carried out will require a prior operating licence granted by the Spanish Agency of Medicines and Medical Devices. For the purposes of this Royal Decree, an import licence shall be required by both importers established in Spain who place a device from a third country on the European Union market and natural and legal persons who, without being importers in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, physically import a device into Spain. - It needs to be clarified whether a genetic diagnostic services (genetic tests) laboratory,	Not accepted. The wording is clear when it indicates that the prior operating licence should only be applied for when activities of manufacturing, importing, or sterilising devices are carried out. If a laboratory for services (genetic testing) does not perform these activities, it does not need to request the licence. This licence is independent of the licence for activity as a health institution or establishment issued by the Autonomous Communities.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

	with an operating authorisation granted by the Autonomous Community where it is located, must also request a prior operating licence. The prior operating licence will also be required for those natural and legal persons who carry out the complete manufacture of devices for third parties. - It should be specified that this point refers to companies established in Spain DELETE PARAGRAPH. Justification Article 8(e) itself sets out the requirements for subcontracted activities: 'Such subcontracted activities may only be carried out by entities which meet the requirements set out in sections (a) and (b) of this Article'. They are the following: '(a) Availability of a quality management system capable of ensuring the quality of the devices and the implementation of the procedures and controls required. (b) Availability of appropriate facilities, procedures, equipment and personnel according to the activities and devices concerned.' Compliance with these requirements by the subcontracted companies is verified by the AEMPS, before the granting of the prior licence requested by the manufacturer, and can be monitored ex post at any time during its validity	Not accepted. It is clear from the wording and references to the legislation that this requirement is for companies located in Spain. Regarding the deletion of the section on third-party manufacturers, this is a requirement established by the General Health Law. On the other hand, it is necessary to differentiate between subcontracted activities which are not complete manufacturing, for which, in the licensing process, the Agency evaluates all the documentation of the activities of critical subcontractors inside and outside Spain. For the complete manufacture, in our country, of a device whose manufacturer is in a third country, the manufacturing activity is not subject to a licence. In addition, this wording is in line with the	

	by the AEMPS' own inspection authority. The requirement of a prior licence also for the subcontracted company that carries out the complete manufacture of devices for third parties constitutes a competitive disadvantage for the development of this activity in Spain, as it is not possible to impose this same requirement on complete subcontracts from third countries or from the European Union itself.	provisions of the new Royal Decree 192/2023 on medical devices	
Article 7	Article 7.7. The Spanish Agency of Medicines and Medical Devices and the health authorities of the Autonomous Communities shall keep one another informed of the operating licences granted pursuant to the terms of this chapter, as well as of their amendments, suspensions or revocations, through the computer application authorised to this end. It is necessary to clarify the difference between the operating licence and the Operating Authorisation available to a laboratory providing diagnostic services (genetic testing).	Not accepted. The purpose of this Article of the Royal Decree is to establish the requirements for the activities of manufacture, import and sterilisation of *in vitro* diagnostic devices. This licence is for an activity completely different from that performed by laboratories providing diagnostic services (genetic testing) as a health institution. For this activity as a health institution, the Autonomous Communities will issue them with the corresponding licence.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 7	Art 7.8. Operating licences shall be valid for a period not exceeding five years, which shall be specified in the authorisation document. They may be revalidated at the request of the interested party submitted before their expiry, once compliance with the requirements has been verified. Any modification of the conditions under which the operating licence was granted must be authorised in advance by the Spanish Agency	Not accepted. The requirement for a prior operating licence is not new. As indicated above, it is a requirement of the General Health Law, which is already provided for in Royal Decree 1662/2000.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

	of Medicines and Medical Devices. A declaration of responsibility could be sufficient for a company to be able to start work on the adaptation of facilities that have already been authorised. The AEMPS can be overwhelmed by this type of management, in the face of a reality that demands immediate and agile responses.		
Article 7	(a) Point 1: 'For the purposes of this Royal Decree, import licences shall be required for both importers established in Spain who place a device from a third country on the European Union market, as well as for natural and legal persons...' In relation to the prior operating licence, it is indicated that one will be required from those who perform 'the complete manufacture'. • What will be considered complete manufacture? • From start to finish? • If there is third-party manufacturing, but the legal manufacturer is the one who affixes the label, is it considered full manufacturing?	Not accepted. It is not a claim, as such, on the proposed text. These questions will be detailed in the procedural instructions, in the questions and answers documents for the application of the Royal Decree.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
Article 7	Concerning Article 7(3). 'Prior operating licence for facilities'. ▪ Proposed wording: '3. The authorisations referred to in paragraph 1 shall be requested by electronic means from the Spanish Agency of Medicines and Medical Devices, which shall examine the	Not accepted. In this licensing procedure, positive administrative silence is applied according to Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations.	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	documentation submitted and notify the decision within three months of the date on which the application was entered on the website of the Spanish Agency of Medicines and Medical Devices authorised for that purpose, **it being understood that the application is refused if that period has elapsed without express notification being given.** All this without prejudice to the provisions of Article 22(1)(a) of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, regarding the suspension of the deadline for the provision of documentation. The decisions of the Spanish Agency of Medicines and Medical Devices put an end to the administrative procedure.' ▪ Justification: Article 7 regulates the prior operating licence that must be obtained by natural and legal persons engaged in the manufacture, import, and sterilisation of medical devices, as well as their facilities, which must be granted by the AEMPS. When regulating the authorisation process, Article 7(3) establishes a period of three months from the receipt of the application, within which the AEMPS must notify its decision. However, that paragraph makes no provision as to the consequences of the expiry of that period without notification of a decision. Therefore, in order to provide this process with the necessary legal certainty for applicants, as		

	well as for other stakeholders (health professionals, authorities, etc.), we consider it necessary to specify the meaning of administrative silence, indicating that if the period elapses without any resolution, the application shall be deemed rejected.		
Article 7	Article 7(10) Delete: 'prior to obtaining the CE marking'. JUSTIFICATION: We consider that, as has been established for all clinical investigations involving medical devices in RD 192/2023, a prior facility operating licence should not be required for the manufacture of a device intended to be used in a performance study, either prior to obtaining the CE marking or for a device bearing the CE marking.	Accepted.	FENIN
Article 8	Article 8 of the draft Royal Decree sets out the requirements for the granting of licences (includes wording of the draft Royal Decree). In this regard, it should be noted that these requirements are very imprecise. In particular: - The quality standard required for the quality management system is that it is 'capable of ensuring the quality' of devices and processes. This requirement, thus configured, does not guide operators and grants excessive discretion to the competent authority responsible for authorisations. - The same applies to the requirements for facilities, procedures, equipment, or personnel, which are required to be 'appropriate', which does not provide guidance on its material content. - Likewise, the training requirement for the	Not accepted. The prior licensing procedure for these activities is a process that has been carried out since it was established in the General Health Law, so it is not a process unfamiliar to companies and does not involve new requirements. However, in order to facilitate compliance for companies, instructions have been developed detailing the documents necessary for the application for the licence, as well as question and answer documents addressing the main queries received by the AEMPS.	NATIONAL COMMISSION FOR MARKETS AND COMPETITION

	technical manager is that they hold an 'appropriate' qualification, a requirement that does not give guidance with regard to the specific requirements of the post, and does not allow an assessment of whether the requirement satisfies the criteria of necessity and proportionality. As regards the requirements relating to the qualifications of the technical manager, it is noted that Royal Decree 472/2021 has established a specific procedure for the approval of requirements for access to, or pursuit of, regulated professions. In accordance with the provisions of the aforementioned Royal Decree, an examination of the proportionality of the requirements demanded of the technical manager of the facilities must be carried out, in the terms provided for in Royal Decree 472/2021. In short, it is noted that the requirements relating to the quality management system, facilities, procedures, equipment, personnel, and the technical manager are imprecise and do not guide companies with respect to the specific requirements of each of them and grant the competent authority for authorisations a high degree of discretion. This contributes to legal uncertainty among operators and makes it difficult to assess whether the specific requirements are necessary and proportionate.		
Article 8	(a) Subparagraph (c). The expression 'in its entirety' should be specified as it is ambiguous.	Not accepted. As indicated above, the diversity of technologies and types of medical devices prevents this aspect	ANDALUSIA

		from being specified in a legal text. The instructions of the procedure will detail, as far as possible, these aspects. However, the assessment will be made on a case-by-case basis on the certification submitted and the type of device that is manufactured, grouped, sterilised, etc. In addition, this text is the same as the one recently approved in Royal Decree 192/2023 on medical devices.	
	(b) Subparagraph (e). The wording should be clarified, since in the event that full manufacturing is subcontracted, it would be sufficient to indicate only the name and address of the subcontractors, and the corresponding contracts, since the rest of the documentation is contained in the subcontractor's licence.	Not accepted. Subcontracting can occur within or outside Spain, so these data would only appear if the manufacturer to whom the complete manufacturing is subcontracted is located in our country.	
Article 8	Article 8 Requirements for the prior operating licence Availability of a technical manager, with the necessary qualification, preferably holding the Specialist Qualification in Health Sciences (*Formación Sanitaria Especializada*, 'FSE') that certifies an appropriate qualification to practise the profession with such a character and to occupy positions with such a designation in public and private centres and establishments, according to Article 16 of Law 44/2003, of 21 November 2003, on the organisation of the health professions.	Not accepted. This requirement is for any activity and all types of *in vitro* diagnostic medical devices; it is not specific to health institutions. On the other hand, the variety of *in vitro* diagnostic medical devices available on the market means that the qualifications and training cycles that may be suitable for being technically responsible are also very different. The technical manager must have knowledge not only of the device itself,	SPANISH SOCIETY FOR IMMUNOLOGY (SEI)

		but also of the manufacturing process and quality systems. The instructions for obtaining the licence further detail these aspects. Ultimately, the suitability of the technical manager and their qualifications will be an assessment that the Agency must conduct as part of the evaluation of the licence, based on the devices and the activity carried out.	
Article 8	SECOND.- Concerning Article 8(c) The aforementioned provision indicates that one of the requirements for the granting of the prior operating licence is the availability of a technical manager, with a university degree or a higher vocational training qualification, accredited by an appropriate qualification according to the devices of which they are in charge, who will exercise direct supervision of such activities. If the qualification referred to in the preceding paragraph does not fully demonstrate proof of competence, it may be supplemented by training and/or experience. Availability shall be demonstrated by contract with the technical manager in which the time commitment will be specified, which must be sufficient depending on the type and volume of the activity carried out. This wording is a copy of Article 8 of Royal Decree 192/2023, of 21 March 2023, on medical devices, so for devices specific to *in*	Not accepted. As stated in the Regulatory Impact Analysis Report, from a general point of view, the draft is considered to have a limited but positive impact on the overall economy. On the one hand, its provisions can be considered as having a positive impact on the economy by extending the eligible qualification requirements for the position of the technical manager to include other types of qualifications and the experience gained in medical devices in the process of choosing the technical manager, which will encourage job creation by making these jobs accessible to a greater number of people. The experience gained in higher vocational training programmes is of interest to the	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA

	vitro diagnostics, the differences in relation to the various *in vitro* diagnostic medical devices must be established, given the curricula of the university degrees in health or industrial engineering, computer science or others with respect to those of the training cycle. However, since they are not just any medical devices but for *in vitro* diagnostics, the qualifications required for each of them must be established and listed; there is neither an approximation nor classification in the draft Royal Decree, nor is there reference to a subsequent implementing regulation. This precept must be studied and, in accordance with the different classes of these devices, determine the qualification without forgetting that the technical manager must know their use, design, purpose, processes, etc. 6 As well as identifying what kind of training and/or experience and its duration would be sufficient to be a technical manager.	activities of the technical manager, especially given the wide variety of medical devices on the market. That said, it should be noted that this text corresponds to the one included in the recently approved RD 192/2023 on medical devices, where, based on the wide variety of devices and *in vitro* diagnostic medical devices, and the innovation present in this field, it is not considered appropriate to include specific qualifications in a legislative text, as they vary depending on the types of devices to be manufactured.	
Article 8	Article 8. 'Requirements for granting the prior operating licence'. ▪ Proposed wording: 'The application for a prior operating licence shall be accompanied by documentation proving the following requirements: (…) III. Availability of a technical manager, with a university degree ~~or a higher vocational training qualification~~, accredited by an appropriate qualification according to the devices of which they are in charge, who will exercise direct supervision of such activities. If the qualification referred to in the preceding	Not accepted. As stated in the Regulatory Impact Analysis Report, from a general point of view, the draft is considered to have a limited but positive impact on the overall economy. On the one hand, its provisions can be considered as having a positive impact on the economy by extending the eligible qualification requirements for the position of the technical manager to	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	paragraph does not fully demonstrate proof of competence, it may be supplemented by training and/or experience. Availability shall be demonstrated by contract with the technical manager in which the time commitment will be specified, which must be sufficient depending on the type and volume of the activity carried out. Availability of a document-filing system to store the documentation generated with each device and maintenance of a register of all devices to ensure traceability of these devices. The documentary archive shall be kept at the disposal of the competent authorities for a period of at least 10 years after the last unit of the device has been placed on the market or put into service. V. In the case of subcontracted activities, declaration of the name and address of the subcontractors, description of the activities and means available for their execution, and submission of the corresponding contracts and the procedures used. Such subcontracted activities may only be carried out by entities meeting the requirements set out in subparagraphs (a), ~~and~~ (b) **and (c)** of this Article.' ▪ Justification: The current regulation in force that establishes the requirements for the granting of a prior operating licence, when regulating the requirement that companies have a technical manager lays down the following: '(e) In order to carry out the activities referred to	include other types of qualifications and the experience gained in medical devices in the process of choosing the technical manager, which will encourage job creation by making these jobs accessible to a greater number of people. The experience gained in higher vocational training programmes is of interest to the activities of the technical manager, especially given the wide variety of medical devices on the market. Based on the experience gained over all these years of applying the previous Regulation, the specific training obtained in higher vocational training programmes represents a type of knowledge that may not be acquired in such detail in university degrees. Therefore, it should not be limited only to holders of university degrees. Finally, it should be noted that this text corresponds to that included in the recently approved RD 192/2023 on medical devices.	

	in this section, companies shall have a technical manager, a university graduate, accredited by an appropriate qualification according to the devices of which they are in charge, who will exercise direct supervision of such activities' [emphasis added] As can be seen, the current regulations require that those who exercise the functions of technical manager hold a university degree; on the other hand, the draft Royal Decree has decided to lower the training requirements for the exercise of these positions, allowing them to be held by people with higher vocational training, and, in the event that they lack a suitable qualification for their activity, they can justify their suitability based on other training or experience. In order to understand the justification for this change, this is clarified in the Regulatory Impact Analysis Report (Section VI, point a), which states the following: 'From a general perspective, the draft is considered as having a limited but positive impact on the overall economy. On the one hand, its provisions can be considered as having a positive effect on the economy by extending the eligible qualification requirements for the position of technical manager to include other types of qualifications and the experience gained in medical devices in the process of choosing the technical manager, **which will encourage job creation by making these jobs accessible to a greater number of**	Not accepted. The manufacturer is responsible for ensuring that the final device, prior to its placing on the market, complies with the requirements established in the legislation. Therefore, the role of the person responsible within the manufacturer is necessary to guarantee this, but it is not necessary for those natural or legal persons who only carry out phases of the manufacturing process.	

	<u>people'</u> [emphasis added] As can be seen, the only explanation that appears in the Regulatory Impact Analysis Report is a justification of an economic nature, which disregards the health perspectives that may arise from lowering the training requirements for the role of the technical manager. The technical manager is responsible for directly supervising the activities carried out by the company, is the one who will ultimately ensure that safe and high-quality devices are produced and who ensures compliance with sanitary standards in the manufacture, import, or sterilisation of the devices that finally end up on the market. It is therefore a fundamental role, whose standard of requirement cannot be lowered by a criterion such as that expressed in the Regulatory Impact Analysis Report. It is important that the person responsible for ensuring this compliance with sanitary standards maintains a university-level education, as placing a professional without a university degree in that position (a possibly cheaper option for companies) may result in lower levels of aptitude for the position's requirements, which could lead to less safe devices being placed on the market, potentially having a considerable impact on public health. Likewise, given the importance of the education level of the person in this role, we consider that these requirements should also be applied to subcontracted activities, and the last paragraph of the provision should be amended.		

	For all these reasons, we suggest maintaining the model currently in force, so that the technical manager must be a university graduate; their suitability cannot be demonstrated by any other means than by holding a degree qualification conferring on them the aptitude necessary for the performance of a key position in the safety and health of the population; this should be extended to subcontracted activities.		
Article 8	Manufacturing companies or those acting as authorised representatives shall have a person responsible for regulatory compliance in accordance with Article 15 of Regulation (EU) 2017/746 of 5 April 2017 on *in vitro* diagnostic medical devices. Instruction PS 1/2022 ON THE PROCEDURE FOR THE PRIOR OPERATING LICENCE TO OPERATE MEDICAL DEVICE FACILITIES states that it is a requirement for obtaining the prior licence. However, it is an aspect that is not mentioned among the requirements included in points (a) to (c) of this Article. The inclusion of this requirement should be considered.	Not accepted. The purpose of Article 8 of the Royal Decree is to establish the requirements for the granting of the prior operating licence, which is a national procedure. The obligation for manufacturers or authorised representatives to have a person responsible for compliance with the regulations is already a direct requirement of the regulation itself that does not need to be repeated in the Royal Decree. Instruction PS 1/2022 ON THE PROCEDURE FOR THE PRIOR OPERATING LICENCE TO OPERATE MEDICAL DEVICE FACILITIES recalls this direct obligation of the regulation to be complied with by manufacturers and representatives.	A3Z Advanced
Article 8	Instruction PS 1/2022 ON THE PROCEDURE FOR THE PRIOR OPERATING LICENCE TO	Not accepted. The second paragraph of Article 8(c) already provides for this	A3Z Advanced

	OPERATE MEDICAL DEVICE FACILITIES provides more explicit information on the qualification of the technical manager: In general, specific university degrees related to the devices and, in their absence, university degrees in health care or related manufacturing technology, supplemented, where appropriate, by specific training in the devices and/or in quality management systems, will be considered appropriate. We propose to expand the information in this section as follows: (c) Availability of a technical manager, with a university degree or a higher vocational training qualification, accredited by an appropriate qualification according to the devices of which they are in charge, and in their absence, university qualifications in health care or related manufacturing technology, who shall exercise direct supervision of such activities	possibility. *If the qualification referred to in the preceding paragraph does not fully demonstrate proof of competence, it may be supplemented by training and/or experience.* On the other hand, it is not considered appropriate in a legislative text to detail all possible qualifications of technical managers, given the wide variety of medical devices and *in vitro* diagnostic medical devices on the market. That is why the details on the different cases are described in the instructions on the licensing procedure.	
Article 8	If the qualification referred to in the preceding paragraph does not fully demonstrate proof of competence, it may be supplemented by training and/or experience. We propose to expand the information in this section as follows: If the qualification referred to in the previous paragraph does not fully demonstrate proof of competence, it may be supplemented by specific training in devices and/or quality management systems and/or experience. On the other hand, it is suggested that the required experience be defined, both in terms of time and activity.	Not accepted. Article 8(c) already provides that the qualification and training must be related to the devices for which the person in charge is responsible, so it is not considered necessary to include that this training must be 'specific'. On the other hand, including training only in quality systems does not guarantee that this training is related to the devices for which the manager will be responsible.	A3 Z Advanced
Article 8	Article 8. Requirements for the granting of the prior operating licence.	Not accepted. The requirement for a prior activity licence and the	SPANISH BIOINDUSTRY ASSOCIATION

	d) Availability of a documentary archiving system to store the documentation generated with each device and maintenance of a register of all devices to ensure traceability of these devices. The documentary archive shall be kept at the disposal of the competent authorities for a period of at least 10 years after the last unit of the device has been placed on the market or put into service. Keeping the archive for 10 years is excessive. A period of 5 years should be sufficient. In addition, it is necessary to clarify whether the documentary system for each device, in the case of genetic tests, could be the technical documentation, Standard Operating Procedures and Technical Instructions necessary to carry out the specific test.	documentation to be submitted and filed are not new. As indicated above, it is a requirement of the General Health Law, which is already provided for in Royal Decree 1662/2000. Again, it refers only to manufacturing, importation, and sterilisation activities. Regarding the periods, these correspond to those established in Regulation 2017/746	ASEBIO
Article 9	• Paragraph 1 refers to the activities provided for in Article 5(5) of the Regulation. For clarity, it is recommended to reflect the activities referred to, which are indicated in the title of this article.	Not accepted. Consistency with Royal Decree 192/2023 of 21 March is considered key in processes that, with the exception of the device, are exactly the same. The modification of the wording for *in vitro* diagnostic medical devices compared to the previous wording that has just been published may create problems due to different interpretation. Article 5(5) of the	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

		Regulation indicates the activities, and the Article itself includes it in its name, Article 9. *Manufacture of devices by health institutions for their exclusive use by the institution itself.*	
	• Since Article 2 sets out the requirements to be met by these institutions by reference to Article 5(5) of the Regulation, it is recommended that paragraph 1 and the first subparagraph of paragraph 2 be merged into a single paragraph. Thus, the first paragraph of Article 9(1) could be worded as follows: (moving the second subparagraph of paragraph 2 to be the second subparagraph of paragraph 1 and renumbering the following paragraphs accordingly): '1. Health institutions, according to the definition established in Royal Decree 1277/2003 of 10 October 2003 laying down the general bases on the authorisation of health institutions, services and establishments, within the scope of their competences, may carry out the manufacture of devices for their exclusive use in the institution itself, provided that they comply with all the requirements laid down in Article 5.5 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5	Not accepted. Consistency with Royal Decree 192/2023 of 21 March is considered key in processes that, with the exception of the device, are exactly the same. The modification of the wording for *in vitro* diagnostic medical devices compared to the previous wording that has just been published may create problems due to different interpretation.	

	April 2017.”		
	• Paragraph 3 establishes the requirement for accreditation to ISO 15189 for laboratories in health institutions carrying out manufacturing ‘following the periods laid down in the eighth transitional provision’. However, this requirement is already laid down in Article 5(5) of the Regulation, so that its reproduction could be dispensed with in this Article, without prejudice to the fact that it may remain mandatory under the aforementioned transitional provision.	Not accepted. The requirement in the Regulation provides two possible options: ISO 15189 or, where appropriate, applicable national provisions. The Royal Decree specifies the obligation at the national level, which will be the accreditation to ISO 15189, and the established transitional periods.	
	In paragraph 8, it is recommended to reconsider the relevance of maintaining the phrase ‘which will provide the necessary means to comply with this obligation’, since either the means are expressly indicated, or it is understood that these material and technological means are already available to make a notification of the start of activity.	Not accepted. It has not been specified because the means are currently in the final stages of development, and therefore do not fall under any of the cases indicated in the claim.	
	• As indicated above, in accordance with guideline 68 of the Guidelines on Legislative Drafting, in paragraph 8(b) and (c), it is recommended that the articles be cited in a concise and descending manner: ‘Article 5(5)(f)’, ‘Article 5(5)(c), (d), (e) and (g)’ and ‘Article 5(5)(g)’.	Accepted.	
	• In paragraph 9, it is recommended to clarify whether the natural and legal persons referred	The manufacturing is done by the institution, but in this section, we discuss the Inspection, which will be	

	to are to be understood as distinct from the health institution itself. • In paragraph 10, it is recommended to indicate that the AEMPS will order the cessation of activities. • In paragraph 11, it is recommended to indicate who makes the notifications, understanding that this will be the health institution itself.	conducted by the specific individuals at the institution who carry out that activity. Accepted Not accepted. Paragraph 11 refers to paragraph 8 and therefore to the notification of the institution, so that any modification of that information must be made by the institution itself, which is responsible for the notification.	
Article 9	Article 9 of the draft Royal Decree provides for the possibility for a health institution to manufacture *in vitro* medical devices for exclusive use by the health institution itself. This provision is contained in Article 5(5) of Regulation (EU) and, as indicated therein, this type of device manufactured in the health institution will not be placed on the market subsequently, but will be aimed at patients for whom there are no alternatives on the market. The draft Royal Decree sets out, in line with the Regulation (EU), a number of limitations on devices manufactured by health institutions for their exclusive use, such as a prohibition on selling them to the public or on ceding them for use by third parties. It is an activity subject to	Not accepted. Regulation 2017/746 clearly states that in-house manufacturing is manufacturing in health institutions for use within the institution itself, provided that there are no alternative devices on the market. This activity is exceptional and has no commercial purpose; it is enabled to provide alternatives to patient populations that need treatment or a diagnosis not otherwise available. The conditions and requirements for manufacturing in health institutions, due to the specific characteristics of	NATIONAL COMMISSION FOR MARKETS AND COMPETITION

	prior notification of commencement of activity, but not to a licence. From the regulation contained in the draft Royal Decree, the possibility that the planned manufacture of medical devices is not restricted to hospitals is positively assessed, in line with the recommendation made by this CNMC on medical devices. However, being aware that Article 5(5) in fine of the Regulation (EU) provides that 'Member States shall retain the right to restrict the manufacture and use of any specific type of such devices [...]', attention is drawn to the provision contained in Article 9(3) of the draft Royal Decree, which states that: 'Health institutions may not subcontract any of the manufacturing activities outside Spanish territory.' It should be pointed out that subcontracting with centres located outside Spanish territory is perfectly possible when it comes to ordinary manufacturing activities. Moreover, Article 5(5) of the draft Royal Decree states that: Where the manufacturing, assembly, sterilisation or storage activities are carried out in facilities established outside Spanish territory, the inspection reports referred to in the preceding paragraphs may be replaced by documentation that adequately supports the activities carried out. In other words, a more flexible control regime is established for such centres. Noting the absence of justification in	the institutions and their facilities, differ from those required by legislation for manufacturers. Manufacturing in health institutions, for example, does not involve an audit of its facility and critical subcontractors by a notified body. Therefore, in order to ensure the maximum control of the manufacturing by the institution itself and that this exceptional manufacturing provides the greatest guarantees for the patients with whom the devices are used, the possibility of subcontracting the activity to a third party is restricted. Finally, this restriction is in line with the one included in this regard in Royal Decree 192/2023 on medical devices, which entered into force last March.	

	the Regulatory Impact Analysis Report in this regard, the motivation for this restrictive measure does not appear to be based on public health criteria, but on territoriality, and must therefore be considered contrary to European internal market legislation, which specifically seeks to strengthen the cited Regulation (EU) itself, therefore its reconsideration is advised		
Article 9	Art 9.7. To carry out this manufacturing activity, health institutions must notify the Spanish Agency of Medicines and Medical Devices of the commencement of activity, which will provide the necessary means to comply with this obligation. Health institutions that manufacture in-house devices for exclusive use by the institution itself will not be required to obtain the manufacturer's licence from the AEMPs. ~~In the case of activities in operation, given the impossibility of prior notification without interrupting the diagnostic activities, an initial notification will be made during the first 6 months after the entry into force of the regulation, which includes the name of each activity, its purpose, the validation method, and a declaration confirming the absence of devices of equivalent performance in the market. As a national registry of in-house software is foreseen, a national registry of in-house tests could be proposed.~~ (...)(a) The person responsible for the activity of	Not accepted. Article 9 deals with in-house manufacturing and does not require a prior licence but communication to the AEMPS. On the other hand, Article 7 makes it clear what kind of activities are subject to licensing and does not include in-house manufacturing.	SPANISH SOCIETY FOR IMMUNOLOGY (SEI)

	manufacturing at the institution or service and their training, by their official qualification as a Specialist in Health Sciences (FSE) accredited by an appropriate qualification to practise the profession with such character and to occupy jobs with such title in public and private centres and establishments, in accordance with Article 16 of Law 44/2003 of 21 November on the organisation of the Health professions. ~~JUSTIFICATION although tests cannot be sold to third parties, protocols could be shared, or it could act as a reference centre (CSUR), etc. In this way, the catalogue of tests would be accessible to the other centres.~~	Not accepted. It is not the purpose of this Royal Decree, nor within the competence of the Agency, to organise the professions or to establish the types of professionals who will carry out this in-house manufacturing activity. In addition, given the wide variety of devices on the market, depending on the type of device, they will be specialists of one type or another.	
Article 9	This section may affect most laboratories that have in-house tests. The content of the Article in terms of regulations is clear; however, at no time does it mention the assessment criteria for the device produced by the health institution. I think it should be mentioned in the form of an annex.	Not accepted. Firstly, the text refers to the requirements that must be met by the sites to carry out the in-house manufacturing activity and the procedure for its notification. With regard to the device assessment criteria, Regulation 2017/746 already states that they must comply with the safety and performance requirements of Annex I, so it is not considered necessary to replicate this same text in the Royal Decree. However, instructions are being developed for health institutions that are going to	SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)

		start in-house manufacturing to facilitate the institution's compliance with the legislation.	
Article 9	Point 3: The EU Medical Device Coordination Group Guide MDCG-2023-1 states in Section 3.2 ‘How to understand the terms “manufactured and used”?’: ‘A device must be manufactured and used only within the same health institution in order for Article 5(5) to apply.’ Paragraph 3 contradicts the recommendation of that guide.	The final part ‘outside Spanish territory’ is accepted and removed from point 3.	A3Z Advanced
Article 9	Substitute ‘Before the start of the activity, the Spanish Agency of Medicines and Medical Devices will verify, through documentary verification and, where appropriate, inspection, the elements and circumstances stated by the interested party in the communication.’ JUSTIFICATION The industry considers that the manufacture of *in vitro* diagnostic medical devices in a health institution should adhere to the same levels of safety and requirements as any device manufacturer and should be subject to the same inspections and controls. The requirement for inspections and controls are the health guarantee that the manufacturer of an *in vitro* diagnostic medical device has the material and human resources, as well as the processes that minimise future risks in the safe and effective use of the devices; therefore, it should not matter who the manufacturer is (a company or a health institution), what matters is that the	Not accepted. This activity is not subject to prior licensing but to prior notification, so the requirements for action by the AEMPS are different. Of course, manufacturing requires the same levels of safety and performance regardless of whether it is carried out in a health institution or by a manufacturer, but it is necessary that, in order to benefit certain specific patient groups for which there are no alternatives, it is not delayed or hindered beforehand, without prejudice to subsequent verification.	FENIN

	manufacturer provides the appropriate health guarantees. Any differences could increase risks and insecurities in devices and their use in patients and place manufacturers at an unfair competitive disadvantage.		
Article 9	In relation to the devices manufactured by health institutions for exclusive use by the institution itself (in-house devices), whose requirements are included in Article 9 of the Royal Decree and Article 5.5 of Regulation (EU) 2017/746, we have doubts regarding certain aspects that we believe are not clearly detailed in the draft Royal Decree. We would be grateful if these were specified in the final document in order to respond to all these new requirements that apply to us and that will entail significant changes in the management of clinical laboratories. The issues are: - In relation to the time for submitting the activity notification to the AEMPS, will it be the same as for the activity licences (one year from the date the Royal Decree enters into force)?	These are not considered as claims on the text per se, but as doubts about the procedure, which will be detailed in the instructions being developed. However, they are clarified as follows: No, the communication of the activity must be made prior to the start. Article 9(7) states: *To carry out this manufacturing activity, health institutions must make* ***a prior*** *notification of the start of activity to the Spanish Agency of Medicines and Medical Devices, which will provide the necessary means to comply with this obligation* This requirement is laid down in	THE BIOMEDICAL DIAGNOSTIC CENTER OF THE HOSPITAL CLINIC OF BARCELONA

	- Regarding the requirement for compliance with ISO 15189, is it necessary to accredit with ENAC under the requirements of ISO 15189 all services using in-house devices? Or is demonstrating compliance with the documentation communicated to the AEMPS sufficient to meet this requirement? - Related to the payment of fees for electronic submission of documentation, what does the unit cost refer to? To the file? The technical procedure? To the service/device? - As regards the various aspects necessary for the implementation of Article 5(5) of Regulation (EU) 2017/746, is it	Article 5(5) of Regulation 2017/746. In addition, in accordance with Article 9(2) of the Royal Decree '2. Health institutions shall comply with all the requirements laid down in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.' The documentation to be submitted to the AEMPS must justify its compliance with the ISO 15189 standard. The ways to justify this compliance with the standard will be detailed in the working instructions of the in-house manufacturing. The fee payment will be made at the beginning of an in-house manufacturing notification of a device type or analytical technique. If the device type or technique varies, or if another service of the hospital is going to start the in-house manufacture of different devices, they must submit another notification with the corresponding fee.	

	really envisaged that the AEMPS will develop additional instructions? When will we have these?	Yes, the AEMPS is developing instructions to facilitate compliance with the regulation for the institutions that will carry out in-house manufacturing activities.	
Article 9	a) Point 2. 'Health institutions must comply with all the requirements laid down in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.' The Royal Decree should clarify whether in-house devices are to be regulated according to the risk class, as is the case with medical devices, or not. b) Point 3. 'Health institutions may not subcontract any of the manufacturing activities outside Spanish territory' The Royal Decree should clarify whether it is possible for health institutions to subcontract in-house devices to a third party. In the case of medical devices, this is not possible and can therefore be confusing. (c) Point 7: 'In order to carry out this	a) Not accepted. This type of activity, commonly referred to as in-house, was an activity that could already be carried out under the previous regulation for all classes of *in vitro* diagnostic devices. Therefore, it is not considered necessary to limit the manufacture of *in vitro* diagnostic medical devices based on the risk class of the device. However, consideration has been given to extending the requirement for class D documentation in accordance with the Regulation to classes B and C. (b) Accepted. The text has been modified to delete the final part 'outside Spanish territory' (c) Not accepted. It is not considered	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI

	manufacturing activity, health institutions must make a prior notification of the start of activity to the Spanish Agency of Medicines and Medical Devices, who will provide the necessary means to ensure compliance with this obligation.' The Royal Decree should explain why health institutions do not need to apply for a prior operating licence. (d) Point 13: 'The activity provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 may not be carried out for the manufacture of devices for self-testing, when these are not used in the health institution itself.' The Royal Decree should clarify this concept in relation to subcontracting activities, as it is confusing. Article 7(3) permits the subcontracting of the manufacture of in-house devices within Spanish territory; however, it is indicated at this point that this activity can only be carried out in the institutions that will use their own devices.	appropriate in a legislative text to include justifications. The explanation of why in-house manufacturing in health institutions requires notification and not a prior operating licence is detailed in the Regulatory Impact Analysis Report. This requirement is also in line with the provisions of Royal Decree 192/2023 regarding the in-house manufacture of medical devices. Accepted. The text has been modified to delete the final part 'outside Spanish territory'. Article 7(3), mentioned in the claim, concerns mass production and not in-house production.	
Article 9	(a) General comments. This Article does not indicate any limitation for this manufacture according to the risk class of the device, a situation that is taken into account in the in-house manufacture of medical devices where	(a) Not accepted. This type of activity could already be carried out on the basis of the previous regulation for all classes of *in vitro* diagnostic devices. Therefore, it is not considered	ANDALUSIA

	the manufacture of Class IIb, Class III, and implantable devices is not allowed.	necessary to limit the manufacture of *in vitro* diagnostic medical devices based on the risk class of the device. However, consideration has been given to extending the requirement for documentation for Class D devices under the Regulation to Classes B and C.	
	(b) Paragraph 2. States that 'Similarly, any health institution that outsources the performance of clinical analyses to a third party performing the activities provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 shall ensure that this entity complies with the requirements set out therein and in this Royal Decree.' It is understood that it is not clear who manufactures this device to be used exclusively in the health institution; in addition, it seems that this contradicts one of the requirements of this in-house manufacture, since the devices will not be transferred to other legal persons.	(b) Not accepted. This paragraph refers to the outsourcing of the performance of the analysis, but not of in-house manufacturing. For example, a centre A sends samples to another centre B to perform the analysis. If centre B manufactures and uses in-house devices to analyse these samples, centre A must verify that site B meets all in-house manufacturing requirements and has notified the AEMPS accordingly.	
	(c) Paragraph 3. It is proposed that instead of stating 'Health institutions may not subcontract any of the manufacturing activities outside Spanish territory', the provision should read that they 'may not subcontract any of the manufacturing activities', based on the principle of free movement of goods. (d) Paragraph 13. The possibility of in-house	Accepted. The text has been modified to delete the final part 'outside Spanish territory'. Article 7(3), mentioned in the claim, concerns mass production and not in-house production. Not accepted. The health institution may manufacture devices for self-	

	manufacture of devices for self-testing is established, which seems contradictory since by definition 'device for self-testing' is any device intended by the manufacturer to be used by lay persons, and therefore they are not used in health institutions.	testing in-house, provided that the patient who uses this test does so within the hospital itself. Article 9(13) makes the manufacture subject to the use of the device for self-testing, which must be in the same institution. This requirement is already stated in the draft when it establishes that it is manufacturing and use within the same institution and is in line with the European Guidelines for in-house devices.	
Article 9	Article 9. 'Manufacture of devices by health institutions for their exclusive use by the institution itself'. ▪ Proposed wording: 'Article 9. Manufacture of devices by ~~health institutions~~ **hospitals** for their own exclusive use by the ~~institution~~ **hospital**. 1. Only ~~health institutions~~ **hospitals** may perform the activity provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as defined in Royal Decree 1277/2003 of 10 October laying down the general basis for the authorisation of health institutions, services and establishments. 2. The ~~health institutions~~ **hospitals** must comply with all the requirements laid down in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.	Not accepted. First, it should be pointed out that Royal Decree 1277/2003 of 10 October laying down general bases on the authorisation of health institutions, services and establishments recognises clinical laboratories of a public or private nature as health institutions. This manufacturing activity, commonly known as 'in-house' in the case of *in vitro* diagnostic medical devices, was already contemplated in the previous regulation and has therefore been carried out in health institutions for a long time. That is why the wording proposed in the Royal Decree aims to	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	Similarly, any ~~health institution~~ **hospital** outsourcing the conduct of clinical analyses to a third-party entity performing the activities provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 shall ensure that this entity complies with the requirements established therein and in this Royal Decree. 3. The ~~health institutions~~ **hospitals** shall not subcontract any of the manufacturing activities outside Spanish territory. 4. The ~~health institutions~~ **hospitals** shall designate a person responsible for the procedures arising from the application of this Article and shall communicate their details to the Spanish Agency of Medicines and Medical Devices. 5. The sale to the public of devices manufactured in ~~health institutions~~ **hospitals** shall not be permitted. 6. The ~~health institutions~~ **hospitals** may not sell or deliver the device manufactured at their site for use by third parties. 7. To carry out this manufacturing activity, the ~~health institutions~~ **hospitals** must make a prior notification of the start of activity to the Spanish Agency of Medicines and Medical Devices, which will provide the necessary means to comply with this obligation. This notification shall contain: (a) The person responsible for the manufacturing activity in the ~~institution~~ **hospital**.	specify what is established in Regulation 2017/746 for this common practice in *in vitro* diagnosis, through the ex post review and inspection of the activities and facilities for in-house manufacturing that are carried out in health institutions nationwide. The AEMPS shall verify whether the institution has the technical means by subsequent verification as referred to in Article 9(8) and (9) On the contrary, in Royal Decree 192/2023 on medical devices, since it is not a common practice and could entail more risks due to the wide variety and type of devices to be manufactured (implants, devices for the administration of cytostatics, etc.), it was restricted to hospitals and only to certain types of devices. **Finally, it should be noted that this criterion is in line with the European in-house guidelines.**	

	(b) The declaration provided for in Article 5(5)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. (c) The documentation provided for in Article 5(5)(c), (d), (e) and (g) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. The requirements laid down in Article 5(5)(g) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 shall also apply to devices in Class B and C. This notification will allow the start of the activities, without prejudice to subsequent verification by the Spanish Agency of Medicines and Medical Devices, by means of documentary verification and, where appropriate, inspection of the elements and circumstances revealed by the interested party in the notification. 8. The Spanish Agency of Medicines and Medical Devices may request from the functional areas of health and social policy of the Government Delegations where the ~~health institution~~ **hospital** is located, a report on the conditions under which natural and legal persons carry out the activity referred to in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, ordering for this purpose the necessary inspections of the facilities. (…) 13. The activity provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 may not be carried out for the manufacture of		

	devices for self-testing, where these are not used in the ~~health institution~~ **hospital.** ▪ Justification: The manufacture of devices by health institutions for their exclusive use in the institution itself (regulated in Article 9 of the draft Royal Decree) originates from Article 5(5) of the Regulation, which details the harmonised requirements for this activity. However, Article 5(5) in fine itself clarifies that Member States are free to restrict the manufacture of such devices. Thus, it is possible that the norm does not allow all health institutions to carry out this activity, but limits it to those that may have the technical means to carry it out. Therefore, the recently approved Royal Decree 192/2023 of 21 March 2023, regulating medical devices, includes an article dedicated to this same issue (Article 9) with wording identical to that of the draft Royal Decree, except that it restricts their use to hospitals, which can meet the associated material and human requirements. In fact, the draft of Royal Decree 192/2013 itself, which was submitted to a public hearing and information, included a wording identical to that of the draft Royal Decree, which was amended at later stages of its processing; in the opinion of this General Council, following a sound criterion. In view of the above, we consider that action should be taken regarding Article 9 of the draft Royal Decree in a similar sense to that of Royal		

	Decree 192/2023, limiting production in health institutions for their own use to hospitals, which, given their larger size, are able to carry out this task in accordance with the requirements of the draft Royal Decree and ensure the safety and health of patients; thus also consolidating the systematic nature of sectoral regulation in this area.		
Article 9	Art.9.7: The prior notification that a health institution is expected to make to the Spanish Agency of Medicines and Medical Devices to carry out the activity of manufacture of *in vitro* diagnostic medical devices for exclusive use in the institution itself should be made to the health authority of the Autonomous Community where the health institution is located, rather than to the Agency. Art.9.8: This Article should refer to the inspections that are expected to be carried out at these institutions by the competent authority of the Autonomous Communities. Art.9.9: The Spanish Agency for Medicines and Medical Devices should be replaced by the health authority of the Autonomous Community, as the competent authority that can order the cessation of the activity when, from the documentation provided or the corresponding	Not accepted. As indicated above, the competence relating to the regulation of import, processing, manufacture, distribution or export activities corresponds to the General State Administration in accordance with the provisions of Article 100 of Law 14/1986, of 25 April 1986, on General Health. These powers concern the activities to be conducted independently of the establishment where they are carried out, as well as the authorisations of health establishments issued by the Autonomous Communities. That is why the communication will be made to the Agency, which will be responsible for carrying out the review and the corresponding inspection. Likewise, it will be the Agency that will carry out the necessary measures to order the cessation or to authorise in-house manufacturing under conditions other than those provided for in this Royal Decree. However, this information will be available to the Autonomous	CATALONIA

	inspection reports, it is not guaranteed that the institution has the appropriate facilities, means, procedures and personnel to carry out the respective activities, or when any essential inaccuracy is incurred with respect to the conditions under which it made its communication. Art.9.10: The notification of any modification of the data indicated in Article 9(7), which a health institution is expected to make to the Spanish Agency of Medicines and Medical Devices, should be made to the health authority of the Autonomous Community where the health institution is located, rather than to the Agency. Art.9.11: Replace the wording of this point with the following: 'The health authorities of the Autonomous Communities shall inform the Spanish Agency of Medicines and Medical Devices of the activities communicated in accordance with the provisions of this Article, through the procedure to be established.' Art.9.12: The Spanish Agency of Medicines and Medical Devices should be replaced by the health authority of the Autonomous Community, as the competent authority that can authorise the manufacture of any device in health institutions	Communities. This text is in line with that recently approved by RD 192/2023 for the same in-house manufacturing activity for medical devices in general.	

	or public health institutes under conditions other than those provided for in this Article, when its use is in the interest of public health or the safety or health of patients. Justification: In accordance with current legislation (Article 108 of the recast text of the Law on Guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015), the health authorities of the Autonomous Communities are competent to carry out the corresponding inspection and control actions to ensure compliance with this Law. Likewise, in accordance with the current legislation on health institutions, services and establishments (Royal Decree 1277/2003 of 10 October, establishing the general bases for the authorisation of health institutions, services and establishments), the health authority of each Autonomous Community is competent for the authorisation, control and inspection of the activities carried out in the health institutions of their Community. Taking into account all the above, and in order to carry out the control actions to verify that the conditions referred to in this Article are met for this manufacturing process, the health authority of the Autonomous Community where the institution is located must receive the notification provided for in this Article.		
Article 9	Article 9. *Manufacture of devices by health institutions for their exclusive use by the*	Not accepted. Based on the wide variety of devices and situations, it is	SPANISH BIOINDUSTRY ASSOCIATION

	institution itself. 1. Only health institutions may perform the activity provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, as defined in Royal Decree 1277/2003 of 10 October 2003 laying down the general basis for the authorisation of health institutions, services and establishments. It is necessary to clarify what can be considered the manufacturing of devices by health institutions. For example, to determine whether a small modification of the intended use already constitutes 'manufacture', or whether the design of genetic tests can be included within the manufacture of devices?	not considered appropriate to detail in a legislative text the different cases. These aspects have already been clarified in the European guidelines on in-house manufacturing and will be further detailed in the instructions that are being developed to carry out the prior notification of in-house manufacturing.	ASEBIO
Article 9	Article 9. 2. Health institutions shall comply with all the requirements laid down in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. It is not clear how to meet all the requirements for the case of genetic testing.	Partly accepted. As indicated above, genetic tests considered as *in vitro* diagnostic medical devices for human use, as defined in Article 2(2) of Regulation (EU) 2017/746, are *in vitro* diagnostic medical devices for all purposes and must therefore comply with all the provisions of Regulation 2017/746 and the provisions of the future RD on *in vitro* diagnostic devices. However, point 14 has been included clarifying this aspect. *14. In the case of the manufacture of genetic tests by health institutions for*	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

		their exclusive use by the institution itself, the requirements established in Articles 10 and 11 of this Royal Decree that apply to them must be met.	
Article 9	Article 9. 3. Health institutions may not subcontract any of the manufacturing activities outside Spanish territory. It is necessary to consider that currently, oligos and probes, polymerases, and many other components are acquired outside Spanish territory.	It is not considered to be a claim on the text. However, the subcontracting refers to the manufacturing activity and not to the procurement or purchase of raw materials, reagents or components. The text has also been amended to delete the part 'outside Spanish territory'.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 9	Article 9.5. The sale to the public of devices manufactured in health institutions shall not be permitted. It may seem a little contradictory in the case of genetic tests, since from the moment they are designed (set up), they are being 'sold'/'offered' to the public in the form of a service.	Not accepted. The manufacture commonly referred to as in-house, and as defined by Regulation 2017/746, is a manufacture by a health institution, for a specific population of patients for whom there are no alternatives and for use within the health institution itself. This in-house manufacturing is not a commercial activity; it refers to an activity to treat or diagnose patients when there are no commercial alternatives on the market and the service cannot be offered to the general population. This manufacture is different from that which can be carried out by the manufacturing companies.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 9	Article 9.7. To carry out this manufacturing activity, health institutions must make a prior	Not accepted. The design of a genetic test for a specific population of patients	SPANISH BIOINDUSTRY ASSOCIATION

	notification of the start of activity to the Spanish Agency of Medicines and Medical Devices, which will provide the necessary means to comply with this obligation. This notification shall contain: (a) The person responsible for the manufacturing activity at the institution. (b) The declaration provided for in Article 5(5)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. (c) The documentation provided for in Article 5(5)(c), (d), (e) and (g) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. The requirements laid down in Article 5(5)(g) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 shall also apply to devices in Class B and C. This notification will allow the start of the activities, without prejudice to subsequent verification by the Spanish Agency of Medicines and Medical Devices, by means of documentary verification and, where appropriate, inspection of the elements and circumstances revealed by the interested party in the notification. If we understand the activity of designing (developing) genetic tests as a manufacturing activity, it is necessary to clarify whether the laboratory should notify the start of an activity each time it develops a genetic test. In addition, it is necessary to specify what	for whom there are no alternatives and for use within the health institution itself is in-house manufacture. Examples are provided in the European guides. In Spain, the notification must be submitted once this Royal Decree enters into force. The notification of in-house manufacturing will be made by type of device or analytical technique. If the type of devices or technique varies, or if another service of the institution is going to start the in-house manufacture of different devices, they must submit another notification with the corresponding fee. Instructions are also being developed to detail and facilitate the process of notification by the institution.	ASEBIO

	happens in the case of a laboratory that has been working and performing these genetic tests for many years; it is necessary to establish how the notification should be made.		
Article 9.	Article 9(10) The activity provided for in Article 5.5 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 may not be carried out for the manufacture of devices for self-testing, when these are not used in the health institution itself. Under no circumstances may the activity provided for in Article 5(5) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 be carried out for the manufacture of devices for self-testing. JUSTIFICATION: Due to the special conditions and requirements for the manufacture of devices for self-testing, it is not possible for a health institution to manufacture these types of devices, whether they are used within the health institution itself or outside it. On the other hand, paragraph 6 establishes that it is not possible to deliver a device manufactured in the health institution to a third party, understood to be a patient of the health institution.	Not accepted. In the event that the use of a device for self-testing for which there is no commercial alternative is necessary for a specific group of patients, it should be possible for the institution to manufacture it, provided that it is used in the institution itself. This wording follows the guidelines of the European MDCG.	FENIN
Article 10 to Article 13	Articles 10 and 11 regulate genetic testing, genetic information and counselling and, Article 13, regulates reference laboratories. Since reference laboratories do not appear to	Not accepted. Reference laboratories may have a relevant role in the use of genetic tests in addition to that in other *in vitro* diagnostic medical devices, so it seems appropriate to include them in	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	limit their activity to genetic testing, it is recommended that this Article 13 be moved to a chapter separate from the regulation of genetic tests or, if necessary, that appropriate links be established.	this chapter.	
Article 10	The second subparagraph of Article 10(1) should specify the additional regulations to which it intends to refer, since the terms in which it has been expressed are ambiguous. • Paragraphs 2 and 3 are a reproduction of Articles 46 and 9(3) of Law 14/2007 of 3 July, on Biomedical Research, bringing into question the need and appropriateness of reproducing them in this Article. You could choose to just make a reference to them, along with the modification of the paragraph indicated above, in a manner similar to the following: 'The requirements laid down in this Royal Decree with regard to genetic testing shall be observed without prejudice to the specific legislation applicable and, in any event, shall be carried out in the cases and under the conditions laid down in Articles 9(3) and 46 of Law 14/2007 of 3 July on Biomedical Research.'	Partially accepted. Text is amended by changing 'additional' to 'specific'. Accepted. The text is amended.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
Article 10	Genetic analyses shall be carried out for the identification of the status of being affected, unaffected, or a carrier of a genetic variant, or that it may predispose to the development of a specific disease, condition the response to a	Not accepted, as the amendment of the wording is an exact reference to the Law. It is understood that tests for the prognosis of a pathology or the reception of transplants or transfusions	SPANISH SOCIETY FOR IMMUNOLOGY (SEI)

	specific treatment, the prognosis of a pathology, or the reception of transplants or transfusions. Comment: According to Article 9(3) of Law 14/2007, of 3 July, predictive tests for genetic diseases or that allow the identification of the subject as a carrier of a gene responsible for a disease, or detect a predisposition or genetic susceptibility to a disease, may only be conducted for medical purposes or medical research and with genetic counselling, when indicated, or in the case of the study of inter-individual differences in the response to drugs and genetic-environmental interactions or for the study of the molecular bases of diseases. Histocompatibility and immunogenetic tests, as well as those for primary immunodeficiencies or innate human immunity errors, should be included	are included within the scope of Law 14/2007 itself.	
Article 10	Article 10. 1. Genetic tests may only be placed on the market, marketed, or put into service if they comply with the requirements laid down in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in this Royal Decree. This statement would be somewhat in contradiction with Article 9. Manufacture of devices by health institutions for their exclusive use by the institution itself. It does not appear that consideration is being given to the possibility of genetic tests manufactured in-	Partly accepted. All genetic tests, like all *in vitro* diagnostic devices, must comply with the requirements laid down in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and in this Royal Decree, which apply to them. Therefore, if it is in-house manufacture, the specific in-house requirements of the Regulation and the Royal Decree will apply, with the exceptions that exist for them.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

	house, which would not have to comply with the requirements of Regulation (EU) 2017/746 except for the corresponding general safety and performance requirements set out in Annex I.		
Article 10	Article 10.*2.* According to Article 46 of Law 14/2007, of 3 July, on Biomedical Research, in the terms provided for in Article 1(2) of the aforementioned Law, genetic analyses shall be carried out for the identification of the status of being affected, unaffected, or a carrier of a genetic variant that may predispose an individual to the development of a specific disease, or condition their response to a specific treatment. According to Article 9(3) of Law 14/2007, of 3 July, predictive tests for genetic diseases or those that allow the identification of the subject as a carrier of a gene responsible for a disease, or detect a predisposition or genetic susceptibility to a disease, may only be conducted for medical purposes or medical research and with genetic counselling, when indicated, or in the case of the study of inter-individual differences in response to drugs and genetic-environmental interactions or for the study of the molecular bases of diseases. It should be included that genetic tests are permitted to report on the ancestry of the individual as well as other characteristics derived from a genetic study for informational and recreational purposes.	Not accepted. It is not considered to be within the scope of this Royal Decree. The Royal Decree regulates *in vitro* diagnostic medical devices. Genetic tests that are not considered *in vitro* diagnostic medical devices are not included in the scope of the Regulation or of this Royal Decree.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 11	• In paragraph 1 and, since the definition in	Accepted. The text is amended.	GENERAL TECHNICAL

	Article 3(1) of Royal Decree 81/2014 of 7 February refers to healthcare, in order to improve its understanding it is recommended that its wording be amended as follows: '1. Any health institution or health professional carrying out a genetic test on persons for medical purposes of diagnosis, treatment improvement or predictive or prenatal testing, in the context of healthcare, as defined in Article 3(1)(1) of Royal Decree 81/2014 of 7 February 2014 establishing rules to ensure cross-border healthcare and amending Royal Decree 1718/2010 of 17 December 2010 on medical prescriptions and dispensing orders, must provide the person who is the subject of the test or, where appropriate, his or her legally designated representative, with the relevant information concerning the nature, importance and consequences of genetic testing, as appropriate.'		SECRETARIAT. MINISTRY OF HEALTH
	• In the second subparagraph of paragraph 1, it is suggested that the term 'situadas' (located) be replaced by 'que se encuentren' (to be found), as it is an expression already used in current legislation.	Accepted. The text is amended.	
	• Due to their close connection, it is recommended to unify paragraphs 2 and 3, jointly establishing the general rule of information and the exceptions where advice	Not accepted. It is considered appropriate to maintain the structure	

	will not be necessary, so that paragraph 2 could be drafted in a similar way to the following: '2. Likewise, health institutions and health professionals shall provide appropriate advice to individuals in the case of the use of genetic tests that provide information on genetic predisposition to ailments or diseases considered, in general, impossible to treated in accordance with the knowledge available in science and technology, unless the genetic test is use for the confirmation of an ailment or illness that has been previously diagnosed or that the diagnostic test is used for therapeutic screening.'	established in Regulation 2017/746 itself, which separates these concepts into two points, Article 4(2) and 4(3).	
	• Paragraph 4 appears to regulate what Article 3(e) of Law 14/2007 of 3 July defines as 'genetic counselling': 'procedure for informing a person of the possible consequences for themselves or their descendants of the results of a genetic analysis or screening and its benefits and risks and, where appropriate, to advise on possible alternatives arising from the analysis. It takes place both before and after genetic testing or screening and even in the absence thereof', and reproduces, in turn, the content of Article 55(2) of that Law: 'The professional who carries out or coordinates the genetic counselling must provide adequate information	Not accepted. As there is no definitions section, reference is made here to genetic counselling.	

	and advice, relating both to the significance of the resulting genetic diagnosis and to the possible alternatives that the subject may choose in view of it.' The need to retain paragraph 4 above is therefore questioned, beyond the reference to compliance with the provisions of the aforementioned Law, as referred to in the draft paragraph 5 in respect of the staff required and the accreditation of the centres for the genetic counselling process.		
Article 11	The draft Royal Decree submitted for report does not contain a general reference to the data protection regulations, but a reference in Article 11(8), referring to the protection of personal data in the specific field of genetic testing, mentioning that Article 5 of Law 14/2007 of 3 July on biomedical research must be observed. However, the seventeenth additional provision, already cited, relating to Health Processing, of the Organic Law on the Protection of Personal Data, contains a broader regulation, subsequent to Law 14/2007, which should be the subject of specific analysis by the drafter of the draft RD to determine whether the regulation of the seventeenth additional provision overlaps in any way with the provisions of Article 5 of Law 14/2007, since paragraph 2 of said seventeenth additional provision refers to the 'processing of health research data' in a broad manner, without, of course, reducing the rights of people participating in the performance studies, or	Accepted. An amendment is made to Article 11(8) to refer to data protection in biomedical research. 11. 8. Regarding data protection, the provisions of Article 5 of Law 14/2007, of 3 July, and current European and Spanish regulations on data protection will be observed and, in particular, the references to biomedical research contemplated in the Seventeenth Additional Provision of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights.	SPANISH DATA PROTECTION AGENCY

	genetic tests or trials provided for in Article 5 of Law 14/2007. Article 11(6) of the draft subject to report states that the information and genetic advice provided to the person must include, at least, 'the identity of the persons who will have access to the results of the tests when they are not subject to dissociation or anonymisation procedures'. This AEPD considers that in the interests of greater security and confidentiality of personal data, the following should also be specified: (a) the organisational and technical measures that will be applied to prevent unauthorised access to the information and personal data processed, as well as their unauthorised disclosure, dissemination, modification or loss; (b) a description of the measures to be implemented to ensure the confidentiality of the medical records and personal data of the test subjects; and (c) a description of the measures to be implemented in the event of a data breach, to mitigate its potential adverse effects. These three measures are only the description contained in Annex XIV, Chapter I, paragraph 4(5), of Regulation 2017/746, and would serve to demonstrate to the data subject that the necessary measures have been taken for the protection of their fundamental right to the protection of their personal data in the development of these genetic tests. This Agency has repeatedly recommended in its reports that the pre-legislator, in those cases, such as the present one, in which the		

	processing has as a legal basis Article 6(1)(c) or (e) of the GDPR (that is, processing whose basis is a legal obligation or a mission of public interest), and is established by European Union law or the law of the Member State that applies to the controller and that law regulates the specific processing operation or set of operations in question, such as the processing operations that derive from the draft RD subject to report, make use of the possibility established by Article 35(10) GDPR so that it is the body proposing the general provision, in the course of the procedure for creating the provision of the norm (law, royal decree etc.) who carries out a risk analysis and, where appropriate, a data protection impact assessment (DPIA) as part of an overall impact assessment in the context of the adoption of that legal basis (i.e. to analyse in the Regulatory Impact Analysis Report the data protection impacts together with the other impacts normally referred to in the Regulatory Impact Analysis Report: by gender, in families etc.). Such a DPIA shall be incorporated, as permitted by - it should almost be said as imposed by, but in any case it does not prohibit it - Article 2(1)(g) of Royal Decree 931/2017 of 27 October 2017 which regulates the Regulatory Impact Analysis Report. This precept is, in addition, sufficiently expressive of the legislature's intention to include in the		

	Regulatory Impact Analysis Report, within the concept of 'Other impacts', the analysis of the 'impact that the development or use of the means and services of the digital administration entailed by the regulation will have for citizens and for the Administration'.		
Article 11	Concerning paragraph 5, the whole process of genetic counselling must be carried out by a qualified person and at least supervised by a qualified Specialist in Health Sciences (FSE) accredited by an appropriate qualification to practise the profession with such a character and to occupy jobs with such a title in public and private centres and establishments, in accordance with Article 16 of Law 44/2003 of 21 November 2003 on the organisation of the health professions JUSTIFICATION Genetic counselling is not currently a speciality. The provision should talk about information about the test and counselling instead of genetic counselling	Not accepted. The Article of the Royal Decree refers to the provisions of Law 14/2007, of 3 July, the entire process of genetic counselling and the practice of genetic analysis and cannot contravene what is indicated in a law. On the other hand, it is not the purpose of this Royal Decree nor the competence of the Agency to organise the professions, nor to determine the professionals who may carry out this activity.	SPANISH SOCIETY FOR IMMUNOLOGY (SEI)
Article 11	Article 11(3) of the draft determines in which cases the requirements of Article 11(2) do not apply. However, it is not understood why a genetic test for the diagnosis of an existing disease should not be accompanied by 'adequate counselling', bearing in mind that the impact of genetic test results is not limited to the person who requires them or for whom they are requested, but extends to their	Partly accepted. These exceptions are already marked by Regulation 2017/746 on *in vitro* diagnostic medical devices since in these cases there is already a diagnosis of the disease. However, the wording has been redrafted in line with that of the above-mentioned regulation.	MINISTRY OF SCIENCE AND INNOVATION GENERAL TECHNICAL SECRETARIAT

	immediate family. This exception can be understood in the case of diagnostic tests for 'therapeutic selection'		
Article 11	THIRD. - Concerning Article 11. 5 That provision provides that, in accordance with the provisions of Article 56 of Law 14/2007 of 3 July 2007, the entire process of genetic counselling and the practice of genetic analyses for health purposes must be carried out by qualified personnel and must be carried out in accredited institutions, in accordance with Article 57 of that Law, which meet the quality requirements laid down by regulation for that purpose. It is a copy of Article 56 of Law 14/2007 of 3 July 2007 and, in accordance with the legislation set out in the first claim, only health professionals specialising in clinical analysis, clinical biochemistry, immunology, microbiology and parasitology are authorised.	Not accepted. It is not the purpose of this Royal Decree or the competence of the AEMPS to establish the health professionals qualified to carry out genetic tests. The wording only refers to the fact that the entire process of genetic counselling and the practice of genetic analysis for health purposes must be carried out by qualified personnel and must be carried out in accredited institutions in accordance with current regulations already established.	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA
Article 11	In relation to the provisions of Article 11(8) of the draft Royal Decree, it is suggested, for greater legal certainty, to supplement it with a direct reference to the two Articles that establish the legal regime of biomedical research (Article 5 of Law 14/2007 and paragraph 2 of the seventeenth additional provision, of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights) Thus, where it currently says, 'With regard to	Accepted. An amendment is made to Article 11(8) to refer to data protection in biomedical research. 11. 8. With regard to data protection, the provisions of Article 5 of Law 14/2007, of 3 July and current European and Spanish regulations on data protection will be observed and, in particular, the references to biomedical research contemplated in the	MINISTRY OF HEALTH - GENERAL SECRETARIAT FOR DIGITAL HEALTH, INFORMATION AND INNOVATION OF THE NATIONAL HEALTH SYSTEM

	data protection, the provisions of Article 5 of Law 14/2007 of 3 July 2007 and current European and Spanish legislation on data protection shall be observed', an alternative wording is proposed, for example: 'With regard to data protection, the provisions of Article 5 of Law 14/2007 of 3 July 2007 and current European and Spanish legislation on data protection shall be observed *and, in particular, the references to biomedical research referred to in the Seventeenth Additional Provision of Organic Law 3/2018 of 5 December 2018 on the Protection of Personal Data and the Guarantee of Digital Rights*'	seventeenth additional provision of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights.	
Article 11	Article 11(6) It is requested that in this point (i) be added to read 'Warn the subject to whom the test is carried out, expressly, that the test may result in the recommendation of treatments or medicines that are not yet available for use in the National Health System.' Justification: We consider it necessary that this warning be given to subjects in order not to generate false expectations in relation to the treatment of their disease when an approved medicine is not available or its financing is not approved by the public health system.	Not accepted. The text refers specifically to information and genetic counselling to the person undergoing the test. This test can be performed inside or outside the National Health System, so it is not considered appropriate to detail that treatment may not be available through the National Health System. Especially when this financing or availability may vary between Autonomous Communities.	CATALONIA
Article 11	Concerning Article 11(9). '*Genetic information, counselling and informed consent*'. ▪ Proposed wording: *'9. Compliance with all information and counselling requirements provided for in*	Not accepted.	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	~~*Articles 10 and 11 of*~~ ***this Royal Decree and in any other applicable legislation,*** *must be ensured in form and time throughout the process of carrying out the genetic test, including sampling'* ▪ Justification: We consider it important that, when limiting the scope of the requirements of information and counselling for genetic tests, it is clarified that this concerns both those of this Royal Decree (condensed in Article 11 and Article 12) and those included in any other regulations that may affect this matter, in order to offer the greatest possible degree of legal certainty.		
Article 11	Article 11.1. Any health institution or health professional carrying out a genetic test on persons for medical purposes of diagnosis, treatment improvement or predictive or prenatal testing, in the context of healthcare, as defined in Article 3(1)(1) of Royal Decree 81/2014 of 7 February 2014 establishing rules to ensure cross-border healthcare and amending Royal Decree 1718/2010 of 17 December 2010 on medical prescriptions and dispensing orders, must provide the person who is the subject of the test or, where appropriate, his or her legally designated representative, with the relevant information concerning the nature, significance and consequences of the genetic test, as appropriate. It is necessary to clarify that this refers to health institutions or professionals established in Spain.	Not accepted. An amendment is made to the text to include that this requirement to provide the person who is the subject of the test or, where applicable, their legally designated representative, with relevant information concerning the nature, significance and consequences of the genetic test, as appropriate is limited only to health institutions and professionals established in the national territory. Added text: This will apply to any health institution or health professional regardless of their location who performs a genetic test on people located in Spain, including those who	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

		perform a service for diagnostic or therapeutic purposes offered through the services of the information society.	
Article 11	Article 11.5. In accordance with the provisions of Article 56 of Law 14/2007, of 3 July, the entire process of genetic counselling and the practice of genetic analysis for health purposes must be carried out by qualified personnel and must be carried out in accredited institutions, in accordance with Article 57 of the same Law, which meet the quality requirements established by regulation for this purpose. To adapt the law to the future, support for genetic counselling via video-call or the internet should be allowed, since many patients cannot travel and this option is more convenient and appropriate to the current reality. Additionally, in relation to accredited institutions, it should be clarified that it applies only to institutions established in Spain	Not accepted. The wording is consistent with current legislation, Law 14/2007 of 3 July 2007, as regards the fact that the entire process of genetic counselling and the practice of genetic analysis for health purposes must be carried out by qualified personnel and must be carried out in accredited institutions. It is not the purpose of this Royal Decree or the competence of the Agency to indicate that this can be carried out via video-call or the internet, which could imply an amendment of the aforementioned Law. Not accepted. The modification is made because the counselling for a person located in Spain must take place regardless of where the health professional or the institution is located. However, the text is amended to clarify this situation. Added text: This will apply to any health institution or health professional regardless of their location who performs a genetic test on people	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

		located in Spain, including those who perform a service for diagnostic or therapeutic purposes offered through the services of the information society.	
Article 11	Article 11(7) In accordance with the provisions of Article 48 of Law 14/2007, of 3 July, it will be necessary to obtain the express and specific written consent for the performance of the test. This consent must be provided at least in Spanish. Informed consent accepted electronically should be explicitly allowed, since this is done in private and public institutions in Spain	Not accepted. The wording is consistent with current legislation, Law 14/2007, and it is neither possible nor the purpose of this Royal Decree to modify the aforementioned Law.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 12	It is recommended that the content of this article be reformulated, since paragraphs 1, 2 and 4 set out requirements for verifying and validating the documentation and requirements for the application for designation, but in a confusing way, so that this Article could be reordered in a way similar to the following: 'Article 12. Reference laboratories. 1. The Spanish Agency of Medicines and Medical Devices will present to the Commission the requests for designation of laboratories located in the National territory, in accordance with Article 100(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.	The proposed wording of paragraphs 1, 2 and 4 is not accepted. Since it does not follow the correct order of the process itself. Paragraph 4 concerns actions that may be taken by the AEMPS once the laboratory has been designated and is therefore not part of the designation process referred to in paragraphs 1 and 2.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	2. Prior to this application for designation, the Spanish Agency of Medicines and Medical Devices shall require the laboratory to submit all relevant information and documentation, including the necessary budgetary documents, and take appropriate action to validate the laboratory's request and verify compliance with the requirements and criteria laid down in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and the relevant implementing regulations, in order to be submitted to the European Commission for designation. The Spanish Agency of Medicines and Medical Devices may, in a reasoned manner, request the laboratory to send, at least in Spanish, the documents provided with the application. 3. The Spanish Agency of Medicines and Medical Devices may carry out support actions to verify the maintenance of these skills in laboratories, in accordance with Article 100(9) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017.' • Notwithstanding the foregoing, it is questioned whether it is necessary to give reasons for the request for the submission of the documentation in Spanish in the second subparagraph of paragraph 2. • It is also recommended to clarify the content of paragraph 3 as it is not clear in its wording to whom support can be given or the reference to	The need to give reasons is accepted and removed.	

	Article 100(9) of the Regulation.	Not accepted, as the wording refers to Article 100(9) of the Regulation which concerns Commission controls. The Commission itself could refer these controls to other bodies, so it is not considered appropriate to specify this aspect.	
Article 12	It is clear that the application to become a Reference Laboratory must come from the laboratory itself, however, it is not clear what functions it will perform or the fees it will receive. fix functions and fees of the reference laboratories	Not accepted. As indicated in the wording of Royal Decree Article 12(1), the requirements for European reference laboratories are already included in Article 100 of Regulation 2017/746.	SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)
Article 12	Article 12.5. Likewise, in order for the 'Country' strategy to be complete and effective, similar steps should be taken to promote 'reference laboratories', which means that in Article 12, a point 5 should be added. 5. The Ministry of Health shall promote the designation of the largest possible number of public and private reference laboratories to the European Commission, in order to ensure full technical, operational and cost-competitive capacity in the national territory in order to safeguard the interests of small and medium-sized enterprises in the sector; as well as a way to foster innovation in medical devices. The costs of the designation process undertaken by the Ministry of Health for the process of designation of laboratories before the European Commission may be passed on to the	Not accepted. The designation of reference laboratories is the responsibility of the Commission, in accordance with the provisions of Article 100(1) of Regulation (EU) 2017/746. *1. The Commission may, by means of implementing acts, designate one or more European Union reference laboratories ('EU reference laboratories') for specific devices, or a category or group of devices, or for risks specific to a category or group of devices, where they fulfil the criteria set out in paragraph 4. The Commission shall only designate EU reference laboratories for which an application for designation has been submitted by a Member State or by the Commission's Joint Research Centre.*	SPANISH ASSOCIATION OF CERTIFIERS AND VERIFIERS OF CONFORMITY ASSESSMENT - ACERTES

	candidates to be reference laboratories through the corresponding fees, if the Ministry deems it necessary. In addition, the aforementioned draft Royal Decree should take advantage of modifying the rest of the regulations on medical devices that are not *in vitro*, including all the above proposed to achieve the robustness and effectiveness of the headings that we have proposed to be added.		
Article 12	12.5. The Ministry of Health shall promote the designation of as many public and private reference laboratories as possible before the European Commission, in order to guarantee full technical, operational and cost-competitive capacity, in the national territory, in order to guarantee the interests of small and medium-sized enterprises in the sector; as well as a way to foster innovation in medical devices. The costs of the designation process incurred by the Ministry of Health for the designation process of the laboratories before the European Commission may be passed on to the candidates to be reference laboratories through the corresponding fees, if the Ministry deems it necessary.	Not accepted. It is not considered appropriate to include in a legislative text a wording on the promotion of designation of reference laboratories by the Ministry of Health when Regulation 2017/746 establishes that the designation of European reference laboratories is carried out by the European Commission, not by the national authorities. That is why the text of Article 12 of the Royal Decree refers to and transfers to the national regulation the actions that the competent authority must carry out in relation to reference laboratories. It should be noted that the commitment of the Ministry and the AEMPS to the reference laboratories is firm, clear proof is that Spain has been the country that has presented the most	FELAB AELI EUROLAB

		candidates for reference laboratories at European level, an activity that has not been subject to any fee for candidates. Applications for designation of candidate reference laboratories are submitted to the Commission by the competent authorities of the Member States. In accordance with Article 100 of Regulation (EU) 2017/746, the tasks performed by the competent authority are to verify and submit EURL applications to the Commission for designation. Article 100 European Union reference laboratories 1. The Commission may, by means of implementing acts, designate one or more European Union reference laboratories (‘EU reference laboratories’) for specific devices, or a category or group of devices, or for risks specific to a category or group of devices, where they fulfil the criteria set out in paragraph 4. The Commission shall only designate EU reference laboratories for which a request for designation has been submitted by a Member State or by the Commission's Joint Research Centre 3. At the request of a Member State, the Commission may also designate EU reference laboratories where the Member State wishes to make use of such laboratories to ensure the	

		verification of the performance declared by the manufacturer and the compliance of Class C devices with the applicable common specifications where available, or with other solutions chosen by the manufacturer to ensure at least an equivalent level of safety and performance.	
Article 13	Article 13 of the draft regulates notified bodies and establishes the Ministry of Health as the responsible authority for these bodies. It is recommended that it be indicated which body of the Ministry should be the responsible authority, given the importance of the functions to be performed. • Moreover, the second paragraph of point 2 and point 3 are repeated as regards compliance with the requirements set out in Annex VII to the Regulation, it is recommended that this be corrected.	Not accepted. It is proposed that the text be maintained in the same form as in Royal Decree 192/2023 of 21 March to align both Royal Decrees, which must be completely consistent, and to avoid discrepancies in interpretation. Especially when the designating authority of notified bodies in Spain is the Ministry of Health through the designation made directly by the Minister. Not accepted. It is proposed that the text be maintained in the same form as in Royal Decree 192/2023 of 21 March to align both Royal Decrees, which must be completely consistent, and to avoid discrepancies in interpretation. In addition, the first mention in point 2 refers to the language of the documentation to be submitted and in	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

		point 3 to compliance with the requirements of Annex VII, without other types of certification being valid.	
Article 13	The current situation, recognised by the EU itself and by the AEMPS, is absolutely critical in terms of the existing capacity in EUROPE to respond to demand, not only for obtaining certification for new devices, but also for maintaining existing certifications in accordance with the new requirements. There is no doubt that public resources are limited, but this does not prevent the Ministry of Health itself from encouraging and urging the private sector operating in the field of conformity assessment and more specifically in the field of device certification, to make the necessary investments to ensure its technical and operational capacity to comply with the requirements established in Regulation 2017/746 for notified bodies. In view of the above, it is proposed that in Chapter IV Notified Bodies Article 13, the following points 5, 6, 7 and 8 shall be added: 5. The Ministry of Health shall promote the notification of as many private notified bodies as possible, ensuring full technical, operational and cost-competitive capacity in the national territory, in order to guarantee the interests of small and medium-sized enterprises in the sector; as well as a way to foster innovation in	Not accepted. The inclusion of wording regarding the promotion by the Ministry of Health of the notification of a greater number of notified bodies is not considered to be the subject of the Royal Decree and of this Article, given that the designation process is at European level, and this is established in the Regulation. Manufacturers may access the certification of their devices by any of the bodies designated for this purpose. As far as devices of Regulation 2017/745 are concerned, the 39 bodies already designated at present cover more than 80 % of the devices certified in accordance with the previous directives. In the case of IVD, there are 10 designated, based on the information provided by the already designated bodies, which currently have the capacity and availability to accept applications for certification of IVD devices. It is important to note that the origin of	AELI EUROLAB FELAB

	medical devices. The costs of the evaluation process incurred by the Ministry of Health for the notification process of the bodies to be notified may be passed on to the candidates to be notified through the corresponding fees, if the Ministry deems it necessary. 6. The Ministry of Health shall set up a coordination committee comprising the Ministry itself, the AEMPS, manufacturers and associations of representatives of bodies that are potential candidates for initiating the process of notification, representatives of the Autonomous Communities that so wish and the national reference laboratories or candidates for it or their sectoral representatives, which will seek to ensure that 'there is full technical and operational capacity for any small and/or medium-sized enterprise to have a response in time, form and cost so that their certification needs are met as quickly as possible in the national territory, without affecting free competition with the notified bodies of the other EU Member States.' 7. The Ministry of Health, through points 5 and 6, should also provide for maximum technical and operational capacity in Spanish territory to address certification needs that may arise in the face of future pandemics. That is, strategic coordination will be established between the public sector (Central Administration and Autonomous Communities) and the private	the current situation of device certification and how it may affect the market is not only due to the capacity of the bodies, but also to the new requirements for the designation of notified bodies, that have prolonged the usual designation times, coupled with the increased requirements for manufacturers and therefore the certification times have also lengthened. That is why the situation will not be solved only by increasing the number of bodies, but requires lines of action at several levels, such as streamlining the processes of designation and re-designation of notified bodies, ensuring the creation and proper functioning of expert panels and reference laboratories, as well as the modification of the transitional periods of both regulations. Likewise, it is not considered appropriate to include in a legislative text the creation of coordination committees with the functions indicated in the claim. There is already a Committee on medical devices, with representatives from various sectors, associations and patients, established	

	sector, both manufacturers and notified bodies or candidates for notification, in the face of the new challenges demanded by society. 8. The Ministry of Health shall establish a market surveillance coordination committee comprising the Ministry of Health, the Autonomous Communities concerned, manufacturers, national notified bodies and national reference laboratories and/or their sectoral representatives, which shall collaborate with and support the Ministry in its market surveillance work.	with its functions in Royal Decree 1275/2011 of 16 September 2011 establishing the Spanish Agency of Medicines and Medical Devices and approving its Statute. In addition, there is also the Technical Inspection Committee with representatives of the AEMPS and the Autonomous Communities as competent authorities for market control.	
Article 13	In order to be able to comply with: 'while promoting innovation and the interests of small and medium-sized enterprises operating in this sector', it is required that the 'Enacting terms' set out the actions/responsibilities/.../ ensure that there is an alignment between what is wanted or intended to be achieved' (Preamble) (...) If all of the above is taken into account, the 'Preamble' would not remain 'good intentions', but the way to achieve the objectives would be transferred to the 'Enacting' part. In view of the above, it is proposed that in Chapter IV Notified Bodies Article 13, the following points 5, 6, 7 and 8 be added to read as follows: 5. The Ministry of Health shall promote the notification of as many private notified bodies as possible, ensuring full technical, operational and cost-competitive capacity in the national territory, in order to guarantee the interests of	Not accepted. The inclusion of wording regarding the promotion by the Ministry of Health of the notification of a greater number of notified bodies is not considered to be the subject of the Royal Decree and of this Article, given that the designation process is at European level, and this is established in the Regulation. Manufacturers may access the certification of their devices by any of the bodies designated for this purpose. As far as devices of Regulation 2017/745 are concerned, the 39 bodies already designated at present cover more than 80 % of the devices certified in accordance with the previous directives. In the case of IVD, there are 10 designated, based on the	SPANISH ASSOCIATION OF CERTIFIERS AND VERIFIERS OF CONFORMITY ASSESSMENT - ACERTES

	small and medium-sized enterprises in the sector; as well as a way to foster innovation in medical devices. The costs of the evaluation process incurred by the Ministry of Health for the notification process of the bodies to be notified may be passed on to the candidates to be notified through the corresponding fees, if the Ministry deems it necessary. 6. The Ministry of Health shall set up a coordination committee comprising the Ministry itself, the AEMPS, manufacturers and associations of representatives of potential bodies applying to initiate the notification process, representatives of the Autonomous Communities that wish to be involved and the national reference laboratories or candidates to be so or their sectoral representatives, which shall aim to 'exist at full technical and operational capacity so that any small and/or medium-sized enterprise receives a response in time, form and cost so that their certification needs are met as quickly as possible in the national territory, without affecting free competition with the notified bodies from other EU Member States.' 7. The Ministry of Health, through points 5 and 6, should also provide for the maximum technical and operational capacity in Spanish territory to meet the needs of certification that may arise in the face of future	information provided by the already designated bodies, which currently have the capacity and availability to accept applications for certification of IVD devices. It is important to note that the origin of the current situation of device certification and how it may affect the market is not only due to the capacity of the bodies, but also to the new requirements for the designation of notified bodies, that have prolonged the usual designation times, coupled with the increased requirements for manufacturers and therefore the certification times have also lengthened. That is why the situation will not be solved only by increasing the number of bodies, but requires lines of action at several levels, such as streamlining the processes of designation and re-designation of notified bodies, ensuring the creation and proper functioning of expert panels and reference laboratories, as well as the modification of the transitional periods of both regulations.	

	pandemics. In other words, strategic coordination will be established between the public sector (Central Administration and Autonomous Communities) and the private sector of both manufacturers and notified bodies or candidates for notification, in the face of the new challenges demanded by society. 8. The Ministry of Health shall establish a market surveillance coordination committee which will include the Ministry of Health, the Autonomous Communities concerned, manufacturers, national notified bodies and national reference laboratories and/or their sectoral representatives, which will assist and support the Ministry in its market surveillance work.	Likewise, it is not considered appropriate to include in a legislative text the creation of coordination committees with the functions indicated in the claim. There is already a Committee on medical devices, with representatives from various sectors, associations and patients, established with its functions in Royal Decree 1275/2011 of 16 September 2011 establishing the Spanish Agency of Medicines and Medical Devices and approving its Statute. In addition, there is also the Technical Inspection Committee with representatives of the AEMPS and the Autonomous Communities as competent authorities for market control.	
Article 13	It is proposed that in Article 13 of Chapter IV, Notified Bodies, the following points 5, 6, 7 and 8 be added to read as follows: 5. The Ministry of Health shall promote the notification of as many private notified bodies as possible, ensuring full technical, operational and cost-competitive capacity in the national territory, in order to guarantee the interests of small and medium-sized enterprises in the sector; as well as a way to foster innovation in medical devices. The costs of the evaluation process incurred by the Ministry of Health for the notification process of the bodies to be notified may be passed on to the candidates to be notified through the corresponding fees, if	Not accepted. The inclusion of wording regarding the promotion by the Ministry of Health of the notification of a greater number of notified bodies is not considered to be the subject of the Royal Decree and of this Article, given that the designation process is at European level, and this is established in the Regulation. Manufacturers may access the certification of their devices by any of the bodies designated for this purpose. As far as devices of	FELAB

	the Ministry deems it necessary. 6. The Ministry of Health shall set up a coordination committee comprising the Ministry itself, the AEMPS, manufacturers and associations of representatives of bodies that are potential candidates for initiating the notification process, representatives of the Autonomous Communities that so wish and national reference laboratories or candidates to be so or their sectoral representatives, which shall aim to ensure that 'there is full technical and operational capacity for any small and/or medium-sized enterprise to have a response in time, form and cost so that their certification needs are met as quickly as possible in the national territory, without affecting free competition with the notified bodies of the other EU Member States.' 7. The Ministry of Health, through points 5 and 6, should also provide for maximum technical and operational capacity in Spanish territory to address certification needs that may arise in the face of future pandemics. That is, strategic coordination will be established between the public sector (Central Administration and Autonomous Communities) and the private sector, both manufacturers and notified bodies or candidates for notification, in the face of the new challenges demanded by society. 8. The Ministry of Health shall establish a market surveillance coordination committee comprising the Ministry of Health, the Autonomous Communities concerned, manufacturers, national notified bodies and national reference laboratories and/or their	Regulation 2017/745 are concerned, the 39 bodies already designated at present cover more than 80 % of the devices certified in accordance with the previous directives. In the case of IVD, there are 10 designated, based on the information provided by the already designated bodies, which currently have the capacity and availability to accept applications for certification of IVD devices. It is important to note that the origin of the current situation of device certification and how it may affect the market is not only due to the capacity of the bodies, but also to the new requirements for the designation of notified bodies, that have prolonged the usual designation times, coupled with the increased requirements for manufacturers and therefore the certification times have also lengthened. That is why the situation will not be solved only by increasing the number of bodies, but requires lines of action at several levels, such as streamlining the processes of designation and re-designation of notified bodies, ensuring the creation and proper functioning of expert panels and reference laboratories, as well as the modification	

	sectoral representatives, which shall collaborate with and support the Ministry in its market surveillance work.	of the transitional periods of both regulations. Likewise, it is not considered appropriate to include in a legislative text the creation of coordination committees with the functions indicated in the claim. There is already a Committee on medical devices, with representatives from various sectors, associations and patients, established with its functions in Royal Decree 1275/2011 of 16 September 2011 establishing the Spanish Agency of Medicines and Medical Devices and approving its Statute. In addition, there is also the Technical Inspection Committee with representatives of the AEMPS and the Autonomous Communities as competent authorities for market control.	
Article 13	Article 13. *Notified bodies*. 1. The Ministry of Health is the authority responsible for notified bodies for the purposes of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. Clarify that these are the notified bodies established in the national territory.	Not accepted. The recitals state that this Royal Decree regulates the aspects that Regulation (EU) 2017/746, which is directly applicable, leaves to the regulation of each Member State. The wording of the Royal Decree as a whole refers to the national territory. '*While Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 is directly applicable in the countries of the*	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

		European Union, it is necessary to regulate at national level the aspects that the European standard leaves to the regulation of each Member State. To this end, this Royal Decree is approved, which specifies issues such as the determination of the competent authority for the purposes of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, the health guarantees for devices, the establishment of the language regime and the regulation of the procedures for the manufacture of devices for use in the health institution itself. With the entry into force of this Royal Decree, the previous legislation, namely Royal Decree 1662/2000 of 29 September 2000 on 'in vitro' diagnostic medical devices, will be repealed, with the exceptions set out in the transitional provisions and in the repealing provision of this norm.' It is not considered necessary to make such a clarification, as the designating authority may only designate bodies whose registered office is in its national territory. On the other hand, the wording follows the line of Royal Decree 192/2023.	
Article 14	(a) The Royal Decree states that the	Not accepted. The requirement refers	Spanish Association of

	documentation provided by the notified bodies must be written at least in Spanish, but we consider that English should also be included	to very specific documentation of the body and also indicates 'at least in Spanish', so the rest of the documentation can be provided in another language once agreed with the authority.	Industry Pharmacists AEFI
Article 14	(b) Conformity assessment certificates. These certificates should also be written in English. JUSTIFICATION: In order to make it easier for companies to trade their devices abroad, the documentation provided by notified bodies should also be provided in English.	Not accepted. The text of the Royal Decree establishes that they must be 'at least in Spanish', which does not prevent certificates from being issued in bilingual format or in another language. In fact, the certificates of the Spanish notified bodies are currently in two languages.	FENIN
Article 15	• Understanding that both the economic operators and the devices placed on the market should be registered, it is suggested that the structure and wording of this Article be reviewed in order to determine whether or not the recording or reporting of data to the Marketing Register is joint and the way in which the communication of devices is made, since it has only been indicated for the inclusion in the register of the economic operator. In this respect, it is recommended that paragraphs 1 and 2 be unified into one paragraph, containing the obligation to register and the devices to be placed on the market by electronic means. • Similarly, it is suggested to revise paragraph 3 to indicate who should report the change in data or the cessation of marketing.	Not accepted. It is proposed that the text be maintained in the same form as in Royal Decree 192/2023 of 21 March to align both Royal Decrees, which must be completely consistent, and to avoid discrepancies in interpretation. Not accepted. Paragraph 3 makes reference to paragraph 2. The economic operator is the owner and responsible for the communication and the only one authorised to modify it.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	• In paragraph 5 it would be advisable to specify the specific time limit for carrying out the update of data, if it relates to the calendar year or if it relates to the entry in the register of the economic operator or of each of the devices which the operator places on the market and, in any case, the period prior to that deadline for carrying out the update.	Not accepted. It is not considered appropriate to specify these aspects in a legislative text in the interests of flexibility for economic operators. The registry's own instructions shall indicate this once the development of the registry itself has been completed and the manner in which the least administrative burden is placed on the economic operator is established.	
Article 15	2. Article 15. Marketing Register This article mentions the Marketing Register, and among the data collected are: (f) Identification of the economic operator who supplied the device. (g) Identification of the economic operator, health institution or health professional to whom the device has been supplied From a personal data protection point of view, if contact details are recorded of natural persons representing economic operators, health institutions or simply by indicating that health professionals are identified, this same rule should have its own personal data protection section (definition of the processing of these personal data, the party responsible for the processing carried out on such data, etc.) In a document sent later (claim 6) they detail: In Article 15. Marketing Register	The claim concerns Article 16. Not accepted. The register itself shall include provisions to ensure data protection. Moreover, the general data protection legislation is fully in force, as specified in the preamble to the draft.	MINISTRY OF HEALTH - GENERAL SECRETARIAT FOR DIGITAL HEALTH, INFORMATION AND INNOVATION OF THE NATIONAL HEALTH SYSTEM

	This article mentions the Marketing Register, and among the data collected is '(a) Data identifying the economic operator making the communication.' From a personal data protection point of view, if contact details are recorded of natural persons representing economic operators, this same rule should have its own personal data protection section (definition of the processing of these personal data, the party responsible for the processing carried out on such data, etc.), or refer to where this register is regulated, if it already exists.		
Article 15 (and fifth transitional provision, first subparagraph)	In Article 15 (as well as in the fifth transitional provision, first paragraph), in order to restrict as much as possible the use of capital letters, it is suggested not to use them in the expression 'marketing register'.	Not accepted.	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID
Article 15	FOURTH. - Concerning Article 15(4). The definitions referred to in this draft indicate Article 2 thereof, which are those laid down in Article 2 of Regulation (EU) 2017/746. The aforementioned mandatory European standard does not cover what this draft calls points of sale exclusively serving the public for medical devices nor of medical devices for self-testing. Article 15(4) of the draft states '4. Pharmacies and any other points of sale exclusively serving the public are exempt from compliance with paragraphs 1 and 2.' Here again is a copy of the recent RD 192/2023, of 21 March 2023, on Medical	Not accepted. Article 15(4) refers to all *in vitro* diagnostic devices, not just devices for self-testing. This is why this type of device includes sample vessels or kits for self-sampling, which can be made available to the public through a different channel than pharmacies.	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA

	Devices. Article 2 refers to the definitions in Article 2 of the EU Regulation, which does not provide for the definition of points of sale exclusively serving the public. In the aforementioned RD 192/2023, which refers to a wide spectrum of medical devices, we can understand this inclusion, although it should have been defined, because in orthopaedics and optics medical devices are dispensed directly to the public, but in the draft of this Royal Decree, *in vitro* diagnostic medical devices are being regulated and in it as 'a point of sale exclusively serving the public' there can be none other than the pharmacy that, on the other hand, dispenses, it does not sell. What are the 'points of sale exclusively serving the public' for self-testing medical devices? This does not exist. It is not in the EU Regulation and if it were a national creation they should be defined and they would not comply with European regulations, obviously laboratories supply these devices just like distributors, and importing companies, but never the public, only community pharmacies dispense *in vitro* diagnostic medical devices to the public but other entities do not. This must be eliminated. And the manufacture in health institutions cannot be for sale to the public but for use within the institutions due to the particular conditions of the patient. Therefore, that concept must be deleted from this provision and from all those that refer to 'points of sale exclusively serving the public', so that it would read: Article 114. Pharmacies shall be		

	exempted from compliance with paragraphs 1 and 2.		
Article 15	(a) Paragraph 1. 'The Royal Decree establishes that any economic operator who markets products on Spanish territory must be included in the Marketing Register of the Spanish Agency for Medicines and Health Products. This registration must be made, prior to the marketing activity, through the authorised means of doing so in the website of the Spanish Agency of Medicines and Medical Devices.' We consider it necessary for the Royal Decree to reflect the interaction that will exist between the CCPS and RPS applications with EUDAMED. Whether these applications are expected to disappear or not, as well as a more detailed description of the responsibilities of each economic operator at both national and European level, as, for example, distributors are not registered in EUDAMED. (b) Point 2: 'Economic operators must inform the Marketing Register of the devices to be placed on the market...' We consider it necessary that the Royal Decree clarifies whether this communication affects all devices and not only those that involve the assessment by a notified body. Existing deadlines for communication and whether there is a possibility of an *ex post* notification indicating the date of first placing on the market should also be indicated. (c) Point 5: 'Economic operators shall, on an	a) Not accepted. The inclusion in a legislative text of the possible interaction between different registers is not considered appropriate. Similarly, a legislative text is not the appropriate instrument to clarify the existence of previous registers. This information will be detailed in the manuals for the use of the registers (b) Not accepted. Article 15 specifies which economic operators must communicate, when they must communicate, which are exempted from this communication and clearly refers to the fact that notification is mandatory for all devices placed on the market, regardless of their classification. The time limits are set out in Transitional Provision Five. (c) Partially accepted. It is not considered appropriate to provide in a legislative text an obligation of one month which may reduce flexibility when the register is still under development. However, the detailed procedure shall be established on the basis of the final design of the register	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI

	annual basis, update their communication to the Marketing Register, indicating the devices they continue to market' We see a need for clarification as to whether there will be a specific month for communication. On the other hand, we consider that it would be more useful for economic operators to report annually devices that have ceased to be placed on the market. The Royal Decree should indicate in which application this communication has to be carried out, whether it is CCPS or another.	and consideration shall be given to the possibility for economic operators to notify annually the devices that have ceased to be placed on the market and for the remainder to be maintained. -	
Article 15	Concerning Article 15(4). '*Marketing Register*'. ▪ Proposed wording: '*4.* '*Pharmacies ~~and any other points of sale exclusively serving the public~~ are exempt from compliance with paragraphs 1 and 2.*' ▪ Justification: As already explained in the general considerations, we understand that there is a problem with the indeterminacy of the concept '*any other points of sale exclusively serving the public*' referred to in the draft Royal Decree; this concept should be dispensed with. In this sense, we do not understand which point of sale exclusively serving the public, other than the pharmacy, should be exempted from a requirement provided for by the draft Royal Decree such as that of the Marketing Register. It should be borne in mind that, at present, pharmacies are the only establishments that are exempted from prior notification or	Not accepted. The draft Royal Decree regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including for example sample vessels that can be made available to the public through a channel other than pharmacies, so it is considered necessary to maintain these points of sale.	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	registration before starting their activity (Article 14 of the Royal Decree currently in force). In this regard, it should be borne in mind that pharmacies are already subject to a strict licensing regime, through which the authorities examine the requirements laid down by the legislation; that is to say, that they meet the material, technical and human requirements necessary for the proper performance of their functions, as provided for in Royal Decree 1277/2003 of 10 October 2003 laying down the general bases for the authorisation of health centres, services and establishments. In addition, the legislation (Law 16/1997, of April 25 1997, on the Regulation of Pharmacy Services) requires the constant presence of a pharmacist; so that while providing services to the public, a pharmacist must necessarily be present to supervise and take responsibility for all activities carried out, including those related to the devices subject to the draft Royal Decree. Therefore, we consider that pharmacies should be exempted from the controls established by the draft Royal Decree for other retailers who **do not have this own authorisation scheme.** Therefore, we propose deleting the reference to 'points of sale exclusively serving the public' in order to exempt them from any obligation established for pharmacies, since the fact that they sell only to the public does not make them comparable to pharmacies, which are health establishments subject to approval and		

	supervision by the corresponding authorities.		
Article 15	Article 15. *Marketing Register*. 1. Any economic operator who markets products in Spanish territory must be included in the Marketing Register of the Spanish Agency for Medicines and Health Products. This registration must be made, prior to the marketing activity, through the authorised means of doing so in the website of the Spanish Agency of Medicines and Medical Devices. The AEMPS reported that only those IVD devices that were reviewed by notified bodies required notification, which in the case of the Regulation would be classes B, C and D. The new Royal Decree does not mention this, but it seems that all the devices are included in said notification. In addition, it is necessary to clarify what type of economic operator is a diagnostic laboratory that designs, develops and 'sells' genetic tests to the public, whether it is a manufacturer or a distributor. Also 5. Economic operators shall, on an annual basis, update their communication to the Marketing Register indicating the devices they continue to market. Failure to update the communication will result in the withdrawal of the devices and the economic operator from the Marketing Register. To this end, it is necessary that the AEMPS Marketing Register informs economic operators annually, in good time before the expiry of their	The communication published by the AEMPS refers to the actions to be carried out during the process of implementing Regulation EU 2017/746, until EUDAMED and the new national application of the Marketing Register are operational. With regard to the need to clarify what type of economic operator is a diagnostic laboratory that designs, develops and 'sells' genetic tests to the public, Not accepted. Each economic operator is identified and their responsibilities defined in Regulation (EU) 2017/746. In the same way, the complementary requirements of the national legislation are included in this Royal Decree. Thus, a laboratory will be considered differently, depending on the activities it performs. With regard to the annual updating of communications in the register, economic operators shall be duly informed in accordance with the instructions of the register itself.	

	respective notifications. It is necessary to establish whether, in order to 'sell' those genetic tests, they must be included in the Agency's Marketing Register.		
Article 15	Art 5. 5. Economic operators shall, on an annual basis, update their communication to the Marketing Register indicating the devices they continue to market. Failure to update the communication will result in the withdrawal of the devices and the economic operator from the Marketing Register. This requires that the AEMPS Marketing Register informs economic operators annually, in good time, of the deadlines for their respective communications.	It is not considered a claim on the text. Economic operators should be aware of the requirements and obligations of the legislation that applies to them. However, as regards the annual update of notifications in the register, economic operators shall be duly informed in accordance with the instructions of the register itself.	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO
Article 15	Article 15(2)(d) Taking into account the European register of devices and economic operators provided for in the Regulation in the EUDAMED database, requiring the registration of devices and the companies that distribute them in the AEMPS Marketing Register and distributors in the Autonomous Communities, entails a very significant workload and time burden for companies, in addition to the payment of additional fees required by all these registrations that are not necessary since EUDAMED provides this information, guaranteeing transparency and access to data for the population and health professionals, avoiding precisely the multiplication of registration requirements that may be established by the different Member States in their territories.	Not accepted. This wording is in line with that included and published in Royal Decree 192/2023 on medical devices. As indicated above, this requirement is included, not only for market control reasons, but in order to improve transparency and ensure the information available to patients, professionals and users. It will be information similar to that provided from CIMA regarding medicines. On the other hand, the design of the register has been carried out so that the information is downloaded from EUDAMED and only the data of the agent who markets the device in Spain and the instructions and labelling with	FENIN

	There should be a direct communication or connection between the data recorded in EUDAMED and the AEMPS. With the latter being responsible for forwarding the information to the respective Autonomous Communities. In this way, the increase in fees would be avoided, together with the burden of additional work that would be entailed by the double recording of data. In the same way and as mentioned in the economic report, in case of maintaining this register, it would be essential that it be connected to EUDAMED to avoid duplicating the work and companies having to upload the same information that is already available in the European database, so that the information available in EUDAMED can be fully traced with the information included in these marketing registers. Finally, we suggest evaluating the elimination of fees in this registry, both the initial rate and the maintenance rate. JUSTIFICATION: We insist again on the elimination of this requirement and in any case, that reference can be made to the website where the company has uploaded this information that is also always updated. We consider that this information should not be included in the database, both because of the workload it entails for companies, given the expansion of the database proposed in this	which it does so have to be specified. The possibility that certain types of devices can be included through a link will be considered.	

	project, and because of the capacity of the database itself. We understand that the AEMPS will not be able to review this information as it goes up, but that the review of the devices will be carried out by the AEMPS through annual market control campaigns where the conformity of the device with all the requirements of the legislation on medical devices will be reviewed including the verification that the notification of placing on the market has been made and that said notification is correct. We therefore understand that it is at that time or in situations of risk to the safety or health of patients, that the AEMPS can request from the companies the labelling and instructions for use of the affected devices.		
Article 15	Article 15(2)(e) Amend to read (e) Date planned on which marketing begins in Spain. Justification As set out in paragraph 1, the registration must be carried out prior to the marketing activity, so it is not easy to estimate the actual date on which the marketing begins in Spain and it should be indicated the expected date on which the marketing begins in Spain. The notification of placing on the market is a necessary requirement to carry out certain procedures before marketing a device in Spain, such as the application for authorisation to advertise a device, the inclusion in the bank of devices of the Andalusian Health Service and	Not accepted. The date of marketing, in many cases, will refer to devices that are already being marketed in Spain and have been for a long time; for new devices, the relevant information at the legal level is the date on which the marketing begins not the forecast.	FENIN

	application for the parapharmacy code. It is therefore important that the registration be prior to the marketing activity and that the expected date of placing on the market is indicated which, on the other hand, could subsequently be corrected in the annual update of the register for any errors that may occur on that date.		
Article 15	Article 15(3) Any modification of the data indicated in the previous section of this Article, as well as the definitive cessation of placing on the market, shall be notified to the register. We consider that the wording should be qualified and include the definitive cessation of the marketing of the device and, in this way, it would be clear that it does not apply to the temporary cessation of marketing of a device due to lack of stock or temporary shortage of devices.	Not accepted. The wording already approved for the same requirement in Royal Decree 1591/2023 is followed. The text makes it clear that it is a cessation of marketing at the decision of the economic operator. If the device is temporarily not placed on the market for reasons beyond the control of the economic operator, this is not a cessation of the activity itself.	FENIN
Article 15	Art 15.5. Economic operators shall, on an annual basis, update their communication to the Marketing Register. indicating the devices which are no longer on the market. JUSTIFICATION: We consider that it is not necessary to make this annual review since, according to paragraph 3, any modification of the data in the communication, as well as the cessation of marketing must be updated in the register. On the other hand, this annual update is a very significant workload for companies due to the large number of notifications that a company may have and the annual cost in fees for this update greatly exceeds the cost that notification of placing medical devices on the	The possibility for the update to be limited to devices which the economic operator does not intend to continue to place on the market is partially accepted. Regarding the rates, discounts have been included based on the number of UDIs marketed both in the initial notification and in the maintenance. In addition, the modification fee has been eliminated, as well as the initial fee for those devices notified to the old registry based on the previous legislation.	FENIN

	market currently has for a company. In the event that the annual review is maintained, we consider that, following the approach of the registration of medicines, the update should be done through a responsible declaration by the company, indicating that all the notifications it has registered are up to date, instead of having to update them one by one. If the update has to be done one by one, we propose that the economic operator should indicate the devices that are no longer marketed instead of those that continue to be marketed, which would mean less work for the economic operators. Comment. It is not indicated when the update of the communication should be done, i.e. if it is always the same month, for example, during the month of December, or if it refers to when one year has passed since the product was notified to the register. In the latter case, would it be possible for the AEMPS Marketing Register to inform economic operators annually, in due time, of the expiry dates of their respective notifications and the need to update them?		
Article 16	• In paragraph 1(c), it is recommended that the acronyms used to refer to the device identifier be reviewed. • In accordance with paragraphs 3 and 4, the distribution activity is subject to a prior notification of commencement of activity to the competent authority of the	They have been checked. The acronyms are correct. It's not the same acronym. One is UDI-DI and the exception is UDI. Not accepted. These communications are not the same. The one made to the	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	Autonomous Community and a communication to the Marketing Register provided for in Article 15, it is therefore recommended that the report of the regulatory impact analysis justifies the appropriateness of maintaining both obligations for the same activity.	Autonomous Communities is with regard to the facility and location of the distributor and its warehouses, which is the responsibility of the Autonomous Communities. The communication to the Marketing Register is from the agent and the devices. It is important to highlight here, regarding the marketing register, that the economic operator can be located in Spain, in Europe or even in a third country.	
	• In accordance with the provisions of Article 3(5) of the recast text of the Law on guarantees and rational use of medicinal products and medical devices 'Health administrations may, for reasons of public health or safety of persons, limit, condition or prohibit the doorstep sale and any type of indirect sale to the public of medical devices'. On the one hand, in the proposed paragraph 6, the reason for 'safety of persons', which is included in the recast text, has been disregarded. On the other hand, the power provided for in a rule with the rank of law referring to the health authorities has been directly attributed to the Spanish Agency of Medicines and Medical Devices, insofar as the establishment of specific conditions of sale implies a limitation on sale. Therefore, it would be advisable to justify appropriately in the report of the regulatory	Accepted Accepted. Text included in Regulatory Impact Analysis Report	

	impact analysis such attribution.		
Article 16	(a) Point 2: 'Pharmacies and any other points of sale exclusively serving the public shall maintain a documented record of the devices they make available in Spanish territory, containing at least the data included in paragraph 1(a), (e) and (f)' The Royal Decree should explain how this registration is going to be carried out by pharmacies or if any other document is going to be published in which it is explained	Not accepted. The Royal Decree establishes the obligation for pharmacies and points of sale to have this traceability register that is specific to each pharmacy or point of sale. This is not a centralised register. All points of direct sale to the public should keep a documented record of the devices they make available in order to ensure the traceability of the devices.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
Article 16	Concerning paragraph 2 of Article 16. '*Device identification and traceability.*' ▪ Proposed wording: '*Pharmacies ~~and any other points of sale exclusively serving the public~~ shall maintain a documented record of the devices they make available in Spanish territory, containing at least the data included in paragraph 1(a), (e) and (f).*' Justification: For the reasons set out in the previous Consideration, we consider it necessary to remove 'points of sale exclusively serving the public' from the regime provided for pharmacies in paragraph 2.	Not accepted. The RD regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels that can be made available to the public through a channel other than pharmacies. All points of direct sale to the public should keep a documented record of the devices they make available in order to ensure the traceability of the devices.	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF
Article 16	FIFTH.- Concerning Article 16(2). It states that: Pharmacies and any other points of sale exclusively serving the public shall maintain a documented record of the devices they make available in Spanish territory, containing at least	Not accepted. The RD regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels or kits for self-sampling, which can be made available	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA

	the	to the public through a channel other than pharmacies.	
Article 17	It should be clarified how to comply with the requirements set out in Article 16(4) of Regulation (EU) 2017/746 and in which cases it would apply as set out in Article 16(2).	Not accepted. The cases in which it applies are established by Regulation 2017/746 itself. Companies, by the regulation itself, are already obliged to notify the Agency. However, in order to provide more legal guarantees, this wording has been included in the Royal Decree and the Agency is developing instructions to assist and facilitate importers and distributors in their notifications.	FENIN
Article 17	Article 17(a) Present in Spanish and/or in English, upon a reasoned request from the health authorities, all information JUSTIFICATION: Economic operators should be allowed to send documentation to the health authorities in Spanish or English. Many companies have this information only in English and by default the authority should accept this information in English and even in other languages.	Not accepted. The Regulation empowers the Member States to establish linguistic requirements and in order to properly evaluate the documentation provided, so it is necessary to present this documentation in Spanish. However, as is currently the case, since it is not a new requirement, the AEMPS will be able to accept the submission of supporting documentation in other languages.	FENIN

Article 18	(b) Attend immediately to the measures issued by the health authorities in the event of non-compliance or infringements, when a device does not bear the CE marking contrary to the provisions of the regulation on *in vitro* diagnostic medical devices, or when it is found to have been improperly affixed, or in cases of non-conformity. Justification: It is proposed that the wording be completed by including '*in vitro* diagnostic medical devices'	Accepted. The text is amended.	FENIN
Article 18	2. Importers and distributors shall ensure that, at the time of entry into service, the device is accompanied by the data and information specified in Article 5(2), both on the labelling and in the instructions for use, and as laid down in that Article. JUSTIFICATION: We propose amending the text to use the same wording as in Royal Decree 192/2023 on medical devices.	Accepted	FENIN
Article 18	4. In the event that a manufacturer established in Spain has been declared bankrupt or has ceased its activity, it shall keep at the disposal of the relevant competent authorities, for a period of at least ten years after the last device has been placed on the market, the documentation referred to in Annexes IX, X, XI and XIII of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. Justification: We consider it necessary to clarify that this is a requirement that applies only to	Accepted.	FENIN

	manufacturers established in Spain.		
Article 18	SIXTH.- Concerning Article 18(1)(c). That cited states (c) Meet the costs of verifying the non-conformity of a device by the health authorities, where the latter requires evaluations or tests on the device or its technical documentation, with the exception of pharmacies and any other points of sale exclusively serving the public. For the same reasons as those set out in the fourth claim, the reference to 'and any other points of sale exclusively serving the public' must be deleted from that provision.	Not accepted. The RD regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels or kits for self-sampling, which can be made available to the public through a channel other than pharmacies.	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA
Article 18	SEVENTH.- Concerning Article 18(3). The importer and the distributor shall ensure, with the exception of pharmacies and any other points of sale exclusively serving the public, that the notification obligations laid down in Article 82 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 are complied with and, if necessary, they shall inform the Spanish Agency of Medicines and Medical Devices. For the same reasons as those set out in the fourth claim, the reference to 'and any other points of sale exclusively serving the public' must be deleted from that provision.	Not accepted. The RD regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels or kits for self-sampling, which can be made available to the public through a channel other than pharmacies.	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA
Article 19	Article 19(7) of the draft Royal Decree provides: 'Devices for self-testing shall be sold to the public exclusively through pharmacies or through the website of the pharmacy itself.'17. According to the Regulatory Impact Analysis Report, this measure is justified in that it is considered that the intervention of the	Not accepted. The text of the Royal Decree has included an important innovation by eliminating the need for medical prescription for all devices for self-testing. This measure has a direct impact on the consumer as it facilitates access to the test for the lay person to	NATIONAL COMMISSION FOR MARKETS AND COMPETITION

	pharmacist when informing the patient of how to handle the test and how to interpret the results is essential and in that the pharmacy, being a health establishment, guarantees adequate conditions of preservation and traceability of the device. However, in the view of this Commission, both reasons are questionable as justification for this reserved activity: With regard to consumer information, in devices sold without a medical prescription, advice at the point of sale is not an indispensable condition for the proper supply to the public: in practice, the dispensing of this class of devices in pharmacies takes place without any kind of advice, which only takes place when the customer expressly requests it. In addition, for these devices, the regulations require that the devices contain in the package leaflet all the necessary and sufficient information in an understandable manner for their correct use and interpretation. In any case, in a 'liberalised' system, in which devices for self-testing can be dispensed both in pharmacy establishments and in other types of establishments, the possibility for the consumer to obtain qualified information from a practitioner would be guaranteed, since the consumer would always have the option of going to the pharmacy to purchase the devices. Regarding the conditions of preservation and traceability, these can be replicated in other	whom it is addressed. However, it should be remembered that it is a medical device for the diagnosis of a disease and therefore aspects such as the conditions of preservation of the device at the point of sale, the guarantees of traceability and, most importantly, the advice of the pharmacist during dispensing of the device make it important to maintain the requirement that these devices for self-testing continue to be sold in pharmacies. Finally, if we refer to the recent COVID-19 pandemic mentioned in the claim, the provision of this type of test in pharmacies with the corresponding information and advice from the health professional was of great relevance for the correct use and interpretation of the tests.	

	commercial establishments. For example, commercial distribution establishments or grocery shops are also subject to strict health requirements to ensure preservation and hygiene. And traceability and post-market monitoring measures can be ensured by measures taken on manufacturers and importers (e.g. licensing obligations and prior communication to health authorities, having a competent technician, complying with regulatory requirements for the preservation of devices, providing information and undergoing inspection and surveillance by health authorities). It would therefore not be a question of jeopardising the traceability and proper use of the devices, but of allowing a wide range of establishments capable of meeting those conditions, with non-discriminatory treatment between the different operators. In fact, other countries around us, such as Germany, France or Italy, have opted not to establish this reservation to pharmacies. It should be noted that the effects of the different intervention models have recently been verified during the dispensing of COVID-19 self-testing kits. While in Spain it was necessary to establish a maximum price for the dispensing of these devices, in order to compensate for the lack of competition due to the reservation of dispensing, in Germany or France, where there was no reservation of dispensing to pharmacies, the prices of the same tests were much lower18.		

	In the light of the above, the Commission recommends that this measure be reconsidered in order to open up the marketing of these devices to all sales channels, face-to-face and online, that meet the required conditions19.		
Article 19	In Article 19(5), in accordance with Guideline 32, it is suggested not to use indentation in the enumeration contained in that Article. With regard to Articles 19(7) and (8) of the draft, which refer to 'distribution and sale', a new wording of paragraph 8 is suggested since, if the current proposal is maintained, it could lead to confusion by implying that any non-health establishment may have one of these vending machines, when in reality we understand that this possibility is only contemplated for pharmacies. In addition, the second paragraph of Article 19(9) of the draft refers to 'health establishments'. This generic mention includes, in accordance with the provisions of Royal Decree 1277/2003 of 10 October, which establishes the general bases on the authorisation of health institutions, services and establishments, pharmacies, dispensaries, opticians, orthopaedics, hearing aid establishments; if the rule is intended to be limited to pharmacies and dispensaries, this should be stated	Accepted Not accepted. Article 19(7) refers to devices for self-testing and the restriction of sales only in pharmacies or on their websites. Paragraph 8 on the sale in vending machines refers to the sale of *in vitro* diagnostic devices in general, except prescription and devices for self-testing. Vending machines may therefore be in pharmacies or other locations. Paragraph 9, when indicating health establishments, does not refer only to pharmacies and dispensaries, it refers to all health establishments that can sell *in vitro* diagnostic devices to the public for use by health professionals, always after verification of the prescription. Accepted. The second paragraph is deleted.	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID

	expressly. In that same point, it is confusing to say that health establishments may sell to the public 'the devices indicated in the previous paragraph' (we understand that it refers to goods for professional use) provided that they are backed by a prescription; it is not clear what devices, intended for use exclusively by professionals, may be necessary for the general public, even if they are dispensed under the prescription of a doctor, unless it is an exceptional situation, in which case this should be indicated.		
Article 19	(a) In general, it is understood that it would be more appropriate for the different paragraphs to refer to the expression 'distribution and/or sale', to clarify that it refers to cases where these activities are carried out separately or jointly. (b) Paragraph 1. This paragraph refers to Regulation (EU) 2017/746, and it should refer to the recent Regulation 2023/607 amending transitional periods MDR and IVDR regulations, since the settlement period for the marketing of devices in the distribution channel is eliminated, and devices lawfully placed on the market with IVDD before 26 May 2022 and devices lawfully placed on the market from 26 May 2022 under	Not accepted. The use 'and/or' is not correct; 'and' is correct when both possibilities are given. (b) Not accepted. The reference to Regulation 2017/746 includes subsequent amendments to its transitional periods. Therefore, these devices that have been placed on the market in accordance with the previous directives based on the provisions of Article 110 of Regulation 2017/746, will also comply with the provisions of the	ANDALUSIA

	the transitional periods of IVDR can continue to be marketed without a time limit.	aforementioned regulation.	
Article 19	Concerning Article 19*.* '*Distribution and sale*'. ▪ Proposed wording**:** *1. Only devices complying with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and this Royal Decree, and which are not expired, may be distributed and sold.* *2. The distribution and sale of the devices shall be carried out in such a way as to ensure the proper storage and preservation of the devices. Distribution and sales activities shall be subject to surveillance and inspection by the health authorities of the autonomous community concerned.* *3. Distributors and natural or legal persons engaged in the sales activity must make prior notification of the start of business to the health authority of the Autonomous Community where the company's registered office is located, as well as to the health authority of the Community where the warehouse or warehouses are located, in the case where they are not in the same community, which shall contain:* *(a) Identification of the establishment of distribution or sale, where applicable.* *(b) The types of devices it distributes or sells.* *(c) The identification and qualification of the technical manager, in accordance with*	Paragraph 4. Not accepted. As indicated above, the Royal Decree regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels or kits for self-sampling, which can be made available to the public through a channel other than pharmacies. That is why, although both are considered distributors based on the new definition of Regulation 2017/746, at the national level this exception of notification of registration applies to both pharmacies and points of sale. Paragraph 6. Not accepted. For reasons of public health, it may be necessary to establish specific conditions of sale for devices not subject to prescription. Paragraph 7. Not accepted. The intervention of a pharmacist and the corresponding personalised advice are activities already required within the activity of the pharmacy and its pharmacist. New paragraph 9. Not accepted. It is not the purpose of this Royal Decree to determine where the financed devices are sold.	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	Article 20(2), where applicable. *Exempted from making such a declaration of activity of sale to the public are pharmacies.* *4. Distributors shall communicate to the Marketing Register in accordance with Article 15, with the exception of pharmacies ~~and any other points of sale exclusively serving the public~~.* *5. According to Article 3(5) of the revised text of the Law on guarantees and rational use of medicinal products and medical devices, the sale to the public by mail order and telematic procedures of medical devices subject to prescription is prohibited.* *For the purposes of this Royal Decree, devices subject to prescription are:* *(a) Those financed by the National Health System.* *(b) Those intended to be used or applied exclusively by health professionals.* *(c) Human genetic tests.* *6. The Spanish Agency of Medicines and Medical Devices may, for reasons of public health, establish by resolution specific conditions of sale to the public by mail order and by telematic procedures of certain devices* ***not subject to prescription****.* *7. The sale to the public of devices for self-testing shall be carried out exclusively through*	New paragraph 10. Accepted. The second paragraph is deleted.	

	*pharmacies or through the website of the pharmacy itself**, with the intervention of a pharmacist and the corresponding personalised advice***. *8. The sale may be made through vending machines designed for this purpose, provided that the integrity and safety of the device is not impaired, except in the cases of prescription devices and devices for self-testing.* ***9. The sale to the public of devices financed by the National Health System will be made exclusively through pharmacies.*** *10. The sale to the public of devices intended to be used or applied exclusively by health professionals shall be prohibited* ***.*** *~~Health establishments~~* ***Pharmacies****, within the scope of their competences, may carry out the sale to the public of the devices indicated in the previous paragraph, after verification of the corresponding prescription.* ***When a device is intended to be used or applied exclusively by health professionals, this must be clearly and visibly indicated on its labelling, and must be recorded in the Marketing Register provided for in Article 16 of this Royal Decree.*** *11. The street sale of in vitro diagnostic medical devices shall be prohibited.*		

	▪ **Justification:** With respect to Article 19 of the draft Royal Decree, it regulates the sale to the public, this being one of the most relevant points of the norm. As this General Council will propose different modifications in different paragraphs, we will address them in an orderly manner by paragraph. **Paragraph 4.** First, the fourth paragraph again reflects the exception for 'points of sale exclusively serving the public' already addressed in the Consideration concerning Article 15. In so far as that provision has already been analysed in that Consideration, we refer to it in order to suggest that the exception to those points should be deleted, in order to be entered in the Marketing Register. **Paragraph 5.** On the other hand, and now turning to the devices subject to prescription, this General Council appreciates the new wording, which more effectively delimits which devices are subject to prescription, allowing greater flexibility for the rest. This will allow, with respect to the current regime (Article 13 of the Royal Decree in force), devices that are not for self-testing to be subject		

	to prescription, while those for self-testing will be sold in pharmacies, with the population being able to access these devices without the need for a prescription; this is now only allowed for a few exceptions (COVID-19, blood glucose, etc.). It should be recalled, in this regard, that an amendment to the Royal Decree in force was necessary in order to make COVID-19 self-testing kits accessible in 2021. **Paragraph 6.** We are also very positive that the draft Royal Decree reflects the prohibition contained in Article 3(5) of the Law on Guarantees on devices subject to prescription. However, with regard to the paragraph in the sixth section - which provides that the AEMPS may, for reasons of public health, establish by resolution specific conditions for sale to the public by mail order and by telematic procedures of certain devices, we consider it necessary to clarify that these 'specific conditions' can only be agreed with respect to devices not subject to prescription. This clarification would eliminate a wording that is certainly ambiguous, and which could be interpreted as providing by means of a regulatory norm for a qualification to the legal norm (Article 3(5) of the Law on Guarantees), which decided to prohibit this practice without		

	qualification. Something that would violate the principle of hierarchy and that would entail the illegality of Article 19(6) of the draft Royal Decree. **Paragraph 7.** In relation to the seventh paragraph, and as stated in the General Considerations, we consider it absolutely necessary to maintain the dispensing of devices for self-testing to be reserved to pharmacies, thus guaranteeing safe access to such devices by the population with the intervention of a health professional. However, the new wording omits an absolutely essential point of the current regime, which is contained in Article 13(7) of the current Royal Decree and which requires that the distance sale of these devices by pharmacies takes place with '*the intervention of a pharmacist and the corresponding advice, for devices for which a prescription is not necessary*'. This provision is of the utmost importance, since it is one of the reasons why the sale of these devices should be reserved for pharmacies; which is none other than the presence of the pharmacist, a health professional who advises the patient not only on the correct use of the device, but also on the proper management and interpretation of the results. Therefore, we consider it strictly necessary to		

	reintroduce this provision, so as to ensure that the dispensing by pharmacies, either face-to-face or through telematic means, is always accompanied by personalised advice from the pharmacist, which is essential for the safe use of these devices. **New paragraph 9.** The draft Royal Decree, although it provides that the devices financed by the National Health System will be subject to prescription, does not regulate the channels through which such sale will take place, something that generates some uncertainty, since while the financed health devices can only be sold to the public in pharmacies taking into account Royal Decree 9/1996, of 15 January, regulating the selection of effects and accessories, their financing with Social Security funds or State funds assigned to health and their regime of supply and dispensing to non-hospitalised patients, (Article 4), this is not clear in the draft Royal Decree for these devices. Thus, the dispensing of these financed devices, when they are included in the pharmaceutical provision regulated in Article 16 of Law 16/2003, of 28 May, on the cohesion and quality of the National Health System, must be carried out through pharmacies, which this Law identifies as collaborators of the National Health		

	System in the performance of pharmaceutical provision, facilitating the management of this provision to the National Health System and guaranteeing its accessibility throughout the national territory, in conditions of equity for patients. For all these reasons, we propose that the reservation of the dispensation to the public of devices financed by the National Health System to pharmacies should be reflected. **New paragraph 10** Paragraph 10 (paragraph 9 in the original wording of the draft Royal Decree) regulates the sale of devices for professional use, which is restricted to health establishments. However, and in line with the arguments made regarding devices for self-testing, we consider that the making available to the public of these devices requires the intervention of a pharmacist, given the consequences that a misuse of them can have for the health of the patient and for community health. In this sense, taking into account the functions of the other health establishments (regulated in Annex II of Royal Decree 1277/2003), none of the other establishments meets the requirements for the safe dispensing of these devices; it would make no sense for opticians or hearing aid establishments to become points of		

	sale for these devices. We therefore propose that the wording be amended so that the dispensing of devices for professional use is **limited to pharmacies**, instead of health establishments as a whole. On the other hand, we consider that to ensure that such dispensing takes place under these guarantees, it is essential that both the labelling and the Marketing Register reflect the professional use of the device. It should be borne in mind that, if this were not the case, the pharmacist would have no way of knowing, except by deduction, which devices are for professional use - and require a prescription. Therefore, we suggest incorporating this obligation, providing sufficient legal certainty to the dispensing of these devices.		
Article 19	Art 19.7. 1) The requirement to sell these devices in pharmacies or through the website of the pharmacy itself is justified in the Regulatory Impact Analysis Report because it is considered that the intervention of the pharmacist is essential since during the dispensation they can inform the patient of the correct handling of the test and the sample, as	Not accepted. The text of the Royal Decree has included an important innovation by eliminating the need for medical prescription for all devices for self-testing. This measure has a direct impact on the consumer as it facilitates access to the test for the lay person to whom it is addressed. However, it should be remembered that it is a medical device for the diagnosis of a	MINISTRY OF ECONOMIC AFFAIRS AND DIGITAL TRANSFORMATION

	well as how to interpret the result. However, it is considered that the text should provide that some non-prescription devices for self-testing can be sold to the public outside the scope of the pharmacy. This would promote more competition which would have a positive impact on the consumer in terms of availability and price. Likewise, this could be extended to situations in which, for reasons of public health, greater access and availability to the population is considered appropriate. It should be noted that, as indicated by the definition itself set out in Regulation (EU) 2017/746, devices for self-testing are intended by the manufacturer to be used by lay persons1. It is understood that there could be devices for which such intervention is not required. For example, in France, Law No 2014-344 of 17 March 2014 on consumption2 provides that pregnancy and ovulation tests are not subject to exclusive sale in pharmacies. 2) The draft Royal Decree specifies the obligation to sell these devices in pharmacies, but does not say anything about the requirement for pharmacists to be present and act in a professional capacity when dispensing them. This requirement should be	disease and therefore aspects such as the conditions of preservation of the device at the point of sale, the guarantees of traceability and, most importantly, the advice of the pharmacist during dispensing of the device make it important to maintain the requirement that, in Spain, these devices for self-testing continue to be sold in pharmacies. On the other hand, this Royal Decree does not regulate the responsibilities and obligations of pharmacists in the pharmacy. This is already regulated in the state regulation of health	

	included in the text as it is the main justification why these devices are sold exclusively in pharmacies. Similarly, for consistency, telematic sales procedures should include measures to ensure that such intervention and pharmaceutical advice occurs, beyond simply indicating that the sale will be through the website of the pharmacy itself.	establishments and in the development of those regulations in the regional regulations.	
Article 19	Art 19(3) It is requested that 'Distributors and natural or legal persons engaged in the sales activity...' be replaced by the following 'Distributors...' . In other words, it is proposed that natural or legal persons engaged in the sales activity be excluded from the obligation to make a prior notification of the start of activity to the health authority of the corresponding Autonomous Community. Justification: From experience in the application of this requirement, which was already included in Royal Decree 1662/2000, we have found that it is not possible to maintain a properly updated register of sales establishments in a way that is useful for the health administration which is assigned the responsibility of creating and maintaining it. In addition, we consider that the administrative effort involved in maintaining this register in relation to the usefulness it may have, is not justified with the resources currently available. If the objective pursued by the obligation to communicate the activity is to identify the sales establishments to be able to	Not accepted. This text is in line with the previous regulation and has been maintained in the recently approved Royal Decree 192/2023. This register is important to be able to carry out the market control tasks that both the Agency and the Autonomous Communities are obliged to carry out to guarantee the safety of patients and users.	CATALONIA

	contact them in the case of device recalls, we consider that this objective can be achieved more easily and effectively through the company that manufactures or distributes it, due to its obligation to maintain the traceability of the devices it distributes.		
Article 19	Article 19(6) and 19(8) It is proposed that these points be drafted in such a way as to prohibit the sale to the public of *in vitro* diagnostic devices by mail order, by telematic means or through vending machines. Justification: Given the characteristics and purpose of *in vitro* diagnostic medical devices, it does not seem plausible or reasonable that these devices are sold or can be sold to the public by these means. In addition, it should be borne in mind that *in vitro* diagnostic medical devices for self-testing, where sale to the public is possible and reasonable, can only be sold in pharmacies and their sale through vending machines is prohibited, as stated in the proposed wording of Article 19(8).	Not accepted. In the case of Class A devices, such as sampling containers, they could be sold to the general public by other means such as the internet or vending machines.	CATALONIA
Article 19	In view of the drafting of the NEW DRAFT ROYAL DECREE FOR *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES, we would like to contribute the following reflection where we consider that this new draft should address and eliminate any hint of doubt, because today online platforms such as Amazon, or the pharmacies on their own websites, are selling self-testing kits to detect lack of vitamin D, lack of iron, urine infections, and similar.	Partially accepted. The text is amended to indicate that the sale has to be **directly** from the pharmacy's own website **without the intervention of intermediaries**.	HEFAME

	As you know, self-testing kits are *in vitro* diagnostic medical devices. To be marketed in Spain, they must comply with the requirements established in Royal Decree 1662/2000 of 29 September 2000. In Spain, in accordance with Article 13(4) and (6) of Royal Decree 1662/2000, the sale to the public of devices for self-testing will be carried out **exclusively through pharmacies.** According to Article 13(7) of Royal Decree 1662/2000, 'it remains **banned** to make sales of devices for self-testing to the public by mail order or **telematic procedures**. However, this method may be carried out by pharmacies, with the intervention of a pharmacist and the corresponding advice, for devices for which a prescription is not necessary.' (The prescription is not necessary in the cases referred to in paragraph 6 ', this prescription shall not be required for devices for the diagnosis of pregnancy and fertility, as well as for devices for self-testing for the determination of blood glucose, for the detection of HIV and for the detection of COVID-19'). Therefore, in the case of self-testing kits, the sale to the public will be made exclusively through the pharmacies, allowing both face-to-face or online sales through the pharmacy's website, as long as the person responsible for		

	the sale and supply is the pharmacist. Based on the above, a pharmacy could sell a self-testing kit provided for in Article 13(6) through a Marketplace as is the case with the Amazon platform, as long as the device is **supplied directly from the pharmacy** to the end user and no medical prescription is required. The person responsible for the **sale and supply** of it must be a pharmacist through their pharmacy, which must be correctly identified in the data included in that platform. If a medical prescription is needed, it cannot be sold online on any type of platform. And this should be included in the infractions to prevent pharmacists who today are not being inspected and their websites are not calling attention to it. There are no statements by any College of Pharmacists, nor even when asked the question do they know how to give an answer, because it is all very ambiguous.		
Article 19	With regard to Article 19(9), which is set out below, it seems to us to be worded confusingly: *9. The sale to the public of devices intended to be used or applied exclusively by health professionals shall be prohibited.* *Health establishments, within the scope of their competence, may sell to the public the devices referred to in the preceding paragraph, subject to verification of the corresponding prescription.*	Partially accepted. The text is amended to clarify the wording. The second paragraph of point 9 which reads 'previous paragraph' refers to the first paragraph of that point. If a reference had been made to a paragraph in point 8, a reference would have been made to point 8. Point 9 is accepted and the second paragraph is deleted.	SPANISH SOCIETY OF PRIMARY CARE PHARMACISTS SEFAP

	We believe that it should be clarified: it is not clear whether the 'previous paragraph' mentioned is that of point 9 or refers to point 8. Whichever one it refers to seems contradictory to us: - If you allow the sale to the public of devices intended to be used or applied exclusively by health professionals, it makes no sense and we oppose it. - If it allows the sale to the public in health institutions through vending machines designed for this purpose, except in the cases of devices **subject to prescription and devices for self-testing,** it makes no sense to indicate 'subject to verification of the corresponding prescription' - similarly, we believe that setting the precedent for a prescribing centre to become a dispensing centre generates a conflict of interest that is difficult to handle legally, which may have an impact on the free choice of patients, taking into account that it also does not exclude publicly owned or subsidised centres. We fail to see what advantages this would offer.		
Article 19	Concerning Article 19. 7. The sale to the public of the devices for self-testing will be carried out exclusively through the pharmacies or parapharmacies or through the website ~~of the pharmacy itself~~ of these establishments.	Not accepted. The text of the Royal Decree has included an important innovation by eliminating the need for medical prescription for all devices for self-testing. This measure has a direct impact on the consumer as it facilitates access to the test for the lay person to	FENIN

		whom it is addressed. However, it should be remembered that it is a medical device for the diagnosis of a disease and therefore aspects such as the conditions of preservation of the device at the point of sale, the guarantees of traceability and, most importantly, the advice of the pharmacist during dispensing of the device make it important to maintain the requirement that these devices for self-testing continue to be sold in pharmacies.	
Article 19	Art 19.8. The sale may be made through vending machines designed for this purpose, provided that device integrity and safety are not impaired, except in the case of prescription devices and devices for self-testing unless the vending machines are controlled by a pharmacy or a parapharmacy. JUSTIFICATION: This paragraph should be deleted in the case of *in vitro* diagnostic medical devices, as we consider that only devices for self-testing that, on the other hand, are restricted to sale exclusively by pharmacies could be sold to the public through vending machines.	Not accepted. In the case of Class A devices, such as sampling containers, they could be sold to the general public by other means such as the internet or vending machines.	FENIN
Article 19	19(9) *The sale to the public of devices intended*	Accepted. The second paragraph is	FENIN

	to be used or applied exclusively by health professionals shall be prohibited. *Health establishments, within the scope of their competence, may sell to the public the devices referred to in the preceding paragraph, subject to verification of the corresponding prescription.* Clarification of this section is needed, as it is not understood which devices for exclusive use by health professionals can be sold to the public so that the diagnosis is made in another health institution, even if a prescription is necessary.	deleted.	
Article 19	**New Article 19a. '*Distance selling of devices for self-testing by pharmacies*'.** ▪ Proposed wording: **'***Article 19a - Distance selling of devices for self-testing by pharmacies.* *1. The distance selling of devices for self-testing referred to in Article 19(7) may be carried out only by those pharmacies open to the public, which are legally authorised, and which have notified the regional authorities of this activity.* *2. The distance selling of devices for self-testing can only be carried out directly from the pharmacy responsible for dispensing them, with the intervention of the pharmacist and prior informed advice, without the intervention of intermediaries.*	Not accepted. However, the text is modified to clarify that it must be done directly on the website of the pharmacy. *7. The sale to the public of the devices for self-testing will be carried out exclusively through the pharmacies or directly through the website of the pharmacy itself without the intervention of intermediaries.*	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN CGCOF

	3. The pharmacy must communicate to the competent authorities of the Autonomous Community where it is located, at least 15 days before the start of the distance selling activity, the following information: *(a) Name and surname of the pharmacist or pharmacists or, where appropriate, of the pharmacist in charge, and address of the pharmacy from which the devices for self-testing will be dispensed.* *(b) Date of commencement of activities for the supply to the public of devices for self-testing by distance selling through the website.* *(c) Address of the website used for this purpose, which must comply with the provisions of this Article, as well as all the information necessary to identify said site.* *(d) Information on the procedures for sending devices for self-testing to the public.* *Likewise, the pharmacy must inform the competent authorities of the Autonomous Communities of any change in the data included in* *the notification, as well as the cessation of this activity, at least 15 days before it takes effect.* *4. The Spanish Agency for Medicines and Health Products will create a website where hypertext links will be included to the websites of the autonomous communities described in section 5, which collect the updated lists of*		

	pharmacies in Spain that offer the public self-diagnosis products through distance sales, through websites, in accordance with this Royal Decree. *5. Those Autonomous Communities in which there are pharmacies that have* *notified the activity of distance selling to the public regulated in this Royal Decree shall create a website containing the updated list of these pharmacies in that Autonomous Community in accordance with this Article, as well as their addresses.* *6. Pharmacy websites must meet the following requirements:* *(a) The contact details of the competent health authority, in charge of its supervision, to which the activity has been notified pursuant to paragraph 3.* *b) A link to the website of the competent authorities of your Autonomous Community, referred to in paragraph 5, as well as to the website of the Spanish Agency for Medicines and Medical Devices, referred to in Article 4.* *(c) The data related to the administrative authorisation regime of the pharmacy, including its official code or authorisation number and tax identification number.* *(d) The name of the owner or owners of the pharmacy, the details of the professional association to which they belong and the*		

	membership numbers. *(e) The physical address of the pharmacy, its email address and any other data that allows direct and effective communication to be established with it.* *(f) Information about holidays or closing periods in which the service will not be available.* *g) Estimated time for the delivery of the self-diagnosis products requested.* *(h) The prices of devices for self-testing offered with an indication of whether or not they include the applicable taxes, as well as information on the price of the shipping service.* *(i) Codes of conduct to which, where applicable, it adheres and how to consult them electronically.* *The website may not offer or link to tools that obviate the mandatory advice of the pharmacist. The information contained on the pharmacy website shall be clear, understandable and easily accessible to the user. In addition, the websites of pharmacies must meet the criteria of accessibility to content for people with disabilities provided for in the fifth additional provision of Law 34/2002, of 11 July 2002, on information society services and electronic commerce, and in the rest of the current applicable regulations.* *7. The supply of devices for self-testing from the dispensing pharmacy to the address*		

	indicated by the user shall be the responsibility of the pharmacy. The transport and delivery must be carried out in such a way as to ensure that it does not suffer any alteration or deterioration in its quality. *In the event that the transport of the devices for self-testing is carried out by a third party, there must be a contract where the responsibilities of each of the parties and the conditions of the service and the provisions required by the regulations on the protection of personal data will be established. The pharmacist responsible must inform the contracted carrier of the required transport conditions and must ensure that these conditions are maintained during transport.* ▪ Justification: Despite the fact that since 2009 the Royal Decree currently in force provides for the sale by telematic processes of devices for self-testing by pharmacies, beyond allowing this sale and ensuring the mediation of the pharmacist, the old regulations did not lay down any further requirements. The draft Royal Decree is, therefore, an ideal opportunity to regulate this sales model to a greater extent, offering greater security to patients and professionals. We should not lose		

	sight of the fact that, during the worst moments of the pandemic, there was a very significant sale of these devices over the internet, and the lack of regulation sometimes led to abuses and malpractices by unauthorised operators. This lack of regulation contrasts sharply with the regime of non-prescription medicines, the distance selling of which is regulated by Royal Decree 870/2013 of 8 November 2013 regulating the distance selling to the public, through websites, of medicines for human use not subject to medical prescription. This regulation has served, to a large extent, to prevent abuses in the distance sale of this type of medicine, articulating a system that has effectively protected the rights of patients. Despite the differences between the two devices, the distance sale of devices for self-testing also requires the configuration of a similar regime, with the draft Royal Decree being the right time to address it. Thus, this General Council proposes the introduction of a new Article 19a that includes the main elements of Royal Decree 870/2013: ▪ The prior notification of the pharmacies that provide this service to their corresponding Autonomous Community. ▪ The obligatory intervention of the pharmacist,		

	and their advice, as well as the prohibition of the intervention of intermediaries. ▪ The creation of the website of the AEMPS and the Autonomous Communities where patients can consult the pharmacies that provide this service and their websites, so that the patient can corroborate the legitimacy of a website. ▪ The requirements of the websites of the pharmacies that provide these services. ▪ The regime of responsibility in the delivery of these devices for self-testing. The establishment of this model will serve to transfer to the field of devices for self-testing, the existing safety in non-prescription medicines, all of which will result in an improvement to public and community health.		
Article 19	(a) Point 4: '*Distributors shall notify the Marketing Register in accordance with Article 15, with the exception of pharmacies and any other points of sale exclusively serving the public.*' The Royal Decree should clarify whether this communication is for all devices including those that do not require an assessment by a notified body as well as the deadlines within which this communication has to be carried out. (b) Point 5: 'In accordance with Article 3(5) of the consolidated text of the Law on guarantees and	(a). Not accepted. Article 15 specifies which economic operators must communicate, when they must communicate, which are exempted from this communication and clearly refers to the fact that notification is mandatory for all devices placed on the market, regardless of their classification. The time limits are set out in Transitional Provision Five. (b). Not accepted. The purpose of this Royal Decree does not deal with the	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI

	rational use of medicinal products and medical devices, the sale to the public by mail order and telematic procedures of medical devices subject to prescription' The condition of prescription for devices for self-testing should be eliminated, as they are not included in the list of medical devices subject to prescription contained in this Article. The Royal Decree should clarify the situation of these devices in terms of advertising. (c) Point 9: 'The sale to the public of devices intended to be used or applied exclusively by health professionals is prohibited' It would be necessary for the Royal Decree to provide greater clarity on the advertising of this type of device.	advertising of medical devices, which must comply with the provisions of the current regulations RD 1/2015 and RD 1662/2000. This legislation will apply until the end of the development of the draft Royal Decree on the advertising of medical devices that is being carried out in parallel.	
Article 19	EIGHTH.- Concerning Article 19(4). Distributors shall communicate to the Marketing Register in accordance with Article 15, with the exception of pharmacies and any other points of sale exclusively serving the public. For the same reasons as those set out in the fourth claim, the reference to 'and any other points of sale exclusively serving the public' must be deleted from that provision.	Not accepted. The RD regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels or kits for self-sampling, which can be made available to the public through a channel other than pharmacies.	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA
Article 19	Article 19. *Distribution and sale*. 5. According to Article 3(5) of the revised text of the Law on guarantees and rational use of medicinal products and medical devices, the sale to the public by mail order and telematic procedures of medical devices subject to prescription is prohibited. For the purposes of this Royal Decree, devices subject to prescription are:	Partly accepted. The wording is changed: Genetic tests with the status of *in vitro* diagnostic medical devices for human use falling within the definition in Article 2(2) of Regulation (EU) 2017/746 are *in vitro* diagnostic medical devices	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

	k. Those financed by the National Health System. l. Those intended for use, or applied exclusively, by health professionals. m. Human genetic testing. 'for diagnostic purposes' should be added to be consistent with the classification stipulated in Europe 'Guidance on Classification Rules for *in vitro* Diagnostic Medical Devices under Regulation (EU) 2017/746'		
Article 19	Article 19 1. Introduction The draft Royal Decree, in the context of the exclusivity of the pharmaceutical channel in the sale to the public of devices for self-testing, includes a new wording with respect to the regime of Royal Decree 1662/2000, currently in force, that affects the online sale to the public of devices for self-testing. Under the current regime of Royal Decree 1662/2000 (i) 'the sale to the public of devices for self-testing shall be made exclusively through pharmacies' (Article 13(4)) and (ii) the online sale to the public of devices for self-testing would be prohibited except for pregnancy and fertility, blood glucose, HIV and COVID-19; online sales that could only be carried out by pharmacies with the intervention of a pharmacist and the corresponding advice (Article 13(7)). That regime has been interpreted in the market as allowing the participation of third-party	Not accepted. The text of the Royal Decree has included an important innovation by eliminating the need for medical prescription for all devices for self-testing. This measure has a direct impact on the consumer as it facilitates access to the test for the lay person to whom it is addressed. However, it should be remembered that it is a medical device for the diagnosis of a disease and therefore aspects such as the conditions of preservation of the device at the point of sale, the guarantees of traceability and, most importantly, the advice of the pharmacist during dispensing of the device make it important to maintain the requirement that, in Spain, these devices for self-testing continue to be	SPANISH ASSOCIATION OF THE DIGITAL ECONOMY - Adigital

	websites or marketplaces in the online sale to the public by pharmacies of devices for self-testing of pregnancy and fertility, blood glucose, HIV and COVID-19, while it is understood that (i) that sale is possible because it is covered by the exceptions of Royal Decree 1662/2000 and (ii) the exclusivity of the pharmaceutical channel is respected. The draft Royal Decree, although it eliminates that general prohibition and exceptions in the online sale to the public of devices for self-testing (it instead refers to Article 3(5) of the Law of Guarantees2 and includes a list of *in vitro* diagnostic medical devices subject to prescription3), maintains the exclusivity of the pharmaceutical channel in the sale to the public of devices for self-testing. However, it includes a wording not provided for in Royal Decree 1662/2000 that affects the possible participation of third-party websites or marketplaces in the online sale of devices for self-testing by pharmacies to the public. Article 19(7) is thus worded as follows: 'The sale to the public of devices for self-testing shall be carried out exclusively through pharmacies or through the website of the pharmacy itself'. This new paragraph radically alters the role that marketplaces have been assuming in the online sale to the public of devices for self-testing not subject to prescription, since they would be expelled from the market by limiting it to the websites of the pharmacy itself, despite the fact that the seller would always be the pharmacy.	sold in pharmacies. With regard to telematic sales, the text has been modified to clarify that this must be done directly through the pharmacy website without the intervention of intermediaries so that the importance of the pharmaceutical advice in dispensing continues to be a priority.	

	Proposals to amend Article 19(7) of the draft Royal Decree The proposed amendments to Article 19(7) of the draft Royal Decree below (from more to less 'ambitious') are intended to prevent the adoption of a measure limiting the market to the websites of pharmacies only and to allow third-party websites or marketplaces to continue to participate in the sale to the public of devices for self-testing as they have been doing so far as normal: Current wording of Article 19(7) 'The sale to the public of devices for self-testing shall be carried out exclusively through pharmacies or through the website of the pharmacy itself'. Proposed amendments: 'The sale to the public of devices for self-testing shall be carried out exclusively through pharmacies or through the website of the pharmacy itself or of a third party.' 'The sale to the public of devices for self-testing shall be carried out exclusively through pharmacies' Rationale for proposals to amend Article 19(7) of the draft Royal Decree To justify and provide arguments on the desirability of eliminating this new reference to the websites of pharmacies and thus continuing		

	to allow the participation of third-party websites or marketplaces in the online sale of devices for self-testing, it is appropriate to try to understand the reasons that have led the Spanish Agency of Medicines and Medical Devices (AEMPS) to introduce this new wording. Annex I to the Report on the Regulatory Impact Analysis of the Draft Royal Decree on the assessment of the contributions received in the prior public consultation procedure provides as follows: 'With regard to the sale to the public of devices for self-testing, the obligation of exclusive sale through pharmacies or through the website of the pharmacy itself remains. It is considered that the intervention of the pharmacist is fundamental, since in the dispensation the pharmacist can inform the patient of the correct handling of the test and the sample, as well as the interpretation of the result, indicating to the user, if necessary, when they should contact the health service. In addition, the community pharmacy, as a health establishment, ensures appropriate preservation conditions. On the other hand, if market surveillance and control measures are necessary, the traceability of the devices in the pharmaceutical channel is guaranteed. In relation to the observation relating to Royal Decree 870/2013 on the remote dispensing of medicinal products not subject to medical prescription, although the inclusion of these terms in the draft Royal Decree is not contemplated, the subsequent legislative		

	development adapted to the field of medical devices will be assessed.' In this sense, it seems to be understood that (i) this reference to the 'website of the pharmacy itself' and all that this entails was already part of the previous regime (the one currently in force), insofar as it states 'is maintained'; and (ii) what is really important is that the pharmacist intervenes in the sale, and that such intervention would only be achieved if the sale takes place either through the pharmacy health establishment or through the websites of those pharmacies. This suggests an obstacle to the entry of marketplaces into the pharmacy sector, so that the reference in Royal Decree 1662/2000 to the intervention and advice of the pharmacist5 (which is not found in the draft Royal Decree) seems to be replaced by the new wording on 'the website of the pharmacy itself', assuming that this guarantees the intervention and advice of the pharmacist in online sales to the public. In addition, this exclusivity is justified in favour of the pharmaceutical channel in which said channel guarantees appropriate conditions for the preservation and traceability of the devices. 'website of the pharmacy itself or of a third party'. 'Devices for self-testing shall be sold to the public exclusively through pharmacies'. That said, there are several arguments that suggest that there would indeed be insufficient reasons to justify such a measure and that it has the most obvious and immediate impact of		

	preventing the participation of third-party websites or marketplaces in those online sales when they are participating in these sales with total normality and protected by Royal Decree 1662/2000. (a) Absence of reasons justifying such a far-reaching change of regime. The regime of Royal Decree 1662/2000, currently in force, although it does reserve in exclusivity the sale to the public of devices for self-testing to pharmacies does not provide that sales by mail order or by telematic procedures must necessarily take place through the websites of pharmacies. Thus, the restriction that is intended to be introduced by Article 19(7) of the draft Royal Decree means expelling from this area operators that have been operating with total normality and protected by Royal Decree 1662/2009. On the other hand, we would be facing a change of regime that is not justified by facts or events that have revealed serious deficiencies or risks due to that participation of those operators. The lessons learned over the years and the fact that there has been no event that calls into question the participation of websites other than those of pharmacies in the online sales of devices for self-testing should lead in itself to the rejection of a restriction such as that proposed in the draft Royal Decree. (b) No impact on exclusivity in favour of the		

	pharmaceutical channel, including the intervention and advice of the pharmacist and the preservation, traceability and safety of the devices The fact that third-party websites or marketplaces participate in the online sale to the public of devices for self-testing by pharmacies has no impact on that exclusivity in favour of the pharmaceutical channel: ● the sellers, and thus the guarantees they must offer to final consumers, would remain being the pharmacies; ● if, as the AEMPS suggests, the main issue in sales of devices for self-testing to the public is the intervention and advice of the pharmacist, nothing suggests that this intervention and advice is altered or harmed due to the participation of third-party websites or marketplaces; in fact, Royal Decree 1662/2000, regarding sales to the public by mail order or by telematic procedures of devices for self-testing not subject to prescription (pregnancy and fertility, blood glucose, HIV and COVID-19), already provides for the intervention and advice of a pharmacist; and ● the conditions of preservation, traceability and safety of devices for self-testing; and if pharmacies decide to use the services of third parties for logistical purposes, for example (as could also be the case in online sales through their own websites), there is nothing to suggest that this would jeopardise the conditions for the preservation, traceability and safety of devices.		

	(c) Restriction negatively impacting competition and access to devices for self-testing by end-consumers. Any measure that unjustifiably restricts the participation of operators in a given sector or market (either expressly or implicitly) has a negative impact on competition and, therefore, on the access to that particular sector or market by the recipients or beneficiaries of that sector or market, in this case potential patients and end-consumers in general. In the present case, this impact on competition not only harms marketplaces (as the most obviously affected by the new wording of Article 19(7) of the draft Royal Decree), but also pharmacies of different sizes that use marketplaces to bring their devices to a greater number of consumers and come closer to competing against those other pharmacies with many more resources. All this, in addition, has a direct impact on consumers' access to this type of device: greater restrictions and narrower dispensing and sales channels, reduced access and ability to meet the needs of the general population. This has been stated by the National Markets and Competition Commission (CNMC) in its study on the market for the retail distribution of medicinal products in Spain (E/CNMC/003/15) ('Study'), which is fully applicable to this case. Indeed, devices for self-testing have many similarities with some types of medicines, mainly non-prescription medicines. Proof of this is that precisely the reference 'the website of the pharmacy itself' is very reminiscent of the		

	regime of distance selling of medicines not subject to prescription. In fact, the AEMPS itself makes express reference to the legislation on distance selling of medicinal products not subject to prescription in Annex I to the Report on the Regulatory Impact Analysis of the Draft Royal Decree, suggesting that they are indeed similar products at least as regards their dispensation. This Study, which reflects the expansion of new technologies in recent years and, in particular, of the internet as a medium in which transactions of all types of devices, including medicines and medical devices, are increasingly carried out, aims to analyse the various restrictions on competition in the market for the retail distribution of medicines from the perspective of efficient economic regulation; that is, to assess, using economic and legal criteria, the necessity and proportionality of the restrictions and to draw conclusions and recommendations on the most favourable configuration of competition and economic efficiency. The CNMC concludes that there are indeed restrictions, both on access to the market and on the exercise of the activity of pharmacies, which limit competition in the market and, in many cases, neither protect public health nor are justified from the point of view of efficiency, such as 'the reservation of the activity of pharmacies in the custody, preservation and dispensing of medicines'. After analysing this		

	restriction on the basis of the principles of necessity and proportionality for non-prescription medicinal products, the CNMC recommends 'eliminating the reservation of dispensing activity to pharmacies', as well as 'allowing the sale of these medicinal products in other establishments'. With regard to the distance sale of non-prescription medicines through pharmacy websites, the CNMC considers that this 'reservation of activity by pharmacies in the sale of non-prescription medicines through websites constitutes an unnecessary and disproportionate restriction of competition to ensure the protection of public health' and proposes to 'liberalise the ownership of websites so that they are not exclusively owned by physical pharmacies'. Following the CNMC's criteria, and without calling into question the particularity of medicines and, to a lesser extent, medical devices (and devices for self-testing in particular), restricting the online sale of devices for self-testing to the websites of pharmacies does not seem to be a sufficiently justified and proportionate measure, even from the point of view of public health protection. On the other hand, and finally, it does not seem reasonable that, at the same time as devices for self-testing are no longer subject to medical prescription, the way in which such devices can be accessed should be more severely limited.		
Article 19	THIRD. - DISTRIBUTION AND SALE OF	Not accepted. Regardless of where the	ANEFP

	DEVICES FOR SELF-TESTING THROUGH VENDING MACHINES (Article 19(8)). According to Article 19(8), 'sales may be made through vending machines designed for this purpose, provided that the integrity and safety of the device is not adversely affected, except in the case of prescription devices and devices for self-testing.' From the wording of this article, it is interpreted that prescription medical devices and devices for self-testing have a restricted dispensing channel that prevents their direct sale to the public through vending machines. As stated in Article 19(7) of the draft: 'The sale to the public of devices for self-testing shall be carried out exclusively through pharmacies or through the website of the pharmacy itself', the sale of devices for self-testing is limited to pharmacies and their websites. However, the pharmacy may have a vending machine on its premises. This situation should be taken into account and reflected in the text of the draft Royal Decree. To this end, the following wording is proposed for Article 19(8): 'Sales may be made through vending machines designed for this purpose, provided that the integrity and safety of the device is not adversely affected, except in the case of prescription devices and devices for self-testing. Where the vending machine is located in a pharmacy, devices for self-testing may be dispensed through it.'	vending machine is located, devices subject to prescription and devices for self-testing may not be sold from it. These two situations require either verification of the prescription by the pharmacist or the possibility of requesting the pharmacist's advice during dispensing.	
Article 20	Paragraph 2 of Article 20. '*Distribution activity*'. ▪ Proposed wording:	Not accepted. The wording of the draft Royal Decree does not limit the possibility that the technical director, in	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN

	'2. The distribution activities will be carried out under the supervision of a technical manager whose university degree or training programmes prove an appropriate qualification depending on the devices they are in charge of. This technical manager shall be directly responsible for the implementation of the activities and obligations provided for in Articles 15 and 16. Likewise, they shall be responsible for maintaining the technical and health information about the devices they distribute or commission in Spain. ***In the distribution entities of medicinal products for human use authorised in accordance with Royal Decree 782/2013, of 11 October, on the distribution of medicinal products for human use, which also carry out the distribution activity regulated in this Article, these functions will be carried out by their technical director.*** *If the qualification referred to in the preceding paragraph does not fully demonstrate proof of competence, it may be supplemented on the basis of training and/or experience. Points of sale exclusively serving the public are exempt from the requirement concerning the technical manager.'* ▪ *Justification:* *It is relatively common for entities distributing medicinal products for human use to combine that activity, regulated by Royal*	those entities that distribute both medicinal products for human use and medical devices, is also the technical manager provided that this person meets the requirements established for this purpose in the regulation.	CGCOF

	Decree 782/2013 of 11 October 2013 on the distribution of medicinal products for human use, with the distribution of other devices, such as those regulated in this draft Royal Decree. *Given that RD 782/2013 requires that these entities have a pharmaceutical technical director (Article 5), it makes no sense to allow there to be a technical manager other than the pharmaceutical technical director, who has the necessary training to also assume the functions of technical manager, without prejudice to the other human resources that may be necessary.* *Therefore, we propose to amend Article 20 of the draft Royal Decree in that sense, so that, when a distribution entity for medicinal products for human use carries out these activities, the technical responsibility falls on the pharmaceutical technical director.*		
Article 20	Paragraph 2. The time commitment should be indicated if this activity is carried out in more than one company. The following wording is therefore proposed: 'If this activity is carried out in more than one company, the time commitment must be justified and activities may be carried out in more than one company as long as the volume of activity, the location of the companies and the time commitment allow all the assigned functions to be carried out, and although the presence of the technical manager is not necessary throughout the opening hours of the	Not accepted. The specification of the time commitment will be detailed in the corresponding instructions made by the Autonomous Community for the distribution establishments in its territory.	ANDALUSIA

	warehouses, provided that the technical means and tools available enable the assigned tasks to be carried out, on-the-spot checks shall be carried out on the premises of the warehouse on a regular basis or where necessary'		
Article 20	NINTH.- Concerning Article 20(2) in fine. 8 It states that points of sale exclusively serving the public are exempt from the requirement concerning the technical manager. For the same reasons as those set out in the fourth claim, the reference to 'and any other points of sale exclusively serving the public' must be deleted from that provision	Not accepted. The RD regulates all *in vitro* diagnostic medical devices, not only those for self-testing, including sample vessels or kits for self-sampling, which can be made available to the public through a channel other than pharmacies.	OFFICIAL COLLEGE OF PHARMACISTS OF VALENCIA
Article 20	Art 20.2. The distribution activities will be carried out under the supervision of a technical manager whose university degree or training programmes prove an appropriate qualification depending on the devices they are in charge of. This technical manager will be ~~directly responsible for~~ responsible for ensuring the execution of the activities and obligations provided for in Articles 15 and 16. Likewise, the technical manager will be responsible for maintaining the technical-health information on the devices distributed or put in service in Spain.	Not accepted. The text of the Royal Decree is not a new requirement, but was already mandatory in the previous Royal Decree 1591/2009. The wording indicates that the activities will be carried out under the supervision of the technical manager in a way that controls the distribution. Both the marketing registration and the traceability of the devices are within the direct responsibilities of the technical manager, so as to ensure compliance.	FENIN

	Justification: We believe that the technical manager should be responsible for ensuring the execution of the activities and obligations provided for in Articles 15 and 16 but should be allowed to delegate their execution to other persons or technicians.		
Article 21	It is considered excessive that there is a specific Article for this topic; on the one hand it is already covered by the European Regulation and thus appears in the preamble to this draft, and on the other hand, it is related to advertising, which will be covered with the necessary nuances in the new advertising regulation that is currently being drafted. Therefore, it could be included as part of another article with a more general content.	Not accepted. The specific text regarding exhibitions has been included to complete the text indicated in the Regulation that only requires compliance with it. This text has been included both to require compliance with this Royal Decree with regard to exhibitions and to specify that these sample devices may not be used on participants. In addition, being a possible activity within the definition of marketing, it has been included in the chapter on distribution and sale.	ANDALUSIA
Article 22	It is recommended to specify the 'justified reasons' referred to in paragraph 5, which may lead to the authorisation of imports of devices which do not comply with the requirements previously defined.	Accepted. For 'justified reasons' is deleted.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
Article 22	The explanatory part of the draft Royal Decree states that: *'although Regulation (EU) 2017/746 of the European Parliament and of the Council*	Not accepted. This requirement is not new; it has existed since at least Royal Decree 414/1996 of 1 March 1996.	MINISTRY OF FINANCE AND CIVIL SERVICE

	of 5 April 2017 is directly applicable in the countries of the European Union, it is necessary to regulate at national level the aspects that the European standard leaves to the regulation of each Member State. To this end, this Royal Decree is approved, which specifies issues such as the determination of the competent authority for the purposes of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, the health guarantees for devices, the establishment of the language regime and the regulation of procedures for the manufacture of devices for use in the health institution itself (...)'. The rules governing external trade in the medical devices covered by the draft are set out in Articles 22 and 23 of the draft. In this respect, in relation to importation, Article 22 seems to establish a system of pre-import control by the '*Spanish Agency of Medicines and Medical Devices, through the services of* *pharmaceutical inspection of the functional areas of health and social policy of the* *Government Delegations',* in such a way that compliance with certain requirements will be verified before importation and, in the event of non-compliance, the goods will be rejected. However, there is no mention of whether such intervention affects the authorisation of the customs procedure by the customs authority. In this regard, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5	Both Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 and Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 lay down in their articles the obligation of the Member States to control the external borders to ensure that they only introduce products which comply with the Community rules applicable to them and products which do not pose a risk to health. Customs authorities shall cooperate with the competent sectoral authorities. The objective of this prior control is therefore to ensure the entry into Spain and the EU of devices that comply with the legislation on medical devices.	

	April 2017 does not provide for a system of pre-import control and, therefore, it might be contrary to the Regulation to make the release of the goods for free circulation subject to the prior intervention of the pharmaceutical inspection services.		
Article 24	Since it is not necessary to indicate that the devices concerned are those falling within the scope of the draft, nor that the specific rules on intervention studies laid down in the Regulation itself will apply, it is suggested that the wording of paragraph 1 be simplified to read as follows: '1. In carrying out performance studies referred to in Article 58(1) and (2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, the ethical, methodological and protection principles for the subjects of the trial, laid down in Royal Decree 1090/2015 of 4 December 2015 regulating clinical trials with medicinal products, the Ethics Committees for Investigation with medicinal products and the Spanish Register of Clinical Studies, shall also apply.'	Not accepted. The intent of the proposal to simplify is understood, but this aspect of the scope of application in performance studies is being very problematic at European level and subject to different interpretations, so it is considered essential to make this first paragraph as complete as possible. Performance studies encompass a multitude of studies so it is considered relevant to limit them to the scope of Article 3(1) of this Royal Decree and Article 58(1) and (2) of the Regulation.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
Article 24	Article 24(3) The criteria to be taken into account when choosing the ethics committees for investigation with medicinal products (CEIm) that will issue the single and binding opinion for this type of study should be detailed when the study is to be carried out in several health institutions in the Spanish State. We propose indicating that it will be the centre corresponding to the health institution to which	Not accepted. The draft refers to the requirements for the conduct of clinical investigations in Spain and therefore the obligation to have the positive opinion of the CEIm. The purpose of the Royal Decree is not to establish the criteria for the selection of a particular CEIm. It will be the sponsor who decides which CEIm to select among	CATALONIA

	the coordinating researcher is linked. Justification: We consider that, in order to ensure transparency in the process of selecting the CEIm that issues the single opinion in this type of multicentre performance study, it is necessary that the draft Royal Decree indicates the criterion or criteria to be taken into account by the sponsor of these studies when choosing the CEIm.	those accredited for the purpose. This information will be clarified in the instructions for the application for a performance study and will follow the requirements established in Royal Decree 1090/2015.	
Article 24	In the fifth paragraph of Article 24(5), it is suggested that capital letters should not be used when referring to 'pharmacy services', in order to restrict the use of capital letters as much as possible.	Accepted. The text is amended.	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID
Article 24	(a) Point 2: 'Devices intended for this type of performance study may only be made available to clinicians or researchers if the study has received the favourable opinion of the Ethics Committee for Investigation with Medicinal Products (hereinafter referred to as CEIm)'. In this point we believe that the Royal Decree should specify whether the CEIm will be those committees listed as accredited according to RD 1090/205. Another important point is that the Royal Decree should specify whether these CEIm should be the same as those evaluating the clinical trial.	(a). Not accepted. The text of the Royal Decree already mentions in paragraph 1 that *the ethical, methodological and trial subject protection principles, contemplated in Royal Decree 1090/2015, of December 4, regulating clinical trials with medicines, the Ethics Committees for Investigation with medicinal products and the Spanish Registry of Clinical Studies will be applied*, which includes the CEIm. Nor is it considered appropriate to limit in a legislative text that only CEIm evaluating clinical trials will be used, when the usual practice is that CEIm evaluate clinical trials and clinical investigations and performance studies and evaluations. Such	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI

	(b) Point 4: 'The Spanish Agency of Medicines and Medical Devices shall inform the relevant Autonomous Communities of the decisions taken to ensure the safety of performance studies' The time periods within which the Autonomous Community will be informed should be indicated. (c) Point 5: 'Devices intended for performance studies shall be provided free of charge by the sponsor. Other forms of supply may be authorised in certain circumstances.' Today there are kits (of course without medication) that are kept by the services that carry out the trial and not in the Pharmacy Service. Is it possible to make this requirement more flexible in these cases? 'The manufacturing and control protocols for batches of devices manufactured for performance study shall be kept by the sponsor in the main test file.' It should be clarified for how long.	recommendations shall be taken into account in the instructions on performance studies. (b). Not accepted. It is not considered appropriate to establish in the text the deadline for communication to the Autonomous Communities, when this is subject to the seriousness of the case. On the other hand, the proposal is that the communication be made directly and immediately through the computer application to which the Autonomous Communities will have access. (c) Not accepted. This is not a new requirement. The legislation on medical devices already provides that, if the investigation takes place in a hospital, the supervision of the supply of samples will be carried out through the Pharmacy Service. The time period for which the documentation of a performance study must be kept is laid down in Regulation 2017/46 in paragraph 3 of Chapter II of Annex XIV and is 10 years.	
Art.24	Article 24. *Interventional clinical performance studies and other performance studies involving risks to subjects.* 1. In carrying out performance studies on devices included in Article 3(1) of this Royal	It is not considered a claim on the text, but a concrete case. It is understood that any performance study that is carried out in Spain needs the authorisation of the AEMPS, whether	SPANISH BIOINDUSTRY ASSOCIATION ASEBIO

	Decree, referred to in Article 58(1) and (2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, the ethical, methodological and protection principles for the subjects of the trial, referred to in Royal Decree 1090/2015 of 4 December 2015 regulating clinical trials with medicinal products, the Ethics Committees for Investigation with medicinal products and the Spanish Registry of Clinical Studies, as well as the provisions of Chapter VI and Annexes XIII and XIV to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, shall apply. Recently one of AseBio's partners has had to report a study using companion diagnostics with left-over samples (Article 58(2) of the Regulation). We believe that, as written, the requirements do not contemplate the possibility of using samples from Spanish patients in this type of study. We understand that in this case the documentation cited in this article does not need to be in Spanish, since the IVD device will not be used in Spain.	samples of Spanish patients are used or not and must comply with the requirements of the Regulation and of this Royal Decree, including linguistic requirements. The different cases that may occur in the performance studies will be clarified in the corresponding instructions.	
Article 24	Article 24.4. The Spanish Agency of Medicines and Medical Devices shall inform the relevant Autonomous Communities of the decisions taken to ensure the safety of performance studies.	Not accepted. It is not considered appropriate to establish in the text the deadline for communication to the Autonomous Communities, when this is subject to the seriousness of the case. On the other hand, the proposal	FENIN

	The reporting times of the AEMPS to the Autonomous Communities should be identified.	is that the communication be made directly and immediately through the computer application to which the Autonomous Communities will have access.	
Article 24	Article 24(5) The manufacturing and control protocols for batches of devices manufactured for performance study shall be kept by the sponsor in the main test file. It should be defined how long the sponsor must keep the documentation indicated in this section The following redrafting is proposed Hospitals or health institutions where performance studies are carried out shall designate a person to supervise the supply of samples. JUSTIFICATION: We consider that pharmacy services should not be assigned the responsibility for supervising the supply of devices intended for performance studies since, in general, pharmacy services do not control laboratory reagents.	The time period for which the documentation of a performance study must be kept is laid down in Regulation 2017/46 in paragraph 3 of Chapter II of Annex XIV, being 10 years. Not accepted. This is not a new requirement. The legislation on medical devices already provides that, if the investigation takes place in a hospital, the supervision of the supply of samples will be carried out through the Pharmacy Service	FENIN
Article 25	It is recommended to indicate that the performance studies for which the authorisation is requested still refer to those provided for in Article 58(1) and (2) of the Regulation, as well as to identify the specific Article of the Regulation indicating the accompanying documentation. Article 25(1)	Not accepted. It is not considered necessary to refer to this as this Article refers, as its title indicates, to the *Procedure for authorisation of interventional clinical performance studies and other performance studies involving risks for subjects*. Which are	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	could therefore read as follows: '1. The sponsor of a performance study referred to in Article 58(1) and (2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 shall apply to the Spanish Agency of Medicines and Medical Devices for authorisation to carry out the study, together with the documentation required by Article 66(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 in accordance with the procedures and time limits laid down therein. This request shall be without prejudice to any communication required by the health authority of the Autonomous Community concerned. • It should also be made clear in Articles 26, 27 and 28 whether they refer only to the studies referred to in Articles 58(1) and (2) of the Regulation. • The second subparagraph of Article 25(2) should read 'Article 58(1)(a)'.	the trials referred to and detailed in the immediately preceding article. Articles 7 and 8 of the licence and the corresponding procedure are drafted in the same way. Not accepted. It is not considered necessary to make any reference to this, since Articles 26 and 27 indicate this in the title of the Article itself and in Article 28 both the title and the wording and references to the Regulation refer to other types of performance studies.	
Article 25	Article 25 of the draft concerns the procedure for the authorisation of interventional clinical performance studies and other performance studies involving risks for subjects. The reference to 'the procedures and time limits laid down in this Regulation' should be clarified or determined directly.	Not accepted. The wording of paragraph 2 of the Article refers to the Article of Regulation 2017/746 itself (Article 66) which establishes the procedures and deadlines to be applied at European level.	MINISTRY OF FINANCE AND CIVIL SERVICE

Article 25	Article 25(1) It is requested that the following sentence be included at the end of this paragraph: 'The Spanish Agency of Medicines and Medical Devices shall inform the health authorities of the Autonomous Communities in which are located the centres in which these studies are carried out of the outcome of the evaluation of applications for the performance of interventional clinical performance studies and other performance studies involving risks for the subjects of the trials.' Justification: For the effective exercise of the powers of the health authorities of the Autonomous Communities in terms of inspection and control of the performance of these studies in their community, and to guarantee the protection of the health of the participating patients, it is necessary that they know the result of the evaluation of the applications for authorisation, to carry out, if appropriate, the appropriate actions.	Not accepted for inclusion in the draft. However, in the EUDAMED database, there will be a performance study module with public information. It is also expected that some of the information from the implementation at national level will be publicly accessible. Article 24(4) already indicates that in the event that the AEMPS takes any decision to ensure the safety of performance studies, the corresponding Autonomous Communities will be informed.	CATALONIA
Article 25	Article 25(1) It is requested that the following sentence be included at the end of this paragraph: 'The Spanish Agency of Medicines and Medical Devices shall inform the health authorities of the Autonomous Communities in which are located the centres in which these studies are carried out of the result of the evaluation of the substantial modifications to these performance studies.'	Its inclusion in the legislative text is not accepted. However, in the EUDAMED database, there will be a performance study module with public information. It is also expected that some of the information from the implementation at national level will be publicly accessible. Article 24(4) already indicates that in the event that the AEMPS takes any decision to ensure	CATALONIA

		the safety of performance studies, the corresponding Autonomous Communities will be informed.	
Article 25	(a) Point 1: 'The sponsor shall apply to the Spanish Agency of Medicines and Medical Devices for authorisation, together with the documentation required by Regulation (EU) 2017/746 of the European Parliament.' It should be specified what the role of the Autonomous Communities is and whether they will only be responsible for receiving the information	Not accepted. It is not the purpose of this Royal Decree, nor is it the responsibility of the AEMPS to establish the role of the Autonomous Communities. The text only indicates that the communication to the AEMPS will be independent of that which the Autonomous Communities may require based on their competences.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
Article 25	Art 25.1. Consider including the data collection logbook in the set of documentation requested in the authorisation procedure.	Not accepted. Chapter I of Annex XIV of the Regulation establishes the documentation that must accompany the application for the study without including the data collection logbook, which is why it is not included in the text of the Royal Decree either. In addition, in line with RD 192/2023, this section only includes documents that must at least be submitted in Spanish. No further documents have been included to provide flexibility in the investigations and in response to other claims aimed at encouraging investigation in our country.	A3Z Advanced
Article 25	Concerning the second paragraph of Article 25. '*Procedure for the authorisation of interventional clinical performance studies and*	Not accepted. In all cases, the AEMPS	GENERAL PHARMACEUTICAL COUNCIL OF SPAIN

	other performance studies involving risks for subjects'. ▪ Proposed wording: "*The Spanish Agency for Medicines and Health Products will evaluate the documentation submitted and give a decision by authorising the studies or communicating a refusal decision based on public health or public policy considerations, taking into account the time limits set out in Article 66 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017*, ***and the application being understood to be rejected in the absence of an express decision being issued***' ▪ *Justification:* *We refer to what has already been stated in the third Consideration, and the meaning of administrative silence should be included for reasons of legal certainty.*	gives a decision authorising or denying the study. The text has been amended to align the wording with RD 192/2023.	CGCOF
Article 25	Art 25.2. 'where the collection of samples does not represent a significant clinical risk for the subject, the same procedure shall be applied with the same deadlines as for the rest of the devices'. I would add 'or are left-over samples' after 'does not represent a significant clinical risk to the subject'.	Not accepted. This paragraph refers to Article 66(7)(a) of the IVD Regulation which makes it available to the national authorities to start the study immediately after validation. This is not going to be allowed at national level, so this point of the Royal Decree establishes that for the performance studies pursuant to Article 58(1)(a) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 in which the	SPANISH SOCIETY OF INFECTIOUS DISEASES AND CLINICAL MICROBIOLOGY (SEIMC)

		collection of samples does not represent a significant clinical risk for the subject, in this case the same deadlines as for the other cases will apply. It does not refer to the use of left-over samples for another type of study.	
Article 27	Liability regime: include duration of the contract Justification: 4) Fourth, as regards the period of insurance cover, Article 27(1) states that 'In the absence of proof to the contrary, it is presumed that damage to the health of the subject during the course of the study and in the year following the end of the treatment has occurred as a result of the study. However, once the year is over, the test subject is required to prove the link between the study and the damage caused.' However, it is considered appropriate to regulate the duration of the contract.	Not accepted. With regard to the duration of the contract, this should be assessed in each case due to the wide variety of types of devices that can be subject to performance studies and that will therefore establish the duration of the study itself.	MINISTRY OF ECONOMIC AFFAIRS AND DIGITAL TRANSFORMATION (40)
Article 28	As in the previous point, the role of the Autonomous Communities should be specified and whether they will only be responsible for receiving the information	Not accepted. It is not the purpose of this Royal Decree, nor is it the responsibility of the AEMPS, to establish the role of the Autonomous Communities in performance studies. The text only indicates that the communication to the AEMPS will be independent of that which the Autonomous Communities may require based on their competences.	Spanish Association of Industry Pharmacists AEFI
Article 28	Article 28.2. The written communication, researcher's manual, performance study plan,	Not accepted. Chapter I of Annex XIV	A3Z Advanced

	informed consent and instructions and labelling of the device for the study must be presented at least in Spanish. Consider including the data collection logbook in the set of documentation requested in the authorisation procedure	of the Regulation establishes the documentation that must accompany the application for the study without including the data collection logbook, which is why it is not included in the text of the Royal Decree either. In addition, in line with RD 192/2023, this section only includes documents that must at least be submitted in Spanish. No further documents have been included to provide flexibility in the investigations and in response to other claims aimed at encouraging investigation in our country.	
Article 29	In order to clarify its understanding, the following wording is proposed for this article: 'Article 29. Other performance studies. Performance studies other than those referred to in Article 58(1) and (2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 shall be governed in accordance with the other provisions laid down in that Regulation for performance studies and in the specific rules applicable to them.'	Not accepted. The term performance studies is a very general term and referring to them as different from 58(1) and (2), could leave some without being within Article 29.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
Article 30	The second paragraph of Article 30(2) states that 'Patients and users may also report serious incidents to the Spanish Agency of Medicines and Medical Devices using the electronic procedure provided for this purpose,	Accepted. The wording indicates *may* so it does not refer to an obligation and is in line with Royal Decree 192/2023 of 21 March, however a reference to Article 16(4) of the Law is included.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	without prejudice to any notification they may have made to the manufacturer, another economic operator or the health professional'. As natural persons are not obliged to interact with the Public Administrations through electronic means, in accordance with Article 14(1) of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, but this obligation can be established by regulation, under Article 14(3) of that Law, 'for certain procedures and for certain groups of natural persons that, due to their economic capacity, technical capacity, professional activity or other reasons, are proven to have access to and availability of the necessary electronic means', it is recommended that the regulatory impact analysis report justifies the concurrence of any of these cases to establish the intended obligation.		
Article 30	Article 30 states that 'Patients and users may also notify serious incidents to the Spanish Agency of Medicines and Medical Devices using the electronic procedure provided for this purpose, without prejudice to any notification they may have made to the manufacturer, another economic operator or the health professional'. In this regard, it should be noted that patients and users are natural persons not obliged to interact electronically with the Administration,	Accepted. The wording indicates *may* so it does not refer to an obligation, but a reference to Article 16(4) of the Law is included.	MINISTRY OF FINANCE AND CIVIL SERVICE

	so Article 14(1) of Law 39/2015 of 1 October 2015 applies, which states: 'Natural persons may choose at any time whether to communicate with the Public Administrations for the exercise of their rights and obligations through electronic means or not, unless they are obliged to interact through electronic means with the Public Administrations'.		
Article 30	Article 30. It is requested that the following paragraph be included, 'The Spanish Agency of Medicines and Medical Devices shall make information on serious adverse incidents - reported to it by health professionals, patients or users - available to the respective health authorities of the Autonomous Communities.' Justification: For the purpose of health protection, the health authorities of the autonomous communities should be aware of adverse incidents that have been reported to the Spanish Agency for Medicines and Health Products by health professionals, patients or users located in their respective communities.	Not accepted. The text included was the one proposed and accepted following this same claim from Catalonia in the development of RD 192/2023. The same wording has therefore been respected.	CATALONIA
Art. 30	Article 30(3) It is requested that the text 'They shall communicate their data to the health authorities of the relevant Autonomous Community and to the Spanish Agency of Medicines and Medical Devices' be replaced by	Not accepted. The aim of having a single register in the AEMPS is to prevent centres from having to duplicate their communication to the AEMPS and the Autonomous Community. Paragraph 3 states that	CATALONIA

	‘They shall communicate their data to the health authorities of the relevant Autonomous Community’. Likewise, and consequently, we ask for this paragraph to be deleted: ‘In the event that the Spanish Agency of Medicines and Medical Devices has enabled an electronic register for the communication of the appointment of the surveillance managers, the health institutions will have the obligation to communicate the data required to said register. The information in this register shall be available to the Autonomous Communities.’ Justification: According to the distribution of powers in the field of health, the Autonomous Communities are responsible for the authorisation and supervision of the activity of the health institutions in their region. In this framework and in relation to the communication of the safety aspects of medical devices that may be necessary to health institutions, this must be carried out through the health authority of each Autonomous Community. Therefore, it is not necessary that the data of the person responsible for procedures related to the surveillance of *in vitro* diagnostic medical devices should be communicated to the Spanish Agency of Medicines and Medical Devices. In this regard, it should be recalled that this is the procedure that has been followed since 2005 in accordance with the information note of the Spanish Agency for Medicines and	“The information in this register shall be available to the Autonomous Communities”, so this communication shall be simultaneous to both authorities. This is the process carried out under the current legislation. The document agreed between the AEMPS and the Autonomous Communities, to which the claim refers, establishes this same procedure in which both authorities are informed at the same time.	

	Medical Devices entitled 'Incident Reporting System by Health Professionals', which was drawn up and agreed between the Agency and the health authorities of the Autonomous Communities.		
Art. 30	(a) Point 2: 'Health professionals and authorities who, in the course of their activity, become aware of a serious incident, shall notify the Spanish Agency of Medicines and Medical Devices through its website'. For this notification, they need the code of the Autonomous Community (or similar) from the economic operators to facilitate this communication with the Autonomous Communities (b) Point 6: Manufacturers shall inform the Spanish Agency of Medicines and Medical Devices of any corrective safety action before such action is carried out, in accordance with Article 82(1) and (8) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. In a performance study, the role of the sponsor in safety issues is unclear as only the manufacturer is referred to.	(a) Not accepted. It is not a new requirement and the procedure has been in place for some time. The notification is made through the NotificaPS portal accessed by both the Agency and the Autonomous Communities. (b) Not accepted. This notification concerns corrective safety actions on devices that are already CE marked and used in already certified indications. This is why, even if they are used in a post-marketing study, the notification of the FSCA to the AEMPS will be an obligation of the manufacturer, not the sponsor of the study.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
Article 30	**Justification** For a long time, the industry has been urging the competent authority to have a contact person in health institutions in charge of surveillance, to speed up and facilitate the communication from companies in relation to the dissemination of safety notes in such a way	Not accepted. The duties of the surveillance manager in the surveillance guidelines document are to 'Ensure the dissemination of the information notes/alerts on medical devices issued by the AEMPS and transmitted by the competent regional	FENIN

	as to ensure their reception by the health institutions. In this regard, the list of those responsible for surveillance in health institutions should be made public or accessible. A possible alternative could be the creation of a generic email address for all institutions, such as: RVPS@name of hospital.es or the extension that each hospital has in each Autonomous Community. This would solve the possible problems derived from data protection or the change, at a given time, of the designation of the responsible person in a centre, which would change the reference address. Another possible alternative could be the development of a platform where all hospitals are located and where companies can upload the FSNs or corresponding documentation so that they receive a notification when the documents have been downloaded, as an acknowledgement of receipt of the note, and which could serve as communication between the company and the institution if necessary.	health authorities, to the health professionals involved at their centre, and to supervise, where appropriate, the implementation of the measures set out therein.' The role of surveillance manager is created mainly for purposes of exchanging information with the health authorities.	
Article 31	It is requested that the wording 'The Spanish Agency of Medicines and Medical Devices shall coordinate the market control activities to be carried out in collaboration with the health authorities of the Autonomous Communities in order to comply with the provisions of Article 88 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017' be replaced by the following 'The Spanish Agency of Medicines and Medical Devices shall	Not accepted. It is not considered appropriate to include limitation of market control coordination activities within the framework of the Technical Inspection Committee in the wording of the Royal Decree. The activities of the Technical Inspection Committee are set out in the By-laws of the AEMPS.	CATALONIA

	coordinate, within the framework of the Technical Inspection Committee, the market control activities to be carried out in collaboration with the health authorities of the Autonomous Communities in order to comply with the provisions of Article 88 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. The Spanish Agency of Medicines and Medical Devices, within the framework of the Technical Inspection Committee, shall take the appropriate measures to encourage cooperation and mutual assistance with the health authorities of the Autonomous Communities, including the inspection and organisation of specific control programmes. Justification: In accordance with Article 27 of Royal Decree 1275/2011 of 16 September 2011 establishing the Spanish Agency of Medicines and Medical Devices and approving its Statute, the Technical Inspection Committee is the coordinating body for the inspection and control of medicines, medical devices, cosmetics and personal hygiene devices and is responsible for ensuring that the criteria and actions of the Agency's inspection and control services and the competent bodies of the Autonomous Communities are uniform. Thus, among others, the functions of this Committee are the following: (a) Promote the harmonisation of criteria in inspection and control actions on medicines, medical devices,		

	cosmetics and personal hygiene devices within the scope of their competences; (i) Develop coordinated inspection programmes for medical devices, cosmetics and personal hygiene devices and approve their implementation		
Article 32	32. 2. provides that 'Infringement of the provisions set out in this Royal Decree and in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 will lead to the adoption by those health administrations of the necessary corrective measures, irrespective of any sanctions that may be applicable.' JUSTIFICATION the sanctioning regime referred to in the second additional provision of Law 20/2015 of 14 July 2015, is not recorded in the text, nor does it make a reference to another provision regulating it.	Not accepted. The sanctioning regime is established in the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015.	MINISTRY OF ECONOMIC AFFAIRS AND DIGITAL TRANSFORMATION
Art.32	It is proposed to replace the phrase '...and the facilities in which they are manufactured, sterilised, imported or exported, provided that they are located in national territory...' Justification: See introduction to this document and justification in relation to Article 9(7)	Not accepted. The competence relating to the regulation of import, processing, manufacturing, distribution or export activities corresponds to the General State Administration in accordance with the provisions of Article 100 of Law 14/1986, of 25 April 1986, on General Health. These powers concern the activities to be conducted independently of the establishment where they are carried out, as well as the authorisations of health establishments issued by the Autonomous Communities.	CATALONIA

FIRST ADDITIONAL PROVISION	(a) 'The procedures referred to in Articles 7, 9, 15, 25 and 28(1) shall be subject to the corresponding fees set out in group VIII...' The fees must be adapted to the provisions of the sixth final provision of Law 38/2022, setting out the fees applicable to medical devices, and amending Article 123(1) AND 123(14) of Royal Legislative Decree 1/2015, to establish a new list of fees, which will be integrated into group V, not group VIII and will be applicable from 28 June 2023.	Accepted. The text is amended.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
FIRST ADDITIONAL PROVISION	FOURTH.- APPLICATION OF FEES (first additional provision). According to the first additional provision, 'the procedures regulated in Articles 7, 9, 15, 25 and 28(1) shall be subject to the corresponding fees set out in group VIII of Article 123(1) of the recast text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015.' However, this wording is not in line with the latest wording of the aforementioned Law on guarantees, which was introduced by the sixth final provision of Law 38/2022. To correct this error, the following wording is proposed: 'The procedures governed by Articles 7, 9, 15, 25 and 28(1) shall be subject to the corresponding fees set out in group V of Articles 123(1) and 123(14) of the recast Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015.'	Accepted. The text is amended.	ANEFP

FIRST ADDITIONAL PROVISION	The following text is proposed: The procedures laid down in Articles 7, 9, 15, 23, 25, and 28(1) shall be subject to the corresponding fees set out in group V of article 123(1) of the consolidated text of the Law on guarantees and the rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015. JUSTIFICATION: According to the amendment to Article 123 of the recast text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015, inserted in the sixth final provision of Law 38/2022 of 27 December 2022, the fees for medical devices, cosmetics and personal care devices are included in group V. Furthermore, the fee for free sale certificates and export certificates issued by the Spanish Agency of Medicines and Medical Devices, as set out in Article 23(2) of this draft Royal Decree, would not be included.	Partly accepted. The text is corrected by amending the group of fees to V. For certificates of free sale or export, the fee has been collected in group IV, 4.1, certifications and reports.	FENIN
SECOND ADDITIONAL PROVISION	It is proposed that the provision be deleted on the basis of the claim against Article 7 Justification In line with the comments made in Article 7(1), we consider that manufacturing as a subcontractor of a device (whether manufacturing in whole or in part) should be excluded from the scope of licences and should only apply to legal manufacturers.	Not accepted. See claim against Article 7	FENIN
THIRD	Additional provision xxxxxxxx. Application within	Accepted.	MINISTRY OF DEFENCE -

ADDITIONAL PROVISION	the Ministry of Defence. When the provisions of this Royal Decree affect the units, centres and bodies belonging to the Ministry of Defence and its public bodies, any actions that are necessary will be implemented by the General Inspectorate of Defence Health, in coordination with the Ministry of Health or with the Spanish Agency of Medicines and Medical Devices, in each case. ” JUSTIFICATION: The military health network does not depend organically on the Autonomous Communities, so the application of the provisions of the draft provision of the ‘matter’ in the sphere of the Ministry of Defence and the Armed Forces, as well as the relations for this purpose with the Spanish Agency of Medicines and Medical Devices, must be the responsibility of the General Inspectorate of Defence Health, as already contemplated in the third additional provision of Royal Decree 192/2023 of 21 March 2023, regulating medical devices.		GENERAL TECHNICAL SECRETARIAT
FIRST TRANSITIONAL PROVISION	(a) ‘The prior operating licence referred to in Article 7 shall not be required until one year after entry into force...” The concept of complete manufacturing, which is ambiguous, should be clarified.	Not accepted. Depending on the types of manufacturing, there may be differences in what is meant by complete manufacturing such as to include in a legislative text a single concept of complete manufacture. However, the instructions for the licence application will clarify the different cases that can be found.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
SECOND	Second transitional provision. *Renewal and*	Not accepted. Licences issued prior to	SPANISH BIOINDUSTRY

TRANSITIONAL PROVISION	*modification of licenses*. Prior operating licences granted prior to the entry into force of this Royal Decree shall be subject, for renewal or modification, to the arrangements provided for in Chapter II, at the time required in accordance with the regulations. Delete as applicable	the entry into force of this Royal Decree are considered valid. However, the renewal or modification of these licences after the entry into force of the Royal Decree, will comply with the provisions of the same as it will be the current regulation.	ASSOCIATION, ASEBIO
FOURTH TRANSITIONAL PROVISION.	(a) 'In accordance with Article 113(3)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 until Eudamed is fully operational...' The Royal Decree should indicate the email addresses to be used until EUDAMED is fully operational and what they are. Until EUDAMED is fully operational, confirm email addresses for: • Reporting of serious incidents for IVDs placed on the market: psvigilancia@aemps.es • Serious Incident Reporting for IVD in Investigation: psinvclinic@aemps.es	Not accepted. The provision refers to continuing the requirements already established in Royal Decree 1662/2000, for which current forms of communication and computer applications are used.	SPANISH ASSOCIATION OF INDUSTRY PHARMACISTS AEFI
FIFTH TRANSITIONAL PROVISION	The following text is proposed: Until the Marketing Register is operational, the notification of placing on the market and putting into service will be carried out in accordance with the provisions of Articles 9 and 10 of Royal Decree 1662/2000, of 29 September 2000 for *in vitro* diagnostic medical devices in lists A and B and devices for self-testing complying with Directive 98/79/EC and for *in vitro* diagnostic medical devices in classes B, C and D covered by Regulation (EU) 2017/746 on *in vitro*	Not accepted. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 provides, in Articles 26 and 30 thereof, for the establishment of a European database on medical devices called EUDAMED and the obligation for manufacturers to register devices in that database before placing them on the market.	FENIN

	diagnostic medical devices and eligible under Article 110 of Regulation (EU) 2017/746. Justification As established in the information note issued by the AEMPS PS-15/2022 and in the user manual for companies of the CCPS application for notification of placing on the market and/or putting into service of medical devices, with regard to the registration of devices, during the transitional period until EUDAMED is fully operational, all devices certified by a notified body (i.e. devices in Class B, Class C and Class D) placed on the market in Spain must make the notification of placing on the market and/or putting into service through the CCPS telematic application, in accordance with the provisions of Article 10 of Royal Decree 1662/2000. Because Article 10 of Royal Decree 1662/2000 only refers to devices included in Annex II and devices for self-testing, classes of devices difficult to extrapolate to those regulated under the IVD Regulation, we consider that this registration obligation for devices of classes B, C and D, established in an information note and an application user manual, should be laid down in a legislative provision.	EUDAMED is not currently fully operational and therefore, as provided for in Article 113(f) of the above-mentioned Regulation, the corresponding provisions of Directive 98/79/EC and, therefore, of Royal Decree 1662/2000, will apply to them in order to comply with the obligations of the Regulation relating to the exchange of information, in particular, information relating to performance studies, surveillance notifications, registration of devices and economic operators, and notifications of certificates. Specifically, as regards the registration of devices, during this transitional period until EUDAMED is fully operational, all devices in a category which must be certified by a notified body (i.e. devices in Class B, Class C and Class D) that are placed on the market in Spain, must make the notification of placing on the market and/or putting into service through the CCPS telematic application, in accordance with the provisions of Article 10 of Royal Decree 1662/2000.	
	In the case of a device notified voluntarily to EUDAMED six months or more before the Marketing Register becomes operational, what	Not accepted. The fourth and fifth transitional provisions are related. The	

	timeframe will companies have to make the notification to the Marketing Register once this becomes operational? It is not clear how the fees will be applied once the new Marketing Register enters into force. Currently, the IVDR devices of classes B, C and D that companies place on the market are being registered in a grouped way according to the information note issued by the AEMPS PS-15/2022. We understand that, once the new register enters into force, all devices registered in a grouped way can be transferred to the new platform without having to pay the fee again.	fourth provision indicates that until EUDAMED is fully operational the notification obligations of Royal Decree 1662/2000 will apply, so notifications will be made to the current register and not the Marketing Register. The Marketing Register will not be operational until EUDAMED is operational, so the period will run from that moment. However, supporting documents for notification to the register will be developed when both databases become operational. It is not considered a claim on the text itself. The question raised is recorded and will be taken into account for instructions regarding the operation of the register and in question-and-answer documents.	
SIXTH TRANSITIONAL PROVISION	In accordance with guideline 80 of the Guidelines on Legislative Drafting, having been fully cited above, the subsequent citation of 'Royal Decree 1662/2000 of 29 September' can be shortened in this case. The same is true of the citation contained in the	Accepted and modified in both transitional provisions	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	seventh transitional provision.		
EIGHTH TRANSITIONAL PROVISION	This provision reiterates the requirement for accreditation laid down in the proposed Article 9(3) and Article 5(5) of the Regulation, which is repetitive, and refers to a maximum period for compliance by reference to the entry into force of legislation, future and uncertain, which should be specified, indicating, at least, by what type of norm and which body must approve the implementing legislation to which it seeks to refer and, if possible, establishing the time period within which such legislation would be framed.	Accepted. The text is amended.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
NINTH TRANSITIONAL PROVISION	Article 113(3) of the Regulation, to whose deadlines this provision refers for the purposes of Article 9 of the draft, contains ten paragraphs (a) to (j), following the amendment made by Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022, with multiple dates of application, most of them already expired, so it is recommended to refer the transitional period to the specific dates of application, in this case, on devices manufactured and used exclusively in health institutions.	Not accepted. Although we understand the intent of the recommendation, these deadlines are again being subject to possible revision, so it seems to me a risk to indicate specific dates. On the other hand, the dates in the Regulations have been updated in the consolidated versions so they are not expired.	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH
SOLE REPEALING PROVISION	• At the beginning of the first paragraph, it should be specified that Article 110(3) and (4) is of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017. • The first subparagraph provides for the repeal of Article 20 and of the obligations relating to monitoring and performance evaluation studies laid down in the relevant annexes to Royal Decree 1662/2000 of 29 September 2000 'with	Not accepted. This reference is made immediately afterwards because the paragraph refers to Articles 110 and 112 of the Regulation. Partially accepted and the text is amended. The transitional periods of	GENERAL TECHNICAL SECRETARIAT. MINISTRY OF HEALTH

	effect from the later date of those referred to in Article 113(3)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017'. However, in transposing the provisions of Article 112(a) of the Regulation into the draft, the reference to Article 113(2) has been omitted, so the comparison of the earlier and later dates does not seem to make sense and reference should be made to the date of Article 113(3)(f) which refers to the date corresponding to six months after the date of publication of the notice referred to in Article 34(3) of the Regulation. • In the second subparagraph, the provisions of Article 112(b) of the Regulation are correctly transposed and the repeal is provided for 'from 18 months after the later date referred to in Articles 113(2) and 113(3)(f) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017'. However, the date provided for in Article 113(2) is a certain and expired date, 26 May 2022, so if only this date has expired and not that referred to in Article 113(3)(f), the reference to both the later date and Article 113(2) may be omitted.	Regulation 2017/746 have recently been amended and Article 112 no longer refers to Article 113(2), so the current wording would be correct. On the other hand, the second paragraph is also affected by the change of the regulation in July, so it is appropriate as indicated by the claim to delete the reference to 113(2) and align it with the new wording	
SOLE REPEALING PROVISION	In the sole repealing provision, the deletion of the numbering of paragraph 1 is suggested, as it only consists of one paragraph, in accordance with Guideline 31; it is suggested that it be subdivided into lower case letters, in	Accepted	GENERAL TECHNICAL SECRETARIAT DEPARTMENT OF HEALTH MADRID

	accordance with the provisions of that Guideline. Moreover, in accordance with Guideline 32, it is suggested not to use indentation in the enumeration contained in that provision.		
SOLE REPEALING PROVISION	As indicated in the descriptive part, the repealing provision maintains the validity of a limited number of provisions of Royal Decree 1662/2000 of 29 September 2000 on *in vitro* diagnostic medical devices. It is worth mentioning the merits of considering whether, for reasons of regulatory technique, it would perhaps be preferable to include the regulation that is not intended to be repealed in the draft Royal Decree under report, and completely repeal the aforementioned Royal Decree 1662/2000 of 29 September 2000.	Not accepted. These repealing provisions transpose into our legislation those provisions indicated in Article 112 of Regulation 2017/746. So that during the transitional periods the obligations established by the previous Directive on *in vitro* diagnostic devices and as transposed by Royal Decree 1662/2000, of 29 September 2000, apply.	MINISTRY OF INDUSTRY, TRADE AND TOURISM
SOLE REPEALING PROVISION	**FIFTH.- TRANSITIONAL REGIME FOR ADVERTISING, PROMOTION, INCENTIVES AND SPONSORSHIP OF SCIENTIFIC MEETINGS (sole repealing provision).** The sole repealing provision excludes from the repeal '*until the development of its specific legislation*', Articles 25, 26 and 27 of Royal Decree 1662/2000 of 29 September 2000 on *in vitro* diagnostic medical devices, concerning the advertising, promotion, incentives and sponsorship of scientific meetings. It should be borne in mind that Article 25(8) of Royal Decree 1662/2000 establishes the prohibition of advertising to the public for most devices for self-testing: *'8. It shall be prohibited to advertise to the*	Not accepted. The purpose of this Royal Decree is not to regulate the advertising of medical devices in general. There is another project underway that will regulate the advertising of medical devices specifically. Therefore, and until that Royal Decree on advertising is published, the current regulation of advertising of medical devices established in Articles 25, 26 and 27 of Royal Decree 1662/2000, of 29 September 2000, on *in vitro* diagnostic medical devices is maintained on a transitional basis.	ANEFP

	public devices for self-testing, with the exception of those intended for the diagnosis of pregnancy and fertility, devices for self-testing for the detection of HIV and devices for self-testing for COVID-19. It shall also be prohibited to advertise devices for genetic testing to the public.' In turn, Article 26(1) and (2) of Royal Decree 1662/2000 provides for the prohibition of offering incentives to pharmacists in relation to the promotion of devices For self-testing, as well as a prohibition on pharmacists accepting them: *'1. In the context of the promotion of in vitro diagnostic medical devices, it is prohibited to grant, offer or promise premiums, pecuniary advantages or advantages in kind to health professionals or any other person related to the use, prescription or dispensing of the devices as well as to their relatives and people with whom they live.* *2. The persons referred to in the previous paragraph may not apply for or accept any of the prohibited incentives.'* Therefore, **it would be necessary to expedite as much as possible the processing and approval of the future Royal Decree on the advertising of medicinal products and medical devices, in order to prevent the situation of regulatory interim and legal uncertainty that this measure may provoke**.		
SOLE REPEALING	(a) 'By way of derogation from Article 110(3)	Not accepted. Reference is already	SPANISH ASSOCIATION

PROVISION	and (4) concerning the transitional legal regime for devices, and considering the repeal of Directive 98/79/EC...' The Royal Decree should specify that: • Article 25 of Royal Decree 1662/2000 on advertising of *in vitro* diagnostic medical devices remains in force until the Royal Decree regulating the advertising of medicines and medical devices is implemented. • Article 26 of Royal Decree 1662/2000 on incentives remains in force until the Royal Decree regulating the advertising of medicinal products and medical devices is implemented. We recall that Article 26(1) and (2) of Royal Decree 1662/2000 prohibits the provision of incentives to pharmacists in connection with the promotion of *in vitro* diagnostic medical devices, as well as a ban on pharmacists accepting them: '1. In the context of the promotion of *in vitro* diagnostic medical devices it is forbidden to grant, offer or promise premiums, pecuniary advantages or advantages in kind to health professionals or any other person related to the prescription or dispensing of the devices, as well as their relatives and people they live with. 2. The persons listed in the previous paragraph may not request or accept any of the prohibited incentives.'	made, in point 3 of the sole repealing provision, to Articles 25, 26 and 27 of Royal Decree 1662/2000 on publicity.	OF INDUSTRY PHARMACISTS AEFI

SECOND FINAL PROVISION.	The Minister of Health is empowered to make such provisions as are necessary for the implementation and application of this Royal Decree and to adopt such provisions as, in relation to the classification or reclassification of *in vitro* diagnostic medical devices or the modification or adaptation, where appropriate, of the rules for the classification of these devices, are adopted at European Union level or are advisable for technical or scientific reasons. Justification: It is proposed that the wording be completed by including '*in vitro* diagnostic medical devices'	Accepted. Alternative text proposed The Minister of Health is empowered to make such provisions as are necessary for the implementation and application of this Royal Decree and to adopt such provisions as, in relation to the classification or reclassification of the devices covered by this Royal Decree or the modification or adaptation, where appropriate, of the rules for the classification of these devices, are adopted at European Union level or are advisable for technical or scientific reasons.	FENIN

LIST OF ENTITIES THAT HAVE SUBMITTED WRITTEN CLAIMS STATING THAT THEY ARE NOT COMMENTING ON THE TEXT

MINISTERIAL DEPARTMENTS

- MINISTRY OF TERRITORIAL POLICY – SECRETARY OF STATE FOR TERRITORIAL POLICY
- MINISTRY OF HEALTH – MINISTERIAL COMMITTEE FOR DIGITAL ADMINISTRATION
- MINISTRY OF CONSUMER AFFAIRS – TECHNICAL SECRETARY-GENERAL

BODIES

- COUNCIL OF CONSUMERS AND USERS (CCU)
- OFFICIAL COLLEGE OF NURSING MADRID

AUTONOMOUS COMMUNITIES

- CANTABRIA
- CASTILE AND LEÓN
- COMMUNITY OF VALENCIA
- EXTREMADURA
- BALEARIC ISLANDS
- MURCIA
- RIOJA
- BASQUE COUNTRY

INSTITUTIONS

- SPANISH SOCIETY OF MICROBIOLOGY (SEM)