EXTENDED REGULATORY IMPACT ANALYSIS REPORT

'Draft decree of the Governing Council partially implementing Law 13/2022, of 21 December, on pharmaceutical care and management in the Community of Madrid, covering opening hours, out-of-hours and holiday services, personalised dosage systems, pharmacy delivery services and dispensing with informed delivery to the patient's home, and the authorisation regime for the transfer of retail pharmacies.'

TABLE OF CONTENTS.

ANNEX: EXAMINATION OF THE ARGUMENTS PRESENTED DURING THE PUBLIC HEARING AND INFORMATION PROCEDURES.

EXECUTIVE SUMMARY SHEET.

Proposing Ministry / Body.	Ministry of Health. Directorate-General of Health Inspection and Management.	**Date**	**November 2025**
Title of the regulation.	Draft decree of the Governing Council partially implementing Law 13/2022, of 21 December, on pharmaceutical care and management in the Community of Madrid, covering opening hours, out-of-hours and holiday services, personalised dosage systems, pharmacy delivery services and dispensing with informed delivery to the patient's home, and the authorisation regime for the transfer of retail pharmacies in the Community of Madrid.		
Type of report.	Extended **X** executive ☐		
TIMELINESS OF THE PROPOSAL.			
Situation being regulated.	It addresses the partial development of Law 13/2022, of 21 December, on pharmaceutical care and management with regard to the matters mentioned in the title of the draft decree, the incorporation of which into a single regulatory instrument allows for clear and consistent regulation, facilitating both its practical application and adherence to its provisions by those subject to it.		

Objectives pursued.	1. The purpose of regulating normal and extended opening hours, as well as the organisation of out-of-hours services and holiday periods for pharmacies, is to ensure that pharmaceutical services are provided to the public 365 days a year without compromising quality and safety. 2. To ensure that retail pharmacies are adequately staffed in all cases for providing individualised, safe and coordinated pharmaceutical care, thereby contributing to the goal of integrated, patient-centred healthcare management, which will enable us to make constant progress in improving health outcomes in our healthcare system. 3. To improve the adherence to, effectiveness of and safety of pharmacological treatments for individuals through personalised dosage systems, particularly those aimed at chronic, polymedicated, and dependent patients. 4. To facilitate access to pharmacy delivery services for people who are dependent, disabled or have lost their functional autonomy, and who have severe difficulties getting to a pharmacy. 5. To organise and streamline the procedure and requirements for obtaining administrative authorisation for transfers of retail pharmacies, thereby advancing the strategy of simplifying and reducing administrative burdens, a fundamental tool for improving the productivity and competitiveness of our economy.

Main alternatives considered.	The first final provision of Law 13/2022, of 21 December, empowers the Governing Council and the head of the competent Regional Ministry to issue the general provisions necessary for ensuring the effective implementation and enforcement of the legal provisions. Given the content of this law, it should be noted that some of its provisions require further clarification to enable their practical application. It is therefore necessary to draw up a regulatory standard. Thus, taking into account the complexity and detail of the provisions of the law to be developed and, on the other hand, the scope of the regulations affected by this draft legislation, it is considered that a decree of the Governing Council is the appropriate type of regulation to be drawn up; this formula is also the one that best allows the objectives of good regulation to be achieved in this case. For these same reasons, a non-regulatory alternative has not been considered.
CONTENT AND LEGAL ANALYSIS.	
Type of regulation.	Decree of the Governing Council
Structure of the regulation.	The draft decree consists of a descriptive part and another operative part, consisting of 49 articles distributed across six chapters, two additional provisions, three transitional provisions, one repealing provision, two final provisions and three annexes.
Reports on the draft.	When drawing up the draft, all mandatory reports and opinions will be collected, as well as any optional ones deemed necessary. Thus, optional consultations have been held with the management centres of the Regional Ministry of Health. Namely: - the Directorate-General of Public Health, - the Directorate-General of Research and Teaching, - the Directorate-General of Humanisation, Care and

	Patient Safety. - Likewise, optional reports of the Madrid Health Service and the National Commission for Markets and Competition have been collected. The following have been requested on a mandatory basis: - Report from the Directorate-General of Cooperation with the State and the European Union of the Regional Ministry of the Presidency, Justice and Local Administration. - Report on regulatory coordination and quality from the General Technical Secretariat of the Regional Ministry of the Presidency, Justice and Local Administration. - Report from the Directorate-General of Citizen Services and Transparency, of the Regional Ministry of the Presidency, Justice and Local Administration. - Reports from the general technical secretariats of the regional ministries. - Economic impact report from the Directorate-General of Economy (currently, Directorate-General of Economy and Industry) of the Regional Ministry of Economy, Finance and Employment. - Report on gender impact from the Directorate-General of Women of the Regional Ministry of Family, Youth and Social Affairs. - Report on the impact on childhood, adolescence and family from the Directorate-General of Children, Family and Birth Promotion, of the Regional Ministry of Family, Youth and Social Affairs. - Report from the Consumer Council of the Community of Madrid. - Public health impact report from the Directorate-General of Public Health of the Regional Ministry of Health. - Report from the Directorate-General of Digital Strategy of

	the Regional Ministry of Digitisation. - Report from the Directorate-General of Human Resources of the Regional Ministry of Economy, Employment and Finance. At the appropriate procedural stage, the following mandatory reports must also be requested, namely: - Report from the General Technical Secretariat of the Regional Ministry of Health. - Communication to the European Commission pursuant to the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015. - Report of the Attorney General. - Opinion of the Legal Advisory Commission.
Participation procedures: public consultation, hearing, and public information.	<u>Public Consultation:</u> It has been submitted to public consultation in accordance with Articles 60.1 of Law 10/2019 of 10 April 2019 on transparency and participation in the Community of Madrid, and Articles 4(2)(a) and 5 of Decree 52/2021, of 24 March, of the Governing Council, which was conducted through the Transparency Portal at https://www.comunidad.madrid/transparencia/, during the period from 18 July to 8 August 2024, inclusive. Contributions have been received from the following organisations and individuals: - Spanish Society of Hospital Pharmacies (SEFH) and the Madrid Society of Hospital Pharmacists (SMFH); - Haemophilia Association of the Community of Madrid; - Adefarma; - General Council of the Official Colleges of Pharmacists (CGCOF); - Official College of Pharmacists of Madrid (COFM);

	- Cofares; - Federation of Spanish Pharmacists (FEFE); - Spanish Society of Retail Pharmacies (SEFAC); - Workers' Commissions (CCOO) of Madrid; - Association of Innovative Pharmacists (AFIN); - European Association for automated dose dispensing (EAADD). - Alliance Healthcare Spain; - and 15 individual pharmaceutical professionals. Public Hearing and Information: The draft legislation will be submitted to public hearing and information procedures in accordance with the provisions of Articles 60(2) of Law 10/2019, of 10 April, and Articles 4(2)(d) and 9 of Decree 52/2021, of 24 March,. To this end, it was published on the Transparency Portal at https://www.comunidad.madrid/transparencia, between 29 July and 19 August 2025, with the result set out in the Annex to this report. Likewise, the report of the following entities has been collected, which have issued it with the result that can be seen in the Annex to this report: - Official College of Physicians of Madrid; - Official College of Qualified Nurses of Madrid; - Official College of Pharmacists of Madrid; - General Pharmaceutical Council of Spain; - Federation of Spanish Pharmacists; - Spanish Society of Primary Care Pharmacists; - Spanish Society of Hospital Pharmacies; - Association of Pharmaceutical Entrepreneurs of Madrid; - Spanish Society of Rural Pharmacies.

<table>
<tr><th colspan="3">IMPACT ANALYSIS.</th></tr>
<tr><td>Compliance with the distribution of powers.</td><td colspan="2">This Royal Decree is issued under Article 149(1) (16) of the Spanish Constitution, exercising the powers referred to in Article 27(12) of the Statute of Autonomy of the Community of Madrid.

For its part, in accordance with Article 21(g) of Law 1/1983 on the Government and Administration of the Community of Madrid, the responsibilities of the Governing Council of the Community of Madrid include ‘approving, by means of decree, the regulations for the implementation and enforcement of the laws emanating from the Assembly, as well as the laws of the State, when that power is to be exercised by the Community of Madrid by virtue of the Statute of Autonomy, or by delegation or transfer, and exercising in general the regulatory power in all cases in which it is not specifically attributed to the president or to the councillors.’</td></tr>
<tr><td rowspan="2">Economic and budgetary impacts.</td><td>General impact on the economy:</td><td>It affects the professional sector included in the scope of application of the draft decree, in the terms set out in the SME test incorporated into this report.</td></tr>
<tr><td>With regard to competition</td><td>X The regulation has no significant impact on competition.

☐ The regulation has positive effects on competition.

☐ The regulation has negative effects on competition.</td></tr>
</table>

	With respect to administrative burdens	☐ It entails a reduction in administrative burdens. Estimated total: _____ X It incorporates new administrative burdens. Estimated total: EUR 109 598 ☐ It does not affect administrative burdens.
	From a budgetary perspective, the regulation does not affect the budgets of the Community of Madrid.	☐ Involves an expense: Estimated total: _____ ☐ Involves a revenue. Estimated total:_____
Gender impact.	The regulation has a gender impact	Negative ☐ None X Positive ☐
Impact on childhood, adolescence and the family.	The regulation has an impact on childhood, adolescence and the family	Negative ☐ None X Positive ☐

1. INTRODUCTION.

This Regulatory Impact Analysis Report has been prepared in accordance with the provisions of Decree 52/2021 of 24 March 2021 of the Governing Council, which regulates and simplifies the procedure for drafting general regulatory provisions in the Community of Madrid, and in accordance with the criteria established in the 'Guide for the drafting and processing of general provisions in the Community of Madrid'.

In accordance with the provisions of Article 7(1) of Decree 52/2021, of 24 March, it is appropriate to prepare this extended Regulatory Impact Analysis Report (MAIN), as it falls within the cases provided for in the aforementioned decree, which establish this obligation. In particular, this requirement applies to preliminary draft laws, draft legislative decrees and executive regulations that have a significant impact of an
economic or budgetary nature.

2. TIMELINESS OF THE PROPOSAL.

2.1 Aims and objectives

The entry into force of Law 13/2022, of 21 December, on pharmaceutical care and management in the Community of Madrid brought about a significant change in the opening hours of pharmacies, as it determined the partial repeal of Decree 259/2001 of 15 November 2001, which regulates opening hours, out-of-hours and holiday services for retail pharmacies in the Community of Madrid. This repeal had a unique impact on the articles related to the mandatory presence of the pharmacist in the pharmacy and to the schedule of opening hours existing until that time. Nevertheless, certain articles that specifically regulate out-of-hours and holiday services have remained in force. Updating these provisions in accordance with the new flexible working hours regime and the criteria set out in Article 26 of Law 13/2022, of 21 December, which now govern the organisation of out-of-hours services, is imperative.

In the field of pharmaceutical care, Law 13/2022, of 21 December, marks a milestone by addressing both personalised dosage systems to improve medication adherence and prevent problems related to medicinal products, as well as the regulation of pharmacy delivery services, recognising the fundamental role of the pharmacist in dispensing, and reserving the task of delivering medicinal products to the patient's home to the staff of the retail pharmacy, without forgetting pharmacy delivery services from hospital institutional pharmacies. This requires detailed regulation of both services, which can only be addressed at the present regulatory level.

On the other hand, in the chapter on transfers of retail pharmacies, the aforementioned legal standard addresses its regulation by establishing specific conditions, requirements and limitations. These represent a significant change from the previous regulations, stipulating that the effects of the transfer are linked to the legal act of the transfer once it has been documented before the competent authority in charge of pharmaceutical regulation. This contrasts with the previous procedure, which deferred the effectiveness of the legal transaction of the transfer until the moment of notification of the administrative decision agreeing to it.

As indicated above, the purpose of this regulation is to partially implement Law 13/2022, of 21 December, addressing the detailed regulation of certain aspects of pharmaceutical management and activity, notably the following: the regulation of extended opening hours and out-of-hours and holiday services; the requirements for the preparation and delivery of personalised dosage systems; pharmacy delivery services; and, finally, the regulation of the transfer of retail pharmacies in the Community of Madrid. The incorporation of the regulation of these matters into a single regulation allows for clearer and more consistent regulation, facilitating its interpretation and application for citizens, pharmaceutical professionals and health authorities alike, while also helping to streamline the regulatory process by addressing various aspects of the law comprehensively in a single regulatory document.

2.2 Adherence to the principles of good regulation

The content of the regulation complies with the principles of good regulation laid down in Article 129 of Law 39/2015, of 1 October, on the common administrative procedure of public administrations, and in Article 2 of Decree 52/2021, of 24 March, of the Governing Council, which regulates and simplifies the procedure for drawing up the general regulatory provisions of the Community of Madrid.

In accordance with the principles of necessity and effectiveness, this draft legislation is justified on grounds of general interest and is based on a clear identification of the objectives pursued, constituting the most appropriate instrument for ensuring the achievement of this interest, which is to enable the provision of pharmaceutical care in line with the new needs of citizens and appropriate to advances in the field of health management and care, and capable of meeting society’s growing healthcare demands, while ensuring effective, rational and sustainable pharmaceutical provision.

Likewise, the principle of proportionality has been complied with, in that the proposed regulatory instrument is the most appropriate for ensuring that the objectives being pursued are achieved, since there are no less restrictive and less distortive measures that would allow the same result to be obtained.

In order to guarantee the principle of legal certainty, this draft decree forms part of the set of regulations that governs the field of healthcare within our legal system. Likewise, in terms of administrative procedure, this draft legislation incorporates, as procedures other than those provided for in Law 39/2015, of 1 October, only those that are essential due to the unique nature of the subject matter, as is the case with transfers of retail pharmacies. In short, it respects the distribution of powers and is intended to be permanent in order to contribute to a stable and integrated regulatory framework.

The principle of transparency has been complied with, as the public consultation, public hearing and information procedures have been carried out through the Transparency Portal, in accordance with the provisions of Article 60(1) and (2) of Law 10/2019, of 10 April, on transparency and participation in the Community of Madrid, as well as Articles 4(2)(a) and (d), 5 and 9 of Decree 52/2021, of 24 March. Furthermore, once the regulation has been approved, it will be published on the Transparency Portal.

With regard to the principle of efficiency, the regulatory initiative avoids unnecessary or incidental administrative burdens, despite incorporating some additional burdens in relation to the previous situation, and rationalises the management of public resources in its application. However, as it does not affect present or future public expenditure or revenue, it is not necessary to quantify its impact and effects on the present and future expenditure and revenue of the Community of Madrid.

2.3 Analysis of alternatives

This general provision responds to the mandate set out in the first final provision of Law 13/2022, of 21 December, according to which '*the Governing Council and the head of the Regional Ministry with competence in health matters, within the scope of their powers, are empowered to issue all regulatory provisions necessary for the implementation of this law, as well as to agree on the necessary measures to ensure its effective implementation and enforcement*.'

This mandate, which is consistent with the content of this law, some of whose provisions require further clarification to enable their practical application, makes it necessary to draw up a regulatory standard. Thus, taking into account the complexity and detail of the provisions of the law to be developed and, on the other hand, the scope of the regulations that will be affected by this draft legislation, it is considered that, in accordance with the provisions of Article 21(g) of Law 1/1983, of 13 December, a decree of the Governing Council is the appropriate type of regulation to be drawn up; this formula is also the one that best allows the objectives of good regulation to be achieved in this case.

For these same reasons, a non-regulatory alternative has not been considered.

2.4 Inclusion in the Regulatory Plan of the Community of Madrid for the 13th Legislature (2023–2027)

The approval of the decree that is the subject of this report is provided for in the section relating to the Regional Ministry of Health of the 'Regulatory Plan of the Community of Madrid for the 13th Legislature (2023–2027)', approved by Agreement of the Governing Council of 20 December 2023.

3. CONTENT AND LEGAL ANALYSIS.

3.1 Content of the draft decree

This draft decree is structured as 49 articles distributed across six chapters, two additional provisions, three transitional provisions, one repealing provision, two final provisions and three annexes.

Chapter I comprises the general provisions relating to the purpose and scope of application.

Chapter II is divided into three sections. Section 1 lays down the provisions relating to the operating hours of retail pharmacies, and those relating to determining the number of pharmaceutical professionals required. It also details the system for reporting opening hours. This is to regulate the necessary number of pharmaceutical staff in retail pharmacies during extended opening hours beyond what is expressly provided for in Article 18(4) of Law 13/2022, in order to ensure the effective fulfilment of the professional function inherent to pharmaceutical dispensing. This is based on Article 13(2) of Law 13/2022, of 21 December, and Article 5 of Law 16/1997 of 25 April 1997 on the regulation of retail pharmacy services, according to which the presence and professional practice of the pharmacist is an essential requirement for the dispensing of medicinal products to the public. In addition, Article 11(3)(p) of Law 13/2022, of 21 December, expressly provides that: '*Retail pharmacies must be staffed with a sufficient number of pharmacists to ensure that, in accordance with the established opening hours, at least one pharmacist is present and available to provide professional services at all times while the retail pharmacy is open to the public*.' It is important to note that the intervention of auxiliary or technical staff does not, in any case, replace the direct availability of the pharmacist while the retail pharmacy remains open to the public, nor does it limit their professional responsibility. Furthermore, the proposed wording is in line with the provisions of Article 18(4) of Law 13/2022, of 21 December, regarding special circumstances such as the age of the owner or the retail pharmacy's connection to in-house dispensaries or rural dispensaries, and is consistent with the principles established in Articles 11 and 13 of Law 13/2022, of 21 December. Its objective is to ensure continuous, effective and professional pharmaceutical care throughout opening hours. This regulation thus reinforces the obligation to ensure adequate staffing levels in retail pharmacies as an essential condition for quality of service and effective fulfilment of the healthcare function inherent to the dispensing of medicinal products, especially during extended opening hours that exceed the standard 40-hour working week.

Section 2 regulates the general criteria for out-of-hours services, their organisation, the provision of local out-of-hours services, changes to out-of-hours services, out-of-hours services in health emergencies and, finally, public information about these services. This chapter concludes with Section 3, which refers to retail pharmacy holidays and the criteria for guaranteeing service.

Chapter III focuses on personalised dosage systems (PDS) and is organised into four sections. Section 1 establishes the general conditions for the provision of the service by both institutional pharmacies and retail pharmacies in the Community of Madrid, which may commence the activity after submitting a declaration of responsibility, with special emphasis on the fact that this activity must be carried out entirely and exclusively by the retail pharmacy itself or by the institutional pharmacy that has dispensed the medicinal products covered by this professional service, without in any case being able to entrust the preparation of these PDS to another pharmacy, an institutional pharmacy or a third party, nor prepare them for third parties; and that they will be prepared only with previously dispensed medicines. Section 2 refers to the technical requirements to be met for the provision of the service and the standards for the preparation and delivery of PDS. Section 3 describes the requirements that pharmacies must comply with in terms of facilities, equipment, tools, documentation, the standard working procedure that must govern the performance of this activity and, finally, the register of actions whose purpose will be to facilitate the verification of compliance with the conditions for the preparation of PDS, as well as the traceability of the medicinal products used. Section 4 is devoted to the activity itself, first addressing medicinal products that can be prepared in PDS, then focusing on assessing patient suitability, obtaining informed consent and patient records, and then regulating the preparation of dosing devices, labelling, pre-delivery verification and delivery of devices. This regulation concludes with the disposal of waste resulting from this activity. In short, the necessary guidelines are established to ensure quality and safety throughout the process of preparing and delivering personalised dosage devices.

Chapter IV specifies the scope of pharmaceutical care and dispensing with informed home delivery, distinguishing between two modalities, namely: that provided by hospital pharmacies, which may include remote assistance, aimed at patients who require hospital-dispensed medicines and subject to specific protocols established by the institutional pharmacies; and that provided by retail pharmacies, which may include home delivery of prescription medicines, non-prescription medicines, medical devices that do not require custom adaptation, and PDS. With regard to the procedure, it establishes that retail pharmacies that intend to offer this service are obliged to submit a declaration of responsibility; and, secondly, that they are obliged to make an annual declaration of the pharmacy delivery services provided by both the retail pharmacy and the hospital institutional pharmacy. This regulation is supplemented by a detailed description of the process of dispensing, preparing and delivering orders in relation to the retail pharmacy, highlighting the essential role of the pharmacist and ensuring that this service does not result in an increase in the price of medicinal products or medical devices or entail additional costs for the user.

Chapter V focuses on regulating the authorisation regime for the transfer of retail pharmacies, addressing aspects relating to the authorisation application, the documentation required to initiate the procedure, the authorisation decision and the documentation that must be submitted after the authorisation decision and which must determine the effectiveness of the transfer. The possibility of maintaining certification for the preparation of compounded medicines and officinal preparations is being considered, as well as for those sections of the retail pharmacy that were authorised, thereby guaranteeing the continuity of the activity that the retail pharmacy had been carrying out if the new owner so wishes.

Finally, Chapter VI is dedicated to the disciplinary regime, with express reference to Law 13/2022, of 21 December, ,and Royal Legislative Decree 1/2015, of 24 July.

The operative part of the draft concludes with the additional provisions, relating to updates to the standard forms for the declarations of responsibility to be submitted pursuant to the provisions of this decree, with express mention of the inclusive language used in the text of this regulation. The transitional provisions determine the legal regime that will govern applications submitted prior to the entry into force of this regulation, as well as the regulations applicable to procedures currently in progress. Lastly, the repealing provision expressly declares that Decree 259/2001, of 15 November, is no longer effective. The final provisions empower the head of the regional ministry responsible for health matters to issue the regulations necessary for the implementation of this decree, and establish that it shall enter into force on the day following its official publication in the Official Gazette of the Community of Madrid. The draft also includes the corresponding annexes containing the standard form for the declaration of responsibility for the preparation of PDS, and the declaration of responsibility for the provision of pharmaceutical care and dispensing with informed delivery to the patient's home, in two versions for retail and hospital institutional pharmacies.

Among the main changes introduced by the decree are the following:

More flexible regulation of the operating hours of retail pharmacies, including variable time slots and extended hours, ensuring that at least one registered pharmacist is present at all times, a new organisation of the out-of-hours service, which includes modalities adapted to territorial and population characteristics, as well as exceptional mechanisms for health emergencies, and the organisation of retail pharmacy holidays, guaranteeing continuity of service throughout the territory.

It addresses the regulatory implementation of of personalised dosage systems (PDS) as a professional service to improve medication adherence and safety in the use of medicinal products, regulating in detail the conditions of provision, the technical and professional requirements, and guarantees of quality, safety and traceability. It is expressly provides that the preparation of PDS must be carried out entirely and exclusively within the retail pharmacy that dispensed the medicinal products or within the authorised institutional pharmacy of the residential centre.

On the other hand, and as the main new feature, dispensing with informed delivery to the patient's home, both from retail pharmacies and from hospital institutional pharmacies, is regulated, establishing specific guarantees to ensure the traceability, quality and professional intervention of the pharmacist, without this entailing an additional cost for the patient. In addition, there is a simplified regime for the transfer of retail pharmacies, which reduces administrative burdens through the use of declarations of responsibility and ensures the continuity of authorised services.

A clear and systematic penalty system is incorporated, with express reference to basic state and regional regulations, reinforcing control capacity and legal certainty in the exercise of pharmaceutical activity.

In its final section, the decree establishes mechanisms for updating standardised models, regulates the use of inclusive language, sets out the transitional regime for procedures initiated before its entry into force, and determines the effective date of application as the day following its publication in the Official Gazette of the Community of Madrid.

3.2 Legal analysis

The legal framework governing the subject matter addressed in this draft regulation consists of the following national and regional regulations. Namely:

Law 14/1986, of 25 April, on general health which, in relation to pharmaceutical management, establishes and determines, in Article 103(1)(a) and (b), which healthcare establishments are responsible for carrying out healthcare activities or functions relating to the custody, storage and dispensing of medicinal products. It notes, among them and specifically, that pharmacies are subject to healthcare planning in the terms established by the special legislation on medicinal products and pharmacies.

Law 16/1997, of 25 April, on the regulation of retail pharmacy services, which established a basic legal framework for the regulation of retail pharmacies, in accordance with the provisions of the aforementioned Article 103 of the General Health Law, a regulation to be developed by the Autonomous Communities. This law sets out the legal definition of a retail pharmacy and its functions, stating that the autonomous communities establish shall specific planning criteria for the authorisation of retail pharmacies. To this end, in its first final provision, it states that articles and, where appropriate, sections constitute basic state legislation on health.

Subsequently, various basic state regulations have had an impact on specific aspects of this subject, including, among others, Law 16/2003, of 28 May, on cohesion and quality in the national health system, particularly Chapter V; Royal Decree 1277/2003, of 10 October, establishing the general bases for the authorisation of health centres, services and establishments; and Royal

Decree-Law 16/2012, of 20 April, on urgent measures to ensure the sustainability of the National Health System and improve the quality and safety of its services.

Finally, Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, a basic regulation and necessary legal reference for Law 13/2022, of 21 December, which gives rise to this draft legislation.

At the regional level, it is essential to refer to Law 12/2001, of 21 December, on health management in the Community of Madrid, which contains the general regulations governing all actions that enable the health system of this autonomous community to enforce the right to health protection enshrined in Article 43 of the Spanish Constitution. In the field of pharmaceutical services, the aforementioned Law 13/2022, of 21 December, on Pharmaceutical Management and Care in the Community of Madrid is an essential reference, and the present regulation is aimed at its partial implementation.

From the point of view of its purpose, this draft contains the partial development of certain aspects of the legal regime governing pharmacies regulated by Law 13/2022, of 21 December. Since it is two years after this law came into force, and given that many of its provisions are conditional – if not contingent – on further regulatory development in order to be fully effective (thus resulting in a higher quality of pharmaceutical service for citizens), there is now unquestionably a need for regulations to implement this development. Moreover, the current situation is the optimal time for this, as this draft joins a list of regulatory initiatives that aim to advance the constant improvement of pharmaceutical care in the Community of Madrid.

With regard to the regulations affected by the provisions contained in this draft legislation, it is worth mentioning Decree 259/2001, of 15 November, which regulates opening hours, out-of-hours services and holidays for retail pharmacies in the Community of Madrid, which will be repealed by this draft decree.

In relation to the rest of the legal system, as explained above, this draft legislation is incorporated into the catalogue of regulations that make up both the legal framework for medicinal products, in its three-pronged approach of authorisation and marketing, inclusion in the pharmaceutical service of the National Health System, and medical prescription and dispensing to patients, and the set of regulations that make up the legal framework for the management of pharmacy establishments in the Community of Madrid.

4. COMPLIANCE OF THE REGULATION WITH THE DISTRIBUTION OF POWERS.

The draft complies with the distribution of powers established in Article 149(1) (16) of the Spanish Constitution, in the Statute of Autonomy of the Community of Madrid, approved by Organic Law 3/1983, of 25 February, and in the specific rules on the subject outlined in the preceding sections of this report.

Indeed, in accordance with the distribution of powers in the field of healthcare as laid down in the aforementioned Article 149(1) (16) of the Spanish Constitution, the State has exclusive competence in matters relating to medicinal and pharmaceutical products, in setting their price and financing, and in user contributions. However, with regard to the public health system and pharmaceutical provision and management, state competence is fundamental, with the State being responsible for approving basic regulations, while the regulation of retail pharmacies as health establishments falls within the competence of the autonomous communities. This competence, in the case of the Community of Madrid, has been assumed in its Statute, with Article 27(12) declaring that this community is responsible for legislative development, regulatory power and enforcement in matters of pharmaceutical management and pharmaceutical establishments.

5. IMPACT ANALYSIS AND DETECTION AND MEASUREMENT OF ADMINISTRATIVE BURDENS

5.1 Economic impact and SME test

The draft regulation does not affect the prices of products and services or result in an increase in the productivity of workers and companies. Nor are there any significant effects on innovation, although it is expected to have an impact on employment, with an increase in the hiring of pharmaceutical professionals due to the requirement for '*the constant presence and availability of at least one properly identified registered pharmacist throughout the time that the retail pharmacy provides service to the public, whether during ordinary opening hours, extended opening hours or out-of-hours service.'* This requirement will be particularly relevant for new hires in cases of extended opening hours, thus affecting companies in the sector that are classified as SMEs due to their size and turnover. That is why the mandatory SME test has been carried out in accordance with the model approved by Resolution of the Directorate-General of Economy (currently, Directorate-General of Economy and Industry) of 13 May 2024, which is reproduced below:

1. Does the draft regulation have an impact on economic activities? Yes.
2. Does the draft regulation affect SMEs? Yes.
3. Has the business sector affected by the draft regulation been consulted through a prior public consultation? Yes.

4. In the course of the hearing, will at least the business associations representing the majority of SMEs in the sector concerned be consulted? Yes.
5. Have the administrative burdens arising from compliance with the proposed measures been quantified? Yes.
6. Have the most relevant financial costs or substantive costs of the draft regulation been quantified? No.

   Comments: although the quantification referred to in the question has not been carried out, data has been collected that allows us to estimate that the hiring of pharmacists once the draft regulation comes into force would amount to a maximum of 1 826. This data has been obtained in accordance with the following parameters:

   According to the operating hours of retail pharmacies reported for the 2025 financial year, the distribution by time slots would be as follows:

   a) Retail pharmacies open to the public less than 55 hours a week: 1 119
   b) Retail pharmacies with reported operating hours of between 56 and 95 hours: 1 706
   c) Retail pharmacies with reported operating hours exceeding 95 hours: 60

      Therefore, according to the wording of the draft regulation, the pharmacies referred to in (a) above would only need one licensed pharmacist; those referred to in (b) would need at least one licensed pharmacist and one assistant pharmacist; and those referred to in (c) would need one licensed pharmacist and two assistant pharmacists.

      Thus, assuming, for the sole purpose of this estimate, that on the date the draft regulation comes into effect, the retail pharmacies referred to in (b) and (c) will only have one licensed pharmacist (which does not correspond to reality), in order to comply with the new draft regulation, 1 706 assistant pharmacists would be required for those under (b) and 120 for those under (c), giving a total of 1 826 new pharmacists.

      Finally, it should be noted that the average salary of an assistant pharmacist in 2025, in accordance with the XXV State Collective Agreement for Pharmacies, is EUR 2 179.77 per month for fourteen payments per year (EUR 30 516.78 per annum), on top of which 23.60 % of the above sum is paid as the employer's contribution to the general social security system.
7. Is it ensured that the costs incurred for SMEs do not entail competitive disadvantages in relation to larger companies? Yes.
8. Is it ensured that SMEs can operate under conditions of fair competition in the market? Yes.
9. Has any option been assessed for compliance with the regulation for smaller companies to be simplified or made more flexible, while achieving the public goals pursued? No, since the adoption of the extended opening hours is voluntary for companies and the provision of PDS services and pharmacy delivery services is also optional.
10. Have any of these regulatory options, which are more flexible for SMEs, been adopted in the current draft regulation? No.

11. Has the proposal been drafted in simple language that is comprehensible for a person without specific legal training? Yes.

In relation to the EU economy and other economies, the draft has no impact.

Nor is there anticipated to be any effect on competition. With regard to market unity and free competition, within the meaning of Law 20/2013, of 9 December, on the guarantee of market unity, a report has been obtained from the National Commission for Markets and Competition, issued on 15 October 2025.

In accordance with the provisions of Article 7(3)(a) of Decree 52/2021, of 24 March, as well as Article 33 of Law 11/2022, of 21 December, on urgent measures to boost economic activity and modernise the administration of the Community of Madrid, the draft has been submitted to the Directorate-General of Economy (currently, Directorate-General of Economy and Industry) of the Regional Ministry of Economy, Finance and Employment, which issued its report on 7 June 2025.

5.2 Budgetary impact

The main purpose of this draft is to draw up detailed regulations for the provisions of Law 13/2022, of 21 December, on certain matters, the practical application of which requires a greater level of detail.

This regulation does not affect the expenditure budget of the Government of the Community of Madrid, nor does it involve any other type of extra-budgetary expenditure. It drafting therefore does not entail any cost or require investment.

Similarly, the content of the draft has no impact on local authority budgets, so any potential negative financial effects resulting from the planned legal changes can be ruled out.

Given the lack of impact of the regulation on the revenue and expenditure of the budget of the Community of Madrid, it is considered unnecessary to obtain a report from the Directorate-General of Budgets of the Regional Ministry of Economy, Finance and Employment.

5.3 Gender impact.

In accordance with the provisions of Article 7(3)(c) of Decree 52/2021, of 24 March, in conjunction with Article 19 of Organic Law 3/2007, of 22 March, on the effective equality of men and women, and Article 9(1)(b) of Decree 241/2023, of 20 September, of the Governing Council establishing the organisational structure of the Regional Ministry of Family, Youth and Social Affairs, the mandatory gender impact report was issued to the Directorate-General of Women of the Regional Ministry of

Family, Youth and Social Affairs on 2 June 2025, concluding that the gender impact of the draft is neutral.

5.4 Impact on childhood, adolescence and the family.

By virtue of the provisions of Article 7(3)(c) of Decree 52/2021, of 24 March, in conjunction with Article 22 *quinquies* of Organic Law 1/1996, of 15 January, on the legal protection of minors, partially amending the Civil Code and the Law of Civil Procedure, and the tenth additional provision of Law 40/2003, of 18 November, on the Protection of Large Families, and Article 47 of Law 4/2023, of 22 March, on Rights, Guarantees and Integral Protection of Children and Adolescents of the Community of Madrid, and Article 7(15) of Decree 241/2023, of 20 September, a report was issued on 3 June 2025 by the Directorate-General of Childhood, Family and Birth Promotion of the Regional Ministry of Family, Youth and Social Affairs, which stated that no impact was expected on family.

5.5 Public health impact report

A positive impact on public health is expected as the personalised dosage system will lead to an improvement in the adherence, effectiveness and safety of pharmacological treatments, in particular those aimed at chronic, polymedicated and dependent patients. This, together with pharmacy delivery services, which facilitates access to pharmaceutical care for people who are dependent, disabled or have lost their functional autonomy and have severe difficulties in travelling to a pharmacy, will undoubtedly lead to an improvement in citizens' health.

That is why, by virtue of the provisions of Article 7(3)(c) of Decree 52/2021, of 24 March, the corresponding report of the Directorate-General of Public Health of the Regional Ministry of Health was issued on 27 June 2025 containing a positive opinion.

On the other hand, with regard to the potential benefits for consumers and users in general, it should be noted that the regulation of various aspects of pharmaceutical management, such as extended opening hours, as well as the preparation of PDS and pharmacy delivery services, will undoubtedly improve services for people taking multiple medications and those with difficulty travelling to outpatient clinics.

In this regard, a report has been requested from the Consumer Council of the Community of Madrid, which issued a favourable opinion on the draft on 23 June 2025.

5.6 Detection and measurement of administrative burdens

An administrative burden is understood to be any activity of an administrative nature that must be carried out by an undertaking or an individual in order to fulfil the obligations arising from the

regulation in question, including the tasks necessary to make an application. In accordance with this definition, it is expected that this draft legislation will entail an increase in administrative burdens in relation to the adoption of extended opening hours for retail pharmacies, as explained above, as well as in relation to pharmacy delivery services activities. With regard to the other activities regulated by the law, no new administrative burdens have been detected other than those arising from the application of Law 13/2022, of 21 December, on pharmaceutical care and management in the Community of Madrid, which this proposed legislation implements.

The analysis of the burdens has been carried out in accordance with the Simplified Method for Measuring Administrative Burdens and their Reduction, referred to in Annex V to the Methodological Guide for the Preparation of the Regulatory Impact Analysis Report, approved by Agreement of the Council of Ministers of 11 December 2009.

This method analysed:

a) Opening hours, out-of-hours services and holidays:

No additional administrative burdens are imposed beyond those that already exist, except with regard to the hiring of assistant pharmacists when necessary due to the opening hours adopted by the retail pharmacy. Thus, Table I quantifies the burdens associated with the administrative procedures arising from these hirings.

TABLE I
ADMINISTRATIVE COSTS ARISING FROM THE OBLIGATION TO HIRE ASSISTANT PHARMACISTS.

Requirement	Total number of documents/actions	Unit cost	TOTAL
Notification of new registrations of assistant pharmacists (Article 18(d))	1 per pharmacist hired	EUR 2 x 1 826 hirings in the Community of Madrid	EUR 3 652
Total of the procedure			EUR 3 652

b) Personalised Dosage Systems (PDS):

As regards personalised dosage systems, the declaration of responsibility prior to the start of the activity contributes to speeding up the procedures for starting the activity. With regard to the obligations established for the preparation of PDS, the rigour required in the actions to be carried out by institutional pharmacies and retail pharmacies in the preparation of these devices (*e.g.* the implementation of a PNT and a quality system) does not represent a greater burden than that

which was already required in practice following the publication of the Criteria Agreed Between the Different Autonomous Communities and the AEMPS for the Preparation of Personalised Dosage Systems (PDS) by Retail Pharmacies.

The same can be said with regard to the requirements relating to the facilities of institutional pharmacies and retail pharmacies, equipment, tools and documentation.

On the other hand, this new regulation will lead to a significant increase in the workload of the Government, which will be responsible for managing the declarations of responsibility and monitoring and controlling them through new inspection programmes, although this will not require an increase in the human resources allocated to the units responsible for the procedures.

c) Pharmaceutical care and dispensing with informed delivery to the patient's home:

The requirement is laid down for retail pharmacies that intend to provide this service to submit a declaration of responsibility, as well as, where appropriate, to make an annual declaration of the pharmacy delivery services actually provided. Thus, a new procedure is incorporated which, although it represents an additional burden, at the same time, to the extent that it avoids a longer, more laborious authorisation procedure, makes the processing more agile and allows the activity to start sooner.

Furthermore, the draft decree regulates in detail the process of dispensing, preparing and delivering orders, which entails the obligation for retail pharmacies to implement a procedure for managing this service that guarantees a high quality standard. This will place an additional burden on establishments that voluntarily choose to provide this service.

To this end, Table II breaks down the various procedural steps that must be completed by those interested in providing this service in order to start the activity. On the other hand, Table III lists separately the procedures associated with the provision of the service, depending on whether it is a hospital institutional pharmacy (A) or a retail pharmacy (B). It should be noted that the provision of this service is voluntary and, in the case of retail pharmacies, the provision of this service is aimed at a patient profile defined in Article 13 of Law 13/2022: '*users, at their request and provided that there is a situation of dependence or disability with a loss of functional autonomy and with difficulty or an impediment to travelling to the retail pharmacy of their choice*'. It is therefore very difficult to quantify the real impact that this regulation will have on the Community of Madrid beyond a mere estimate per retail pharmacy or institutional pharmacy. To this end, the number of declarations of responsibility registered for the performance of PDS activities in the period between May 2024 and April 2025, which amounts to 229, will be taken into account, and it will be assumed that all retail pharmacies performing PDS activities provide pharmaceutical care and dispensing services with informed delivery to the patient's home. With regard to pharmacy delivery services

provided by hospital institutional pharmacies, the estimate has been made on the assumption that this will be carried out by the 37 public hospitals.

TABLE II

PROCEDURES FOR THE PROVISION OF PHARMACY DELIVERY SERVICES.

	Total number of documents/actions	Unit cost	TOTAL
Submission of a notification by electronic means (Article 34(1))	1 (x229)	EUR 2 (declaration of responsibility)	EUR 458
Electronic submission of documents (Article 34(2) and Annex II)	4 Hospital institutional pharmacies only: inclusion protocol and standard working procedure for delivery of medicines (x37) All: tax identification number of the interested party and, where applicable, proof of representation (x266)	EUR 4 per document	EUR 2 424
Electronic notification of cessation of activity (Article 34(5))	1 (x266)	EUR 2/document	EUR 532
Preparation of the annual activity declaration (Article 34(6))	1 (x266)	EUR 300	EUR 79 800
Electronic filing of the annual activity declaration (Article 34(6))	1 (x 266)	EUR 2/document	EUR 532
Total of the procedure			EUR 83 746

TABLE III(A) REQUIREMENTS FOR THE PROVISION OF PHARMACY DELIVERY SERVICES BY A HOSPITAL INSTITUTIONAL PHARMACY.			
Requirement	Total number of documents/actions	Unit cost	TOTAL
Development of a protocol for patient inclusion (Article 35(2))	1 (x 37)	EUR 300	EUR 11 100
Development of a procedure for the delivery of medicines (Article 34(2))	1 (x 37)	EUR 300	EUR 11 100
Total of the procedure			EUR 22 200

TABLE III(B) REQUIREMENTS FOR THE PROVISION OF THE SERVICE BY A RETAIL PHARMACY.			
Requirement	Total number of documents/actions	Unit cost	TOTAL
Completion of dispensation form (Article 38(2))	1 per patient (x 229)	EUR 2 (provision of data)	EUR 458
Proof of delivery of medicines (Article 39(4))	1 per delivery (x 229)	EUR 2 (provision of data)	EUR 458
Obligation to retain documents (Article 41(1))	1 x proof of delivery (x 229)	EUR 20/document	EUR 4 580
Total of the procedure			EUR 5 496

d) Regulations governing the transfer of retail pharmacies

With regard to this section, it should be noted that the regime established by the draft decree does not entail any additional administrative burden for the parties concerned. This is because it envisages the possibility of maintaining certification for the preparation of compounded medicines and officinal preparations, as well as the previously authorised sections of the retail pharmacy

subject to the transfer. This saves the purchaser of the retail pharmacy from having to go through a new authorisation process. If they wish to carry out these activities, all they need to do is make a declaration to that effect during the transfer process.

6. DESCRIPTION OF THE PROCESS AND CONSULTATIONS.

6.1 Main contributions received during the public consultation.

This draft decree has gone through the public consultation process in accordance with the provisions of Article 60(1) of Law 10/2019, of 10 April, on transparency and participation in the Community of Madrid and Articles 4(2)(a) and 5(1) of Decree 52/2021, of 24 March, of the Governing Council, which regulates and simplifies the procedure for drawing up the general regulatory provisions of the Community of Madrid.

In fact, by means of the Resolution of 1 July 2024, the Directorate-General of Health Inspection and Management, as the proposing body, expressed its intention to proceed with the drafting of a partial implementation decree for Law 13/2022, of 21 December, accompanied by the corresponding report from the Deputy Minister of Health, and ordered its publication on the Transparency Portal of the Community of Madrid, so that, within the period between 17 July and 8 August 2024, all potential subjects of the future regulation could express their opinion and make any contributions they deemed appropriate.

Therefore, within the deadline set for this purpose, contributions were submitted by the following individuals and entities:

.- Spanish Society of Hospital Pharmacies (SEFH) and the Madrid Society of Hospital Pharmacists (SMFH);

.- Haemophilia Association of the Community of Madrid;

.- Adefarma;

.- General Council of the Official Colleges of Pharmacists (CGCOF);

.- Official College of Pharmacists of Madrid (COFM);

.- Cofares;

.- Federation of Spanish Pharmacists (FEFE);

.- Spanish Society of Retail Pharmacies (SEFAC);

.- Workers' Commissions (CCOO) of Madrid;

.- Association of Innovative Pharmacists (AFIN);

.- European Association for automated dose dispensing (EAADD).

.-Alliance Healthcare Spain;

.- and 15 individual pharmaceutical professionals.

Of the contributions received, those relating to the objective and subjective scope of the draft regulation of the Spanish Society of Hospital Pharmacies have been incorporated into the text of the decree with regard to hospital institutional pharmacies that may provide pharmacy delivery services and the preparation and delivery of personalised dosage systems; of those relating to the opening hours and out-of-hours services of retail pharmacies, those that are in line with the needs of the sector have been accepted; in the chapter on personalised dosage systems, the regulatory proposals made by AFIN regarding the requirement for high quality standards in the preparation of PDS coincide with the criteria of the proposing body; for this reason, the proposals of some individual professionals aimed at guaranteeing the quality of the PDS service (*e.g.* existence of an exclusive space for their preparation, guarantee of traceability, performance of quality controls on their records, existence of standard working procedure for their preparation) are accepted. It also includes the proposal of the COFM and the CGCCOOF not to allow the contracting of a third party for the preparation of PDS. With regard to pharmacy delivery services, the draft incorporates the COFM's proposal to allow the service to be provided by retail pharmacies bordering the corresponding basic health zone, as well as to prohibit the intermediation proposed by the CGCCOOF. In short, proposals regarding the transfer of retail pharmacies are not accepted because they do not comply with the legal regulations that have given rise to the proposed legislation.

6.2 Reports to which this draft decree is subject

- On an optional basis, since the regulation could affect the scope of their powers, reports have been requested from the management centres of the proposing regional ministry, namely, the Directorate-General of Public Health, the Directorate-General of Research and Teaching, and the Directorate-General of Humanisation and Patient Care, which have issued them on the dates and with the content set out below.

- Report of 7 March 2025 of the Directorate-General of Public Health, which makes no comments.

- Report of 14 March 2025 of the Directorate-General of Research and Teaching, which makes no comments.

- Report of 19 March 2025 of the Directorate-General of Humanisation, Care and Patient Safety, proposing to remove references to the need for written informed consent. Justification: From reading this draft legislation, it appears that a written informed consent document may be required. It should be pointed out that Article 8(2) of Basic Law 41/2002, of 14 November, regulating the autonomy of the patient, and rights and obligations regarding information and clinical documentation, provides as follows: 'Consent shall generally be given verbally. However, it shall be provided in writing in the following cases: surgical intervention, invasive diagnostic and therapeutic procedures and, in general, the application of procedures that involve risks or inconveniences with a known and foreseeable negative impact on the patient's health.'

  The assumptions made in this draft decree do not meet the requirements of the written informed consent document required by Law 41/2002, of 14 November, cited above.

  The document CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES, as the starting point for regulating PDS in Law 13/2022 (Article 14), expressly states that '*patients must sign a written consent form in order for pharmacies to prepare their PDS medication. This consent form must be signed by the patient themselves or by their legal representative, in the event of incapacitation. For institutionalised patients, the consent form may be signed by the legal representative of the centre, provided that the patient has signed a legal document transferring this procedure to the former*.' Law 13/2022, of 21 December, reflects this in Article 14(3). '*Patients included in this service must reliably express their consent*.'

  It should be noted that the provision of the PDS service is voluntary for both the retail pharmacy and the patient, hence an informed consent form need not be signed. Due to the nature of the service to be provided, the patient's participation is required in order for the preparation of the PDS to fulfils its objective as a tool for the patient's own medication management. This is only possible if the patient makes a series of commitments and cooperates. This type of consent is not uncommon in procedures involving prolonged or follow-up treatment, and even in informed consent forms for patient participation in clinical trials. The wording is therefore maintained since no contradiction with Law 41/2002, of 14 November, or Law 13/2022, of 21 December, is apparent.

- Similarly, on an optional basis, in accordance with Decree 246/2023, of 4 October, of the Governing Council establishing the management structure of the Madrid Health Service, the Madrid Health Service has been consulted and has issued reports dated 18 and 24 March 2025. The assessments made in these reports have been incorporated into the text of the draft, with the following exceptions:

1.- The Directorate-General of Economic and Financial Management, through the Subdirectorate-General of Pharmacy and Medical Devices, makes the following comments and suggestions:

A) Article 3 on definitions does not agree with the observations of this Directorate-General since this article has been deleted following the comments made by the Technical General Secretariat. Although the draft initially presented at an internal meeting included definitions relating to pharmacy delivery services and PDS, the Technical General Secretariat indicated that these concepts are already provided for and defined in legally binding regulations. Therefore, the introduction of new definitions could contravene the principle of regulatory hierarchy and, consequently, it has been decided to delete the aforementioned article dedicated to definitions.

B) Article 15. General conditions of service provision

Section (3) states: '*PDS may only be prepared with medicinal products previously dispensed by the retail pharmacy or by the hospital institutional pharmacy responsible for their preparation, thus ensuring the control and traceability of treatment*.'

Comment:

As we have pointed out above, we understand that, by including only hospital institutional pharmacies, the possible action that can be carried out by the other institutional pharmacies referred to in Chapter V of Law 13/2022, of 21 December, is limited in this regard. In support of this argument, we cite the provisions of Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices.

In Article 83(2)(a), this regulation states that one of the functions of primary care institutional pharmacy services or units is as follows: '*To guarantee and assume technical responsibility for the acquisition, quality, correct storage, coverage of needs, custody, preparation of compounded medications or officinal preparations and dispensing of medicinal products to be administered within primary care centres and those requiring special monitoring, supervision and control, as established in Article 103 of Law 14/1986, of 25 April, on general health and in the regulatory provisions that implement it*.' Furthermore, including only hospital institutional pharmacies closes the door to future institutional projects in residential centres with fewer than 100 places or other types of centre.

The same comment also applies to the references to hospital institutional pharmacies in Articles 16(1), 32(7) and 34(2).

The reference to '*hospital-based*' has been removed, but the inclusion of specific regulations for the preparation of PDS and pharmacy delivery services from primary care has not been accepted.

C) Article 25. Medicinal products suitable for preparation in a personalised dosage system.

Point (2) states '*The preparation of medicinal products in personalised dosage systems may be carried out either with their own primary packaging material in reusable multi-compartment devices, or without such material, in sealed multi-dose containers, provided that they are medicinal products with a solid oral formulation and whose physico-chemical and galenic characteristics ensure that they can remain stable at room temperature outside their original packaging for the period covering extraction, preparation, delivery and use*. '

Comment:

We propose that medicinal products without their primary packaging can be used in reusable multi-compartment devices. Many of the users of these devices are elderly people who have difficulty removing tablets from blister packs due to problems with fine motor skills, osteoarthritis and arthritis in their fingers, etc. This is the view expressed in the document issued by the Spanish Agency for Medicinal Products and Medical Devices (AEMPS) entitled 'CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES'. It states that, as a general rule, the validity of a blister pack prepared for a PDS will be a maximum of two weeks from the date the medicines are removed from the blister pack until the last day scheduled for their administration. This supports the possibility of removal from the blister pack. The Spanish Agency for Medicinal Products and Medical Devices (AEMPS) published the document Criteria Agreed Between the Different Autonomous Communities and the AEMPS for the Preparation of Personalised Dosage Systems (PDS) by Retail Pharmacies, with the aim of providing a framework of consensus criteria that must be complied with by the different autonomous communities in relation to the preparation of personalised dosage systems (PDS) by retail pharmacies. Based on this minimum requirements document, each autonomous community had to draw up its own document setting out criteria adapted to its specific circumstances and territorial characteristics (regulations, guidelines, protocols, etc.). This document served as the starting point for regulating PDS in Law 13/2022, of 21 December, (Article 14) in which it expressly refers to their regulatory development. It is expressly stated in this document that, in the case of multi-compartment devices, medicinal products cannot be removed from their blister packs since they are reusable and must be subject to a strict cleaning protocol.

D) Article 26. Assessment of the patient's suitability for inclusion in personalised dosage systems

In Point (1), it is indicated that '*The inclusion of a patient in a PDS should be based on an individual assessment, carried out by the pharmacist, which will take into account objective criteria related to medication adherence, the capacity to handle the medication and the specific needs of the patient*. '

Comment:

We understand that a key point for a patient to be included in a PDS service to improve their adherence is that they have already had their medication reviewed and optimised by the clinical care team. Therefore, the pharmacist must coordinate with other healthcare professionals caring for the patient. In fact, the philosophy behind the Polymedicated Older Patients programme (agreed with the COFM) and the Adherence Improvement Plan is based on coordinated work between the primary care team and the retail pharmacist. The wording of this section would therefore run counter to this programme.

The AEMPS document CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES' defines 'Personalised dosage system (PDS)' as the pharmaceutical service provided to individuals who request it, consisting of a set of post-dispensing actions involving the repackaging of dispensed medicines into a personalised dosing device with the aim of facilitating the correct intake of medicines by the patient and improving their adherence to prescribed treatments through good patient information and adequate preparation and supervision of the treatment. This implies that the action is the responsibility of the retail pharmacy when carried out after the prescribed medicinal products have been dispensed. No one questions the role of primary care pharmacists and other healthcare professionals in reviewing treatments, reconciliation, etc.; these functions are recognised for these professionals, but at a stage prior to dispensing. However, Article 25(2) does provide for the possibility of conducting an interview with the responsible healthcare professional, during which aspects established in line with the criteria set out in the polymedicated patient programme and included in this article would be assessed.

E) Article 35. Pharmacy delivery services from the hospital institutional pharmacy

Comment:

The Subdirectorate-General of Pharmacy and Medical Devices is promoting plans for pharmaceutical care (the Atento programme, the paxlovid dispensing programme) as well as other programmes aimed at improving access to medicinal products.

In accordance with the definition of pharmaceutical care in Law 13/2022, the other institutional pharmacies described in Chapter V of the Law cannot be ignored, given that these services also provide pharmaceutical care, in accordance with the definition assigned to them in Article 3(6) of Law 13/2022, of 21 December,: an organised set of technical resources and facilities in which, under the responsibility of a pharmacist, professionals holding official qualifications provide pharmaceutical care to the public through the acquisition, custody, storage and dispensing of medicinal products and medical devices and other functions set out in the applicable regulations. This concept includes retail pharmacies, institutional pharmacies, rural dispensaries, in-house dispensaries and radiopharmacy units.

It has been agreed to remove the reference to 'hospital' as already stated in the response to the comment on Article 15. With regard to the programmes mentioned in the comment, it should be noted that Law 13/2022, of 21 December, affects each and every one of the elements that make up pharmaceutical management and care in all areas: retail pharmacies; primary and hospital care; and residential social services centres and prisons.

On the other hand, pharmaceutical care from primary care services, such as the implementation of the Atento programme, the paxlovid dispensing programme and other programmes aimed at greater accessibility to medicines, is recognised in the law itself (Article 37). In other words, Law 13/2022, of 21 December, recognises their fundamental and essential role in optimising the quality of primary care in collaboration with other healthcare professionals.

However, the pharmaceutical care that the decree aims to implement is that established in Article 13(3) of the law in conjunction with the dispensing of medicinal products with informed delivery to the patient's home and subject to regulatory development, and pharmaceutical care from the hospital institutional pharmacy within the framework of the provisions of Article 40(j) of Law 13/2022, of 21 December, and that provided for after the approval of the Pharmacy Law, in Royal Legislative Decree 1/2015, of 24 July (Royal Decree-Law 5/2023, of 28 June), which incorporates a Section (8) into Article 3 in this regard and which would justify the development in this decree. It is precisely this dispensing

of medicinal products and delivery outside the health centre which is not covered by Law 13/2022, of 21 December, on primary care institutional pharmacies, that would justify not addressing its regulatory development.

2.- With regard to the comments made by the Directorate-General of Social Welfare, a distinction shall be made between:

A) Article 3. Definitions

The observation of this Directorate-General is not accepted, since this article has been deleted following comments made by the Technical General Secretariat. Although the draft initially presented at an internal meeting included definitions relating to pharmacy delivery services and PDS, the Secretariat indicated that these concepts are already provided for and defined in legally binding regulations. Therefore, the introduction of new definitions could contravene the principle of regulatory hierarchy and, consequently, it has been decided to delete the aforementioned article dedicated to definitions.

B) Article 15(4): '*The preparation of PDS shall be carried out exclusively by pharmaceutical professionals with specific training or by pharmacy technicians, always under the supervision of a pharmacist with such specific training. The entire process must strictly comply with the standard working procedure accompanying the corresponding declaration of responsibility*.'

Replace with: '*4. The preparation of PDS shall be carried out exclusively by pharmaceutical professionals or pharmacy technicians with specific training, always under the supervision of a pharmacist with such specific training. The entire process must strictly comply with the standard working procedure accompanying the corresponding declaration of responsibility*.' It must be ensured that all professionals involved have the appropriate training for the preparation of PDS.

Although the original wording proposed training and the acquisition of technical expertise as a necessary quality criterion for participating in the preparation of PDS and opened up the possibility of developing accredited training programmes, following the observations made by the Technical General Secretariat, it was considered imperative to remove any reference to the requirement for specific technical training and, consequently, to delete the current Article 18, entitled: '*Training and acquisition of specific technical competence for pharmaceutical personnel involved in the preparation and delivery of personalised dosage systems*'.

C) Article 29(5): '*The medicinal product shall be packaged in the multi-dose devices referred to in Article 26(2) of this decree, which must be approved devices and which must have the corresponding certificate of conformity of the manufacturer to contain medicinal products, which guarantees that the manufacturing materials will prevent interactions with the content and that the product meets the legal conditions to provide sufficient protection during storage and transport and allow easy opening and extraction by the patient. The sealing or closing of the devices shall be carried out in accordance with the manufacturer's instructions, without their reuse being permitted under any circumstances*.'

Replace with:

'*5. 'The medicinal product shall be packaged in the multi-dose devices referred to in Article 26(2) of this decree, which must be approved devices and which must have the corresponding certificate of conformity of the manufacturer to contain medicinal products, which guarantees that the manufacturing materials will prevent interactions with the content and that the product meets the legal conditions to provide sufficient protection during storage and transport and allow easy opening and extraction by the patient. The sealing or closing of the devices shall be carried out in accordance with the manufacturer's instructions, without the reuse of the disposable devices being permitted under any circumstances*.'

This is not accepted, since this paragraph refers to multi-dose devices and the current wording already states that reuse is not allowed under any circumstances.

The drafting of the preliminary draft decree in this regard has taken into account the document entitled 'CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES,' a document that served as the starting point for regulating PDS in Law 13/2022, of 21 December, (Article 14) and which expressly states:

'*Multi-dose packaging (blister packs or similar) must be approved and have a certificate of conformity [issued by the manufacturer and in the official language] for containing medicines. The certificate must guarantee the safety of the materials with which it has been manufactured in order to prevent them from interacting with the contents and that the product complies with the legal requirements defined in the standards (relating to moisture and oxygen permeability, the number, quality and thickness of layers of the material and, where appropriate, information on protection from light) and which provide sufficient protection during storage and transport, allowing easy extraction and opening by the patient and/or caregiver.*

Under no circumstances is the reuse of this type of PDS device permitted.'

D) Article 29(6): '*The multi-compartment devices provided for in Article 26(2) may under no circumstances contain medicinal products outside their primary packaging, in order to ensure their stability. These devices must undergo a strict cleaning and disinfection protocol after each use, and their proper maintenance status must be verified before reuse*.'

Replace with:

'*6. Multi-compartment devices must undergo a strict cleaning and disinfection protocol after each use, and their proper maintenance status must be verified before reuse*.'

This observation is not accepted, since the drafting of the preliminary draft decree, as in the previous case, has taken into account the document entitled 'CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES,' a document that served as the starting point for regulating PDS in Law 13/2022, of 21 December, (Article 14) and which expressly states:

'*In the case of multi-compartment devices (weekly pill boxes or compartmentalised medication trays), since they are reusable devices and their closure system does not provide adequate barrier properties against environmental factors, they may under no circumstances contain medication outside its primary packaging and must undergo a strict cleaning and disinfection protocol after each use and be checked that they are in a perfect state of maintenance before new use*.'

E) Article 29: Include a new point:

'*In the event that the patient has repeat prescription medicines, they shall only be included in the device when the patient reports a fixed frequency. Otherwise, they shall not be included*.'

The justification is that if the patient takes an analgesic once a week on average, it should not be included every day.

This recommendation is not accepted, as it is already provided for in the current Article 24(3)(c). Furthermore, it is proposed in an article dedicated to the preparation of PDS and not in the article dedicated to medicines that may be included in these devices.

F) Article 32(4)(b) *'Identification of the prescribing doctor and dates of prescription or last modification of treatment*.'

Replace with:

'*(b) Identification of the prescribing doctor or nurse who has indicated it and dates of prescription or last modification of treatment, as well as the date of the medication chart that has been used as a guide*.'

Nursing professionals may also modify the patient's therapeutic regimen. It is advisable to check the date on the medication chart to ensure that it is the most recent one.

Not accepted. New wording is provided in response to the comment made by the Directorate-General of Economic and Financial Management referring to '*responsible doctor*', standardising the name throughout the text.

- In accordance with Article 2 of Decree 244/2000, of 16 November, of the Governing Council on notifying the European Commission of draft technical regulations and of rules on Information Society services, and in relation to Article (7)(2)(n) of Decree 229/2023, of 6 September, of the Governing Council establishing the organisational structure of the Regional Ministry of the Presidency, Justice and Local Administration, a report dated 26 May 2025 has been received from the Directorate-General of Cooperation with the State and the European Union of the Regional Ministry of the Presidency, Justice and Local Administration which draws a conclusion on the inclusion of this draft within the scope of 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. The European Commission will therefore be notified of the draft in accordance with Article 5(1) of that directive, and its adoption will be postponed in accordance with Article 6.

- Similarly, pursuant to the provisions of Article 5.2 of Law 3/2013, of 4 June, establishing the National Commission for Markets and Competition, an optional report was requested from this body on 16 September 2025, which was issued on the following 15 October. The request for this report stems from the fact that the draft regulation addresses the regulation of certain activities and services whose provision may affect the principles of good regulation and the promotion of competition.

The report in question proposes a series of recommendations based on the principles of good regulation and the promotion of competition, to which a response is provided below. Namely:

A) Articles 4 and 6 on extended opening hours and minimum staffing levels for pharmacists state that the draft decree establishes fixed extended opening hours, which cannot be modified for one year, and recommends that, once adequate service coverage is guaranteed through ordinary opening hours and out-of-hours services, these requirements

restricting the freedom of pharmacies that wish to voluntarily extend their opening hours and, therefore, their ability to compete in the market to do so should be removed.

Not accepted.

Law 13/2022, of 21 December, reflected the reality of our autonomous community and the demand for liberalisation and flexibility already set out in Law 16/1997, of 25 April, on the regulation of retail pharmacy services, which established, in general terms, in Article 6 that retail pharmacies would provide their services freely and flexibly. On the other hand, the issue of opening hours must be addressed in such a way that out-of-hours services can be organised to ensure the continuity of pharmaceutical services and adapt them to the needs of citizens, which requires advance planning. The choice of one schedule or the other is up to the pharmacist, always respecting the fact that this is a regulated activity that is subject to planning, which is why the corresponding out-of-hours services must be established. Therefore, it has been deemed that a wide time slot, established between 06:00 and 23:00, allowing flexibility over opening hours is in line with the spirit of the law that integrates the hours currently authorised in pharmacies in the Community of Madrid and the possibility of opting for a 24-hour service.

In this regard, the report also points out that the obligation to hire additional staff based on extended opening hours and the age of the owner should be reconsidered, given that it increases management costs, harms smaller pharmacies and discourages both the extension of hours and the entry of new operators, reducing the supply and accessibility of pharmaceutical services to patients.

Not accepted.

The need to regulate this aspect stems from the provisions of Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, which establishes '*the presence and professional practice of the pharmacist as an essential condition and requirement for the dispensing of medicinal products to the public, taking into account the number of pharmacists necessary depending on the activity of the pharmacy*'.

Law 16/1997, of 25 April, establishes, in general terms, that the presence and professional practice of a pharmacist is an essential condition and requirement for the dispensing of medicinal products to the public; that the autonomous communities may regulate the minimum number of assistant pharmacists who, in addition to the owner, must provide services in retail pharmacies in order to guarantee adequate professional care for users;

and that this regulation must take into account, among other factors, the volume and type of activity of retail pharmacies and the opening hours schedule.

In other words, state regulations make it clear, in general terms, that the presence and professional practice of the pharmacist is an essential condition and requirement for the dispensing of medicinal products to the public, and this presence is linked both to the volume of activity and to the hours during which the service is provided.

Furthermore, Law 13/2022, of 21 December, establishes that the presence of a pharmacist on the pharmacy's staff is a sine qua non requirement for dispensing; that pharmacies must be staffed with a sufficient number of pharmacists to ensure, in accordance with the established schedule of opening hours, the constant presence and professional practice of at least one pharmacist throughout the entire time that the pharmacy provides service to the public; and that the appointments of managing, substitute and assistant pharmacists must be communicated to the regional ministry responsible for health matters in order for them to be able to perform their duties in the pharmacy.

B) With regard to Articles 8 and 13 on out-of-hours shifts and holidays, the National Commission for Markets and Competition recommends that objective, transparent and non-discriminatory criteria be developed to be taken into account by the college of pharmacists when establishing out-of-hours shifts and holidays in order to ensure pharmaceutical care for the population, without restricting competition between pharmacies. Likewise, this should be used to justify the organisation of holiday shifts by the college of pharmacists.

Not accepted.

The current wording includes a set of criteria established in Article 26 of Law 13/2022, of 21 December, which are: health planning and its territorial distribution, the hours and structures of the emergency health services provided in the health system of the Community of Madrid, the population to be served, the provision of communications infrastructure, retail pharmacies open 24 hours a day and geographical barriers, as well as any other criteria or unique features that are worth considering. With regard to holidays, the current wording develops the provisions of Law 13/2022, of 21 December, which establishes that retail pharmacies may cease their activities during the holiday period. In this regard, the draft decree establishes the time frame for notifying the National Commission for Markets and Competition so that holiday periods can be organised, taking into account the fact that at least 50% of retail pharmacies in each basic health zone or grouped neighbouring zone must remain open.

C) With regard to Article 14 on the requirements for the development of personalised dosage systems, the CNMC proposes eliminating the reservation of the provision of the service to the pharmacy dispensing the medicinal product in order to promote the competence and specialisation capacity of retail pharmacies and, even, to incentivise the emergence of innovative management models or common platforms that could improve the efficiency of the service, without compromising the safety and health conditions required.

Not accepted.

The draft decree strictly complies with Article 86(1) of Royal Legislative Decree 1/2015, of 24 July. This provision establishes that pharmacists, as those responsible for dispensing, may provide personalised dosage systems once the medicinal product has been dispensed. In this way, the PDS is configured as a professional post-dispensing service, focused on medication management and improving medication adherence and safety, especially in chronic or polymedicated patients. The document entitled 'Criteria agreed between the autonomous communities and the AEMPS' confirms this interpretation, establishing that the PDS must be prepared in the same retail pharmacy that dispensed the medicinal product, expressly prohibiting its preparation by third parties. It should also be recalled that Article 6(2)(x) of Law 13/2022 establishes the obligation not to accept the delivery of medicinal products by patients or the general public. This principle, which seeks to guarantee safety, traceability and professional control in the medicine circuit, prevents a retail pharmacy from receiving medicinal products dispensed by another pharmacy for repackaging in PDS and then returning them to the dispensing pharmacy for delivery to the patient, as this would be equivalent to accepting medicines from outside its own dispensing circuit. This approach is essential to protect patient safety, ensure traceability and the professional responsibility of the pharmacist, and avoid outsourcing of the process, which would pose a risk of loss of control and non-compliance with the obligations laid down in both state and regional legislation.

D) With regard to Article 24, the report proposes extending access to the service to more patients, as there is no legal restriction preventing this.

Not accepted.

Article 24 is devoted to the assessment of patients for inclusion in PDS; it does not mention a specific profile of patients for whom this service is intended. As stated in Article 14 of Law 13/2022, of 21 December, *'... to patients who request it*'. However, given the purpose of PDS as a tool for improving the effectiveness of pharmacological treatments and medication adherence, it seems obvious that the patient profiles that can benefit the most are polymedicated, chronic or dependent patients. A different matter is the profile that has

been established in Law 13/2022, of 21 December, for dispensing with informed delivery to the patient's home, as regulated by Article 13.

E) In relation to Article 18, this supervisory body proposes the review of the various administrative and economic burdens arising from the technical and organisational requirements to carry out the activity so that only those that are necessary and proportionate and effectively contribute to better service provision are required, ensuring the necessary health and safety conditions.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities, and to be taken into account in the regulatory developments carried out by the autonomous communities in this regard.

F) With regard to Article 19, the National Commission for Markets and Competition recommends that the introduction of automated systems for the preparation of PDS that favour efficiency and safety under appropriate conditions should not be made more difficult.

Not accepted.

PDS are a healthcare activity specific to pharmacists, integrated into pharmaceutical care and aimed at optimising treatment and rationalising the use of medicinal products. The draft decree does not start with the incorporation of automated systems. Nor does it regulate automated systems or robots used in the preparation of PDS, since these constitute only a means of support or an instrument for the care activity of the pharmacist, without being an end in themselves. What is relevant is the professional practice and compliance with the technical and health requirements of the service, regardless of whether the process is manual or automated.

At the same time, it is suggested that the five-year validity period of the declaration of responsibility for the commencement of activity be reconsidered.

Accepted. This requirement has been removed.

G) With regard to Article 39 on the development of pharmaceutical care and home delivery services, the report recommends that, provided that the health requirements for storage and hygiene, integrity and safety in transport are met, ensuring patient safety, home delivery of medicinal products and medical devices should be permitted, both by the

pharmacies that dispense them and by operators designated by them and under their supervision.

Not accepted.

Law 13/2022, of 21 December, expressly states that home delivery of medicines must be carried out by qualified pharmacy staff, ruling out the possible involvement of other operators.

It is also recommended to justify the necessity and proportionality of the territorial restriction on the provision of services and to assess less restrictive alternatives that would allow these objectives to be reconciled with greater freedom of provision and effective competition between pharmacies.

Not accepted.

For reasons of proximity to the homes of patients eligible to receive this service, it seems reasonable to establish the basic health zone (ZBS) as the geographical area in which the retail pharmacy is located. However, there is a caveat that patients may exercise their right to freely choose a retail pharmacy not only in the basic health zone but also retail pharmacies located in other basic health zones.

- Furthermore, in accordance with the provisions of Article 8(4) of Decree 52/2021, of 24 March, reports have been obtained simultaneously and on a mandatory basis from the following management centres, namely:

.- General Technical Secretariat of the Regional Ministry of the Presidency, Justice and Local Administration, Office of Regulatory Quality, which on 9 June 2025, issued the mandatory report, in accordance with the provisions of Article 34 of Law 11/2022, of 21 December, urgent measures to boost economic activity and modernise the administration of the Community of Madrid, Articles 4(2)(c) and 8(4) of Decree 52/2021, of 24 March, of the Governing Council, and Article 25(3)(a) of Decree 229/2023, of 6 September, establishing the organisational structure of the Regional Ministry of the Presidency, Justice and Local Administration. In general, their comments, both those referring to the draft, notably those relating to the procedure for the transfer of retail pharmacies, and those referring to the Regulatory Impact Analysis Report, have been taken into account, with the following exceptions.

a) With regard to simplifying the title of the draft, this suggestion is rejected in the interests of clarity regarding the subject matter of the regulation. Indeed, considering the broad and diverse content of the developed law, Law 13/2022, of 21 December, and taking into account that this is a partial implementation of it, the proposed title accurately reflects the multiple aspects regulated by

the decree, the purpose of which is not limited to ‘opening hours and services’, as the proposed simplified title would erroneously suggest.

b) With regard to the recommendation concerning the content of Article 5(1) of the draft, it is not accepted on the understanding that the purpose of this provision is exclusively to regulate the procedure for the communication of opening hours by the owner of the retail pharmacy. Issues relating to the validity of the communicated opening hours, their possible automatic extension and the possibility of modifying or withdrawing them are already covered in general terms in Article 25 of Law 13/2022, of 21 December, making it unnecessary to reproduce these aspects in the implementing regulation.

c) With regard to the proposal to amend Article 28(1)(b) and (c), it is considered appropriate to maintain the current wording, since the full identification of professionals is necessary for the purpose of ensuring traceability, safety and proper supervision of the care process, especially in the field of PDS. In addition, the recording of their data would not infringe the right to personal data protection since the records and documents generated in the framework of the pharmaceutical activity are subject to the duty of confidentiality and other data protection obligations established by the current regulations.

d) In relation to the suggestion concerning the title of the second transitional provision and the revision of the term ‘*hospital*’, the wording is amended by maintaining the title and removing the reference to hospital from the content of the provision, since PDS have been regulated in the field of retail pharmacies and institutional pharmacies in general, and not specifically in the hospital field.

e) On the other hand, with regard to the observation concerning the request for a report from the Directorate-General of Budgets in accordance with the report of 7 March 2024 from that management centre, this is not considered, since, as explained above, the rule has no impact on the revenue and expenditure budget of the Community of Madrid. In fact, the regulation incorporated into the draft does not give rise to any fees for administrative action, nor does it contemplate an increase in the number of civil servants assigned to processing the various procedures regulated by the law. For this reason, the issuance of this report is not appropriate.

.- Directorate-General of Citizen Care and Transparency of the Regional Ministry of the Presidency, Justice and Local Administration, which, pursuant to the provisions of Article 9(2)(f) of Decree 229/2023, of 6 September, of the Governing Council, and in accordance with the provisions of Article 4(g) and criteria 12 and 14 of Decree 85/2002, of 23 May, regulating the systems for assessing the quality of administrative action and approving the quality criteria of administrative action in the Community of Madrid, which issued its report on 6 June 2025, indicating that ‘*the application form, as well as those others that are regulated and that constitute*

the initiation phase of an administrative procedure, must be constructed and validated in accordance with the criteria established, and at the appropriate time, subject to a report from this management centre'.

. - Similarly, in compliance with the provisions of Article 4(3) of Decree 52/2021, of 25 March, the texts of the draft and this report have been forwarded to the general technical secretariats of each regional ministry for study, assessment and, where appropriate, comment. The secretariats have issued the corresponding reports in which they do not make any comments, with the exception of the general technical secretariat of the Regional Ministry of Economy, Finance and Employment, which, in its report of 12 June 2025, makes the following observations.

a) A mandatory report must be requested from the Directorate-General of Human Resources, which is accepted.

b) With regard to the recommendations of the Directorate-General of Economic and Industrial Promotion (currently the Directorate-General of Economy and Industry), in its report of 2 June 2025, relating to the State metrological control of the thermometer referred to in Article 19(3) of the draft, these are accepted, being incorporated into the text of the draft.

c) Comments relating to Articles 41 and 42 are accepted. With regard to Article 43, concerning the transfer of retail pharmacies, a change has been made to the wording in order to strengthen the legal certainty and clarity of the transfer procedure. In this regard, it should be noted that the transfer request is a single document and signed by both interested parties, as an expression of their joint will. Consequently, the notification of the decision is addressed to the person who has submitted the application on behalf of both parties to the transaction, which makes it possible to objectively determine the time from which the deadline for the submission of the required documentation should be calculated. Similarly, in accordance with the provisions of Article 31(1) of Law 13/2022, of 21 December, which states that the transfer shall take effect '*once the transfer has been accredited by means of the corresponding legal act*,' the wording has been amended to expressly condition the effectiveness of the authorisation decision on the provision of supporting documentation. In addition, a provision has been incorporated that allows for correction in the event that the documentation provided is incomplete or incorrect.

- Directorate-General of Economy (currently the Directorate-General of Economy and Industry) of the Regional Ministry of Economy, Finance and Employment in accordance with the provisions of Article 33 of Law 11/2022, of 21 December, on urgent measures to boost economic activity and modernise the administration of the Community of Madrid, which on 7 June 2025 issued the mandatory report on the economic impact of the draft regulation, in which it makes a number of

observations on its impact on businesses, employment and innovation, which, however, do not require the modification of the text, for the reasons set out below.

Indeed, starting with the obligation to report the annual opening hours and holidays of retail pharmacies, this is justified by the need to guarantee continuity and stability in the provision of pharmaceutical services, which constitute a health service of public interest in accordance with the provisions of Law 13/2022, of 21 December. This provision allows the health authority to plan shifts and out-of-hours services properly, ensuring adequate territorial coverage. This is a proportionate obligation that does not impede the retail pharmacy's internal organisation, establishing a predictable framework for the management of resources. It is, therefore, a proportionate measure, justified by reasons of general interest and aligned with the regulations in force in other autonomous communities.

As for the regulatory regime governing PDS, this complies with the legal framework set out in Royal Legislative Decree 1/2015, of 24 July, which requires that the PDS be prepared by the pharmacist responsible for dispensing the medication. This ensures the traceability of the dispensed medicinal product in accordance with the requirements of EU regulations, as well as the professional responsibility and personalised supervision of the drug treatment of the patient for whom the PDS is intended. Outsourcing the preparation of PDS and having them made by and for third parties compromises traceability and, therefore, patient safety. Furthermore, the draft regulation is compatible with the use of technological or automated means, without restricting organisational innovation. In short, it is about establishing a framework of guarantees to protect the patient. It is considered that this does not prejudice free competition or market unity, since it is based on criteria of public health, quality of care and patient safety in the use of medicinal products. It should be noted that the professional associations in the sector expressly requested that the hiring of third parties for the preparation of PDS be prohibited.

As regards the prohibition of intermediation in pharmacy delivery services, its rationale lies in the need to preserve the direct relationship between the pharmacist and the patient, ensuring the quality, safety and monitoring of treatment. This requirement is set out in the state regulation establishing that dispensing is a non-transferable professional activity. The intervention of non-healthcare third parties could introduce clinical risks, blur the professional responsibility of the pharmacist and generate conflicts of interest that compromise the quality of the service. The aim is to prevent the commodification of an essential pharmaceutical service. However, this does not preclude the use of technological means or collaboration with other healthcare professionals, provided that the provision of pharmaceutical care remains under the direct responsibility of the pharmacist.

In view of the above reasoning, it is considered that the observations in the aforementioned report by the Directorate-General of Economy (currently the Directorate-General of Economy and

Industry) do not justify amending the text, insofar as its provisions comply with the current regulatory framework, respond to legitimate objectives of general interest and do not introduce disproportionate or unjustified restrictions that could be considered contrary to market unity or free competition.

.- Directorate-General of Women of the Regional Ministry of Family, Youth and Social Affairs, which in accordance with the provisions of Article 19 of Organic Law 3/2007, of 22 March, issued the corresponding report on 2 June 2025.

.- Directorate-General of Childhood, Family and Birth Promotion of the Regional Ministry of Family, Youth and Social Affairs, in accordance with the provisions of Article 7(15) of Decree 241/2023, of 20 September, of the Governing Council, approving the structure of the Regional Ministry of Family, Youth and Social Affairs of the Community of Madrid, issued the corresponding report dated 3 June 2025.

.- Consumer Council of the Community of Madrid, in accordance with the requirements of Article 28 of Law 11/1998, of 9 July, on consumer protection in the Community of Madrid, and Article 4(1)(e) of Decree 1/2010, of 14 January, of the Governing Council, approving the Regulations of Law 11/1998, of 9 July, on consumer protection in the Community of Madrid, issued a favourable report on the draft on 23 June 2025.

.- Directorate-General of Public Health of the Regional Ministry of Health, which on 27 June 2025 issued a favourable report on the impact on public health, pursuant to Article 35(1) of Law 33/2011, of 14 October, on general public health, which requires the assessment of the impact on health when, among other things, regulatory proposals may have a significant impact on health, under the terms provided for in said law.

.- Directorate-General of Digital Strategy of the Regional Ministry of Digitisation, pursuant to Article 6(3)(d) of Decree 261/2023, of 29 November, of the Governing Council establishing the organisational structure of the Ministry of Digitisation. On 10 June 2025, a report was issued by the Deputy Regional Ministry for Digitisation, accepting its comments on the standard forms.

.- Directorate-General of Human Resources of the Regional Ministry of Economy, Finance and Employment, in accordance with the report of 12 June 2025, of the General Technical Secretariat of the Regional Ministry of Economy, Finance and Employment, and in accordance with the provisions of Article 7 of Decree 230/2023, of 6 September, of the Governing Council establishing the organisational structure of the Regional Ministry of Economy, Finance and Employment and the First Additional Provision of Law 9/2024, of 26 December, on the general budgets of the Community of Madrid for the year 2025. The report was issued on 3 July 2025 in favour of the draft's processing, provided that the Regulatory Impact Analysis Report includes an express

mention that no additional staff will be required to implement the regulation, an observation that is accepted.

6.3 Public hearing and information procedures

In accordance with Article 60(2) of Law 10/2019, of 10 April, and Articles 4(2)(d) and 9(1) and 9(2) of Decree 52/2021, of 24 March, of the Governing Council, the draft has undergone the public hearing and information procedures, which were conducted during the period from 29 July to 19 August 2025, through the publication of the draft decree and its Regulatory Impact Analysis Report on the Transparency Portal. The summary and comment on the arguments presented therein are contained in the Annex to this report.

At the same time, opinions have been directly obtained from the following legally recognised organisations or associations that group together or represent people whose lawful rights or interests are affected by the regulation and whose purposes relate directly to that of this regulation:

- Official College of Physicians of Madrid;
- Official College of Qualified Nurses of Madrid;
- Official College of Pharmacists of Madrid;
- General Pharmaceutical Council of Spain;
- Federation of Spanish Pharmacists;
- Spanish Society of Primary Care Pharmacists;
- Association of Pharmaceutical Entrepreneurs of Madrid;
- Spanish Society of Rural Pharmacies.
- Spanish Society of Hospital Pharmacies.

The examination and commentary on the arguments presented by the above are contained in the Annex to this report.

Following completion of the above procedures, a report was obtained from the National Commission on Markets and Competition (CNMC), whose conclusions have already been addressed above in the section on the reports obtained.

Once the public hearing and information procedures have been completed and a new text of the draft decree and a new regulatory impact analysis report have been drawn up, the General Technical Secretariat of this Regional Ministry of Health will be asked to provide the mandatory report required by Article 8(5) of Decree 52/2021, of 24 March.

The European Commission will also be notified of the draft as provided for in 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, given that this draft decree contains technical specifications in its third chapter, i.e. characteristics specific to pharmacies, as well as those relating to the preparation, preservation, storage and delivery of personalised dosage systems, which affect both establishments and the provision of their services, specifically in Articles 19 and 20.

Then, also on a mandatory basis, the report of the Attorney General will be requested in accordance with Articles 4(1)(a) of Law 3/1999, of 30 March, on the organisation of legal services of the Community of Madrid and 4(2)(f) of Decree 52/2021, of 24 March.

Finally, the opinion of the Legal Advisory Commission will be sought, in accordance with the provisions of Article 8(6) of Decree 52/2021, of 24 March, as well as Article 5(3)(c) of Law 7/2015, of 28 December, on the abolition of the Advisory Council.

7. EX-POST EVALUATION.

In accordance with the provisions of Articles 3(4), 7(4)(e) and 13 of Decree 52/2021, of 24 March, the analysis of the results of the application of this decree shall be carried out after the entry into force, once the deadlines laid down in the transitional provisions have elapsed, as part of the control procedures established by the Regional Ministry of Health. Specifically, the following parameters will be taken into account:

- number of declarations of responsibility for the provision of personalised dosage systems and compliance with the obligations and requirements established for the preparation and delivery of personalised dosage systems necessary for the development of this activity by retail pharmacies;

- number of declarations of responsibility for the provision of the pharmaceutical care service and dispensing with informed delivery to the patient's home;

- number of penalty proposals in relation to compliance with the requirements laid down in relation to the matters covered by this decree.

THE DIRECTOR-GENERAL OF HEALTH INSPECTION AND MANAGEMENT.

ANNEX

Pursuant to the provisions of Article 9 of Decree 52/2021, of 24 March, of the Governing Council regulating and simplifying the procedure for drawing up the general regulatory provisions of the Community of Madrid, the public hearing and information procedures took place from 29 July to 19 August 2025 by publishing the text of the draft and the regulatory impact analysis report on the Transparency Portal of the Community of Madrid, with the result set out below.

The analysis of the proposals received has been organised, within each chapter, according to the specific article of the draft to which they refer, indicating the persons or entities that submitted them and stating the outcome of the examination carried out for the purposes of their acceptance (and incorporation into the text of the regulation) or rejection.

It means that no proposal has been received from the following entities:

.- Official College of Qualified Nurses of Madrid;

.- General Pharmaceutical Council of Spain;

.- Association of Pharmaceutical Entrepreneurs of Madrid;

.- Spanish Society of Rural Pharmacies.

1.- General observations.

1.1.- Association of Innovative Pharmacists (AFIN), Coello de Portugal Abogados, Federation of Spanish Pharmacists (FEFE): **Automatic nullity due to failure to notify the European Commission under Directive (EU) 2015/1535:**

This procedure is expected to be carried out at the appropriate procedural moment, that is, after the examination and analysis of the arguments made during the public hearing and information procedures, with any modifications to the text that this may entail.

1.2.- FEFE, AFIN: **Infringement of matters reserved to a regulation with the status of law** as regards:

1.2.1 Staffing requirements for the operation of a pharmacy. This argument is not accepted on the ground that it is unfounded, since there is indeed a legal provision on the staffing allocations of pharmaceutical establishments. Thus:

Law 16/1997, of 25 April, on the regulation of retail pharmacy services establishes, in general terms, that the presence and professional practice of a pharmacist is an essential condition and requirement for the dispensing of medicinal products to the public; that the autonomous communities may regulate the minimum number of assistant pharmacists who, in addition to the owner, must provide services in retail pharmacies in order to guarantee adequate professional care for users; and that this regulation must take into account, among other factors, the volume and type of activity of retail pharmacies and the opening hours schedule.

Furthermore, Law 13/2022, of 21 December, establishes that the presence of a pharmacist on the pharmacy's staff is an essential requirement for dispensing; that pharmacies must be staffed with a sufficient number of pharmacists to ensure, in accordance with the established schedule of opening hours, the constant presence and professional practice of at least one pharmacist throughout the entire time that the pharmacy provides service to the public; and that the appointments of managing, substitute and assistant pharmacists must be communicated to the regional ministry responsible for health matters in order for them to be able to perform their duties in the pharmacy.

1.2.2 Limitation on access to health services not provided for in the law.

Law 13/2022, of 21 December, expressly provides that pharmacists may provide pharmacy delivery services and dispense medicinal products and medical devices from the pharmacy that do not require individual adaptation, with informed delivery to users' homes, at their request and provided that there is a situation of dependency or disability with loss of functional autonomy and with difficulty or an impediment to travelling to the pharmacy of their choice.

1.3 FEFE, Coello de Portugal Abogados, AFIN: **Infringement of the principles of good regulation:**

1.3.1 Principle of proportionality. It is claimed that the regulation imposes burdens that are not justified by its intended purposes. Thus, in relation to personalised dosage systems (PDS) and pharmacy delivery services, the space, equipment and staffing requirements are unaffordable for many retail pharmacies.

Not accepted.

In this regard, it should be noted that these are voluntary services provided by retail pharmacies, as are the preparation of compounded medicines and the establishment of sections within the retail

pharmacy. The draft decree does not seek to enable all pharmacies to provide as many services as possible, but to ensure that the services provided are provided under minimum conditions which ensure the quality and safety of the patients for whom they are intended. That is why it is considered that the requirements established for carrying out these activities are proportionate to the aim of ensuring patient safety.

With regard to insufficient adaptation deadlines in terms of personnel and infrastructure, these are considered adequate given the complexity and scope of the obligations to be fulfilled.

With regard to the requirements for facilities for the production of PDS, the period of six months to start the adaptation works that may be necessary seems appropriate.

With regard to the recruitment of staff, the established deadline is sufficient to publish the job offer, assess the applications and make the selection, taking into account the technological means available in today's society.

Regarding the omission of the proportionality test in professional regulations, there is no need to carry out the test indicated, since the purpose of the draft regulation is the regulation of pharmacy establishments in terms of their operation, responsibilities and services they can provide. It does not regulate the practice of the profession of pharmacist.

1.3.2 Principle of efficiency: the introduction of unnecessary bureaucracy relating to the notification of opening hours through the Official College of Pharmacists of Madrid (COFM) is criticised.

Not accepted.

This provision aims to avoid having to submit two notifications about opening hours, since the procedure is deemed to have already been carried out once the COFM is notified. It is thus more efficient for the administration to receive a single communication from the COFM with the opening hours of all retail pharmacies in the Community of Madrid.

1.3.3 Principle of legal certainty: the use of undefined legal concepts creates uncertainty.

Not accepted.

The technique of undefined legal concepts is accepted as appropriate provided that the Administration provides a reasoned justification for its interpretation of them.

As for the covert penalties referred to in various articles of the regulation, these are rejected as they are legal consequences linked to failure to comply with the requirements for carrying out an activity.

With regard to infringements and penalties, it is noted that the generic reference to the law infringes the principle of the legal definition of infringements. It is rejected on the grounds that the infringing conduct is sufficiently described in a regulation with legal status, i.e. Law 13/2022, of 21 December.

1.4 FEFE, Coello de Portugal Abogados, AFIN: **Infringement of the freedom to conduct a business, the guarantee of market unity, and the guarantee of defence of competition.**

It is claimed that freedom to conduct a business is limited by the high requirements of the regulation in terms of personnel, opening hours and outsourcing of services, which restrict the free provision of services. This is rejected, since, in line with the above, the aim of the regulation is not so much to enable all pharmacies to provide as many services as possible, but to ensure that the services provided are provided under minimum conditions which ensure the quality and safety of the patients for whom they are intended.

As regards the fragmentation of market unity resulting from the geographical limitation of pharmacy delivery services to the basic health zone, it is accepted, with Article 38(4) amended to allow the patient free choice over the retail pharmacy that will provide this service.

1.5 TRÉBOL: On the excessive use of undefined legal concepts .

Not accepted.

Terms such as exceptional circumstances, basic health zone and patient suitability are defined in the context of the draft decree and are interpreted in accordance with objective criteria established in current health regulations.

1.6 SEFH: Concerning the preliminary part:

1.6.1 It is proposed that the following phrase be added to Paragraph (3): *'(...) and institutional pharmacies*.'

Not accepted. However, the scope of the provisions in the draft decree has been clarified, including an explanation regarding hospital institutional pharmacies.

1.6.2 Include in the fifth paragraph: *'... or, where appropriate, in the authorised institutional pharmacy of the corresponding residential centre*'.

Not accepted.

It proposes deleting the phrase '*expressly prohibiting its preparation by and for third parties*'. Other arguments have been raised on this matter, which have been addressed in the Regulatory Impact Analysis Report.

1.6.3 In the sixth paragraph, it proposes the deletion of 'institutional pharmacy'.

Accepted.

2. **Chapter I. General Provisions (Articles 1 and 2).**

2.1 **Article 1. Purpose.**

2.1.1 Spanish Society of Primary Care Pharmacists (SEFAP), JOSÉ MANUEL IZQUIERDO PALOMARES: The removal of the term 'hospital' is requested, as well as the incorporation of a provision that expressly regulates pharmacy delivery services from the primary care institutional pharmacy.

Not accepted.

Law 13/2022, of 21 December, recognises the fundamental role of pharmacy units in primary care for optimising the quality of the care process in collaboration with other healthcare professionals at this level of care. However, the pharmaceutical care regulated by the draft decree is that provided for in Article 13(3) of Law 13/2022, of 21 December, which refers exclusively to retail pharmacies. The draft decree also includes pharmaceutical care provided by the hospital institutional pharmacy within the framework of the provisions of Article 40(j) of Law 13/2022, of 21 December, as well as the provisions of Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices (TRLGURM), which incorporates a Section (8) into Article 3 in this regard and which would justify development in this decree. It is precisely this dispensing of medicinal products that exceeds the functions that Law 13/2022, of 21 December, attributes to primary care institutional pharmacies.

2.1.2 COFM: It is requested that the term 'home' be added to the care through hospital institutional pharmacies, since it is that service that will be regulated in the decree.

Not accepted.

This regulation has been implemented in accordance with Article 40 of Law 13/2022, of 21 December, which provides for the non-face-to-face dispensing of medicinal products that are restricted to hospital settings, including via remote assistance. All of this is included in Chapter IV, in accordance with the scope of the provisions explicitly set forth in Article 13 of the aforementioned Law 13/2022, of 21 December.

2.1.3 AFIN: With regard to excessive regulation ‘by seeking to regulate matters which, by their scope, go beyond mere regulatory development and affect the core of rights and obligations’.

It is rejected as unfounded, since the draft merely regulates in greater detail aspects of pharmaceutical management already provided for in Law 13/2022, of 21 December, the practical application of which required further clarification.

2.1.4 SEFH: It is requested that dietary supplements be included in the subject matter of the regulation.

Not accepted.

These products are listed in the article specifically dedicated to pharmacy delivery services provided by retail pharmacies.

2.1.5 TRÉBOL: It is proposed that payment for the service provided be included in the title of the article and that a Paragraph (4) be added to this effect.

Not accepted.

Law 16/1997, of 25 April, defines retail pharmacies as*’... private healthcare establishments of public interest’* and expressly recognises in Article 1 the following as basic services to be provided to the population: information and monitoring of pharmacological treatments for patients, collaboration on the control of individualised use of medicinal products in order to detect adverse reactions and report them to the bodies responsible for pharmacovigilance, collaboration on programmes promoted by the health authorities on quality assurance in pharmaceutical care and healthcare in general, health promotion and protection, disease prevention and health education, collaboration with the health administration on training and informing other health professionals and users about the rational use of medicinal products and medical devices. Coordinated action with the healthcare structures of the health services ... without, under any circumstances, taking economic criteria into account. In this regard, it should be recalled that Article 6, in accordance with the first final provision of the aforementioned regulation, constitutes basic state legislation on health, enacted under Article 149(1) (16) of the Spanish Constitution, without the autonomous community being able to extend its regulation beyond the planning criteria established in state regulation. Therefore, the remuneration would exceed the limits set by the state regulation.

2.1.6 SEFAC: As regards the proposal to use the term ‘*community pharmacy*’ instead of ‘*retail pharmacy*’.

Not accepted.

The term ‘retail pharmacy’ is used uniformly in Spanish legislation (Law 16/1997, of 25 April; Royal Legislative Decree 1/2015, of 24 July; Law 13/2022, of 21 December) to refer to the authorised pharmaceutical establishment, ensuring terminological consistency, legal certainty and linkage with administrative procedures and official registers.

3. **Chapter II. Opening hours, out-of-hours services and holidays (Articles 3–13).**

3.1 **Article 3: Ordinary and official opening hours.**

3.1.1 COFARES and TRÉBOL: It is proposed that new Points (4) and (5) be added to Article 3 with the following wording:

‘*4. The ordinary and official hours shall be Monday to Friday from 10:00 to 13:00 and from 17:00 to 20:00. Saturdays, from 10:00 to 13:00.*

5. *Both the ordinary and official opening hours and the voluntarily extended opening hours must be displayed in a place visible to the public and remain in place for one year*.’

Not accepted, as it is already included in Law 13/2022, of 21 December, in Article 25(1).

3.1.2 ADEFARMA: A new wording of Section (3) is proposed, which should read: ‘*In municipalities with fewer than two thousand inhabitants, the ordinary and official opening hours may be 35 hours per week and carried out continuously, and [the pharmacy] must be open to the public every working day with the same hours*’.

This is not accepted because it would mean removing the requirement that there be no health centre, which is expressly set out in Law 13/2022, of 21 December, in Article 25(5).

3.1.3 ADEFARMA: It is suggested to add a Section ‘*4. Retail pharmacies may establish alternative opening hours between 15 June and 15 September, with fixed afternoon opening hours from 17:30 to 20:30 due to the climate in the Community of Madrid and in accordance with the recommendations of the health authorities to avoid going outside during the hottest hours of the day.*’

Not accepted, since the proposed opening hours would not meet the minimum and official hours set by Law 13/2022, of 21 December, in Article 25(1).

3.2 Article 4. Extended opening hours.

3.2.1 COFARES, TRÉBOL: The options in this article for choosing flexible opening hours do not comply with Article 25 of Law 13/2022, of 21 December, which states: *‘... The flexible range will be determined voluntarily by retail pharmacies*...’, to adapt to the needs of their basic zone.

Not accepted, since Law 13/2022, of 21 December, deals with the reality of the Community of Madrid, and the demand for liberalisation and flexibility already set out in the earlier Law 16/1997, of 25 April, on the regulation of retail pharmacy services, which established, in general terms, in Article 6 that retail pharmacies would provide their services freely and flexibly.

On the other hand, the issue of opening hours must be addressed in such a way that out-of-hours services can be organised to ensure the continuity of pharmaceutical services and adapt them to the needs of citizens, which requires advance planning. The decision to opt for one schedule or the other is up to the pharmacist, always respecting the fact that this is a regulated activity that is subject to planning, hence the corresponding out-of-hours services must be established. Therefore, it has been deemed that a wide time slot, established between 06:00 and 23:00, allowing flexibility over opening hours is in line with the spirit of the law that integrates the hours currently authorised in pharmacies in the Community of Madrid and the possibility of opting for a 24-hour service.

3.2.2 COFM: In Section (4), it is suggested that the term 'during' be replaced by the term 'within'.

Accepted.

3.2.3 ADEFARMA: It is proposed that Article 4(5) be amended as follows: '5. In health or weather emergencies, special opening hours may be established and the cooperation of a certain number of retail pharmacies may be requested, as deemed appropriate by the health authorities and the Official College of Pharmacists of Madrid.'

Not accepted. This refers to weather conditions, which are already covered by the exceptional circumstances referred to in this section in its current wording.

3.3 Article 6. Requirements for pharmaceutical staff during extended hours and special circumstances.

3.3.1 COFM: Proposed wording for Section (5): '*5. In cases where it is impossible to maintain the minimum number of pharmacists required, and provided that it is duly justified, the owner of the retail pharmacy must notify the competent authority of a temporary reduction in opening hours, adapting them to the staffing requirements established in this article and, where appropriate, disassociate themselves from any associated in-house dispensaries or rural dispensaries if they do not have the necessary pharmaceutical staff within three months.*'

Accepted.

3.3.2 ADEFARMA: Add the phrase '*if there are two co-owners and one of them is over 70 years of age and the other is under 70 years of age, it is not necessary to hire an assistant pharmacist*'.

Accepted.

3.3.3 ADEFARMA: It is suggested that the wording of Section (4) be replaced with: '*When the retail pharmacy has a linked in-house dispensary or rural dispensary and the opening hours of these coincide with those of the retail pharmacy, a full-time or part-time assistant pharmacist must be hired.'*

This is not accepted because the current wording is much more precise.

3.3.4 ADEFARMA: Point (5) should be replaced with: '*In cases where it is impossible to maintain the minimum number of pharmacists required, and provided that it is duly justified, the owner of the pharmacy must notify the competent authority of a temporary reduction in opening hours, adapting them to the staffing requirements established in this article and, in the event that the linked rural dispensary cannot be staffed by a pharmacist, disassociate themselves from it. Likewise, it must also sever ties with the linked in-house dispensary if the opening of the latter coincides with the opening of the retail pharmacy*.'

Not accepted, but a better wording is suggested.

3.3.4 MARÍA GONZÁLEZ: Suggestion to add the following phrase at the end of Section (4): 'which guarantees adequate pharmaceutical care during the operating hours of the rural dispensary or in-house dispensary and is adjusted to the workload generated by it.'

Accepted.

3.3.5 IGNACIO ARCOS: It is claimed that there is disagreement with the provisions of Article 6(2)(a) 'as it states that the minimum opening hours are 40 hours (as set out in Law 13/2022, of 21 December, on pharmaceutical care and management in the Community of Madrid, Title II, Chapter III, Article 25) and that it would not be necessary to hire a pharmacist until 55 hours is reached, provided that the pharmacist is under 70 years of age. The current minimum of 40 hours should be removed and brought into line with current regulations, such as the preliminary draft to reduce the working week to 37.5 hours, which follows EU directives, in order to prevent subsequent changes from 40 hours per week to 37.5 hours, facilitating voluntary and free opening on Saturdays. In other autonomous communities such as the Basque Country, there is greater freedom in terms of opening hours, with a minimum of 30 hours per week and the option of whether or not to open on Saturdays, provided that the health zone is covered by other pharmacies. Health inspectors do not carry out inspections at weekends, and many pharmacies fail to have a pharmacist on duty during opening hours, putting the public who use these pharmacies at risk. In turn, allowing a licensed pharmacist with extended hours NOT to hire pharmacists if the pharmacy is open 55 hours per week would lead to the same situation: pharmacies without pharmacists and without inspections at

weekends. The assistant pharmacist is once again being overlooked by the administration, which allows licensed pharmacists to work 55 hours while assistant pharmacists are not permitted to work more than 40 hours.'

This is not accepted, as self-employed professionals are not limited by a 40-hour working week.

3.3.6 FEFE, AFIN: Excessively rigid regulation that imposes disproportionate burdens.

Not accepted.

The need to regulate this aspect stems from the provisions of Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices, which establishes 'the presence and professional practice of the pharmacist as an essential condition and requirement for the dispensing of medicinal products to the public, taking into account the number of pharmacists necessary depending on the activity of the pharmacy'.

Law 16/1997, of 25 April, establishes, in general terms, that the presence and professional practice of a pharmacist is an essential condition and requirement for the dispensing of medicinal products to the public; that the autonomous communities may regulate the minimum number of assistant pharmacists who, in addition to the owner, must provide services in retail pharmacies in order to guarantee adequate professional care for users; and that this regulation must take into account, among other factors, the volume and type of activity of retail pharmacies and the opening hours schedule. In other words, state regulations make it clear, in general terms, that the presence and professional practice of the pharmacist is an essential condition and requirement for the dispensing of medicinal products to the public, and this presence is linked both to the volume of activity and to the hours during which the service is provided. Furthermore, Law 13/2022 establishes that the presence of a pharmacist on the pharmacy's staff is an essential requirement for dispensing, that pharmacies must be staffed with a sufficient number of pharmacists to ensure, in accordance with the established schedule of opening hours, the constant presence and professional practice of at least one pharmacist throughout the entire time that the pharmacy provides service to the public and that the appointments of managing, substitute and assistant pharmacists must be communicated to the regional ministry responsible for health matters in order for them to be able to perform their duties in the pharmacy.

3.4 Article 7 Retail pharmacy out-of-hours services.

3.4.1 SEFAC: Change the reference to out-of-hours services to emergency services, as this is the wording used in Law 13/2022, of 21 December.

Not accepted.

3.4.2 ADEFARMA: Proposal to add that ‘out-of-hours services should be remunerated when the retail pharmacy carries out its out-of-hours duty outside its normal working hours. This remuneration should be higher in the case of pharmacies with compromised economic viability.’

This is not accepted: the autonomous community cannot extend its regulation beyond the planning criteria established in the state regulation. Therefore, the remuneration would exceed the limits set by the state regulation.

3.4.3 ADEFARMA: Section (a) should be replaced by ‘Daytime out-of-hours service: this is the service provided by retail pharmacies without interruption from 09:30 to 21:30’. And (b) should be replaced by ‘Night-time out-of-hours service: this is the service provided by retail pharmacies without interruption from 21:30 until 10:00 the following day’.

Not accepted, as these periods have been defined the same as before in order to maintain continuity with previous planning. Changing the time slots may lead to confusion and distortions.

3.5 Article 8. Organisation of out-of-hours pharmaceutical services.

3.5.1 JAVIER CABELLO: With regard to the organisation of out-of-hours pharmaceutical services, it is argued that night shifts should be organised around the local public hospital, which always has emergency medical staff on duty. Pharmacies located within a 15-kilometre radius or 15 minutes of the local hospital will be responsible for organising the out-of-hours services. In line with this, the wording of this section should be as follows:

‘*1. Whenever there is a public health centre with emergency medical services in a basic health zone, the out-of-hours services necessary to ensure the continuity of pharmaceutical care should preferably be organised there.*

Basic Health Zones that have a public health centre with emergency medical services must organise out-of-hours shifts with other neighbouring basic zones, provided that the distance between urban centres does not exceed 15 kilometres or a 15-minute journey. ’

Not accepted. The current wording considers not only the importance of emergency health centres when organising out-of-hours services, but also other decisive factors established in Article 26 of Law 13/2022, of 21 December, which are: health planning and its territorial distribution; the hours and structures of the emergency health services provided in the health system of the Community of Madrid; the population to be served; the provision of communications infrastructure; retail pharmacies open 24 hours a day; and geographical barriers, as well as any other criteria or unique features that are worth considering.

3.5.2. AFIN: It is recommended that objective, transparent and non-discriminatory criteria be developed to be taken into account by the college of pharmacists when establishing out-of-hours shifts in order to ensure pharmaceutical care for the population, without restricting competition between pharmacies.

Not accepted.

The current wording includes a set of criteria established in Article 26 of Law 13/2022, of 21 December, which are: health planning and its territorial distribution, the hours and structures of the emergency health services provided in the health system of the Community of Madrid, the population to be served, the provision of communications infrastructure, retail pharmacies open 24 hours a day and geographical barriers, as well as any other criteria or unique features that are worth considering.

3.6. Article 11. Out-of-hours services in health emergency situations.

3.6.1 ADEFARMA: It should be replaced with '*In situations of health or weather emergencies, extraordinary out-of-hours services may be established and extended to the retail pharmacies that the health administration deems appropriate to meet the demand for extraordinary assistance for as long as necessary due to said emergency*.'

Not accepted. Weather conditions can be included in the broader, more generic category of *'exceptional circumstances*' as argued in the article on extended opening hours in exceptional circumstances.

3.7. Article 13. Holidays.

3.7.1 MARÍA GONZÁLEZ: Include a Section (4): *'Retail pharmacies that have a linked rural dispensary or in-house dispensary must guarantee the service during the period in which these are in operation.'*

Accepted

3.7.2 AFIN, FEFE: The COFM is granted discretionary powers without objective criteria (Article 13), which infringes legal certainty.

Not accepted.

The current wording develops the provisions of Law 13/2022, which establishes that retail pharmacies may cease their activities during the holiday period and, in this regard, the draft decree establishes the time frame for notifying the COFM so that holiday periods can be organised, taking

into account the fact that at least 50% of retail pharmacies in each basic health zone or grouped neighbouring zone must remain open.

4. CHAPTER III. Personalised dosage systems (Articles 14–35):

4.1 Article 14. General conditions of service provision.

4.1.1 SEFAP: It is important to establish a clear distinction in some articles of the PDS intended for people living at home and those who are institutionalised, as their circumstances and needs differ and the administrative burden could be reduced while ensuring service quality and regulatory compliance.

Accepted. A distinction is made in the article dedicated to the delivery of PDS (Article 34) which is broken down into two (Articles 33 and 34).

4.1.2 RUBÉN MARTÍN LÁZARO, COFARES, COELLO DE PORTUGAL, AFIN, NATIONAL BUSINESS ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY (FARMAINDUSTRIA), TRÉBOL, regarding the possibility of PDS being outsourced to a third party.

Not accepted.

The possibility for PDS to be entrusted to a third party conflicts with Article 86(1) of the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices (TRLGURM), according to which '*In retail pharmacies, pharmacists, as persons responsible for dispensing medicinal products ... Once the medicinal product has been dispensed, they may provide personalised dosage systems to patients who request it*'. This provision limits the provision of this post-dispensing service to the retail pharmacy that dispenses the medicine. Along the same lines, the AEMPS document CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES establishes that, in any case, the preparation of medicinal products in PDS must be carried out by the same dispensing pharmacy, expressly prohibiting the possibility of entrusting the preparation of PDS to another retail pharmacy or a third party.

4.1.3 RUBÉN MARTÍN LÁZARO, COFARES, COELLO DE PORTUGAL, AFIN, FARMAINDUSTRIA, TRÉBOL, FEFE: On the proposed differentiation between dispensing pharmacies and compounding pharmacies in accordance with the provisions on compounding and appealing to the freedom of choice of retail pharmacy.

Not accepted.

The reason for this is that PDS preparation is always a post-dispensing service. The wording of this article complied with Article 86(1) TRLGURM, '*In retail pharmacies, pharmacists, as persons responsible for dispensing medicinal products ... Once the medicinal product has been dispensed, they may provide personalised dosage systems to patients who request it, …'.* The same is stated in the CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES, which establish mandatory minimum requirements for the preparation of PDS and exclude the possibility of preparation by third parties. On the other hand, Law 13/2022 recognises the free choice of the retail pharmacy responsible for dispensing, and this does not in any way prevent the preparation by a retail pharmacy other than the dispensing pharmacy.

4.1.4 RUBÉN MARTÍN LÁZARO, FARMAINDUSTRIA, TRÉBOL: On the requirement that PDS must be prepared in accordance with good manufacturing practice for medicinal products.

Not accepted as it does not apply to them, since there is no manufacturing process, unlike in the case of compounded medicines.

4.1.5 RUBÉN MARTÍN LÁZARO, AFIN: On renumbering the PDS.

Not accepted.

Law 16/1997, of 25 April, which defines retail pharmacies as private healthcare establishments of public interest, expressly recognises in Article 1 the following as basic services to be provided to the population:

Providing information on and the monitoring of pharmacological treatments for patients, collaboration on the control of individualised use of medicinal products in order to detect adverse reactions and report them to the bodies responsible for pharmacovigilance, collaboration on programmes promoted by the health authorities on quality assurance in pharmaceutical care and healthcare in general, health promotion and protection, disease prevention and health education, collaboration with the health administration on training and informing other health professionals and users about the rational use of medicinal products and medical devices. Coordinated action with the healthcare structures of the health services ... without, under any circumstances, taking economic criteria into account. The autonomous community cannot extend its regulation beyond the planning criteria established in the state regulation. Therefore, the remuneration would exceed the limits set by the state regulation.

4.1.6 COFARES: The following wording is proposed: 'PDS preparation and delivery activities must be carried out, for all the processes involved in their preparation and exclusively, by a retail pharmacy or a hospital institutional pharmacy.'

This is not accepted since the regulation of PDS also includes the possibility of preparing PDS in the institutional pharmacies of residential centres. The general term 'institutional pharmacy' includes hospitals and residential centres' own institutional pharmacies.

4.1.7 COELLO DE PORTUGAL: It is proposed that Section (1) expressly state that the post-dispensing service is a non-pharmaceutical act.

Not accepted.

Personalised dosage systems (PDS) are a healthcare activity specific to pharmacists, integrated into pharmaceutical care and aimed at optimising treatment and rationalising the use of medicinal products. Far from being a mere material act in the pharmacy, the PDS involves the assessment of the prescribed treatment, the detection of possible problems related to medicinal products and the medication management of the patient, functions requiring the professional intervention of the pharmacist, in accordance with the framework established by Law 13/2022 and the state regulations on pharmaceutical management.

4.1.8 COFM: It is proposed that Section (3) be amended as follows:

'3*. PDS preparation activities must be carried out entirely and exclusively in the same retail pharmacy or institutional pharmacy that dispensed the corresponding medicines. PDS may be delivered in authorised rural dispensaries or in-house dispensaries linked to the retail pharmacy that has prepared them. Under no circumstances may this task be delegated* to another pharmacy, institutional pharmacy or third parties, nor may it be carried out for third parties.'

This is accepted and included in Article 33(1) (current) dedicated to the delivery of these devices, with the exception of in-house dispensaries, which are covered in Article 34 (current) in relation to residential social service centres.

4.1.9 COFM: Regarding the proposal to expressly mention the prohibition of using the service for the purpose of attracting patients, adding a seventh section to Article 14 of the draft:

'*In order to promote the rational use of medicinal products and patient safety, the use of this service as a means of attracting patients is prohibited in order to avoid possible incentivisation of the use of medicinal products, in accordance with Article 80 of Royal Decree 1/2015*.'

Not accepted.

Article 80 TRLGURM is invoked, which regulates the advertising of medicinal products and medical devices intended for the general public, which does not apply to the advertising of a service provided by the retail pharmacy. On the other hand, Law 13/2022, of 21 December, does provide for the possibility of advertising the activities and services provided by the retail pharmacy.

4.1.10 COFM: In relation to agreements with other public or private entities for the preparation of PDS for certain groups, it is proposed that an eighth section be added to Article 14 of the draft stating the following:

'*8. When a public administration or public or private entity wishes this service to be provided specifically to a particular sector or population group, it may arrange for the COFM to provide it*.'

Not accepted.

The regulation of the draft decree stems from the mandate established in Article 14(4) of Law 13/2022, of 21 December, on the specific technical health conditions and requirements necessary for the provision of PDS. The above proposal is more in line with health/pharmaceutical policy strategies through the use of agreements. Furthermore, this suggestion is already included in general terms in Article 4 on institutional cooperation.

4.1.11 MARÍA GONZÁLEZ: It is proposed that it be specified that PDS are intended for people at home, as the definition may be confused with the functions of hospital institutional pharmacies carried out within the hospital environment, which are not covered by this standard and for which procedures already exist to guarantee their quality, differentiating them from the preparation of PDS for residential centres if the institutional pharmacies have in-house dispensaries in associated residential centres.

Accepted.

4.1.12 MARÍA GONZÁLEZ: Preparation should not be limited to pharmacy technicians in the case of institutional pharmacies, and the range of professionals who can perform this task should be expanded.

Accepted.

4.1.13 MARÍA GONZÁLEZ: Proposal that medication should not be identified by user.

Not accepted. Medication is personalised because it is tailored to specific patients.

4.1.14 MARÍA GONZÁLEZ: It is proposed that institutional pharmacies be exempted from the spatial and material requirements for the preparation of PDS.

This is not accepted, since exactly what is being regulated has already been clearly defined and, therefore, institutional pharmacies are subject to the same requirements and guarantees.

4.1.15 MARÍA GONZÁLEZ: It is suggested that PDS be classified depending on whether they are prepared manually or with the help of automated preparation systems.

Not accepted.

The purpose of the regulation of PDS has been clarified. The draft decree does not regulate automated systems or robots used in the preparation of personalised dosage systems, since these constitute only a means of support or an instrument for the care activity of the pharmacist, and are not an end in themselves. What is relevant is the professional practice and compliance with the technical and health requirements of the service, regardless of whether the process is manual or automated.

4.1.16 MARÍA GONZÁLEZ, SEFH: Proposal to delete, in Section (1), the expression '*by the patient*', since in the case of institutionalised users this medication can be administered by professionals.

Accepted.

4.1.17 MARÍA GONZÁLEZ, SEFH: In Section (2), it is suggested that the declaration of responsibility for the preparation of PDS be omitted in the case of institutional pharmacies, since repackaging and preparation are part of the specific functions of these services, and they are already required to have adequate areas for these activities when applying for authorisation for the pharmacy unit.

Not accepted. The purpose of the regulation of PDS has already been clarified.

4.1.18 MARÍA ÁNGELES MONTERO: It is proposed that Section (3) be amended as follows: '*PDS preparation and delivery activities must be carried out entirely and exclusively in the same retail pharmacy or institutional pharmacy that dispensed the corresponding medicines exclusively by personnel hired for these activities.*'

Accepted.

'*Under no circumstances may this task be delegated to another pharmacy, institutional pharmacy or third parties, nor may it be carried out for third parties, and pharmacies are expressly prohibited from subcontracting to self-employed pharmacists who are not members of their staff.*'

Not accepted, as the new wording already reflects this, avoiding a new prohibition not provided for in Law 13/2022, of 21 December.

4.1.19 MARÍA GONZÁLEZ, SEFAP: In Section (5), in order to avoid excluding those institutional pharmacies that do not have pharmacy technicians available during all opening hours, the wording 'pharmacy technicians' should be changed to '*by technicians in pharmacies or, in the case of institutional pharmacies, by duly qualified and trained healthcare personnel*.'

Accepted, except for the indication that the personnel must be trained, given that there is no formal training for these functions.

4.1.20 EAADD: It is proposed that Section (4) be amended as follows: '*PDS may only be prepared with medicinal products previously dispensed by the retail pharmacy or by the institutional pharmacy responsible for their preparation, thus ensuring the control and traceability of treatment*. *Exceptionally, in cases where the retail pharmacy responsible for pharmaceutical care at a social and healthcare centre changes, the professional service of the PDS may be provided by the incoming pharmacy with regard to the medication for residents provided through the outgoing pharmacy, ensuring the preservation and traceability of the drugs at all times.'*

Not accepted.

If the in-house dispensary is unlinked from a retail pharmacy, the new retail pharmacy takes over the preparation of PDS, and this requires an appropriate transition in workflows and responsibilities, bearing in mind that medicines that have already been dispensed and are intended for identified patients cannot be transferred. Compliance with the decree (PDS 14 days) ensures that the preparation process can be properly transferred in order to ensure the traceability of the process.

4.1.21 SEFH: It is proposed that the reference to the institutional pharmacy in Section (4) be deleted.

Not accepted.

Reference is made, in general, to institutional pharmacies, and not specifically to hospital institutional pharmacies, in order to accommodate both the institutional pharmacies authorised in social and healthcare centres and those linked to their in-house dispensaries and that are responsible for pharmaceutical provision in those centres. The draft expressly regulates personalised dosage systems (PDS), without extending its scope to other activities specific to hospital institutional pharmacies.

4.1.22 SEFAC: It is requested that personalised dosage system be replaced with personalised repackaging system.

Not accepted.

The current wording is consistent with the provisions of Law 13/2022, of 21 December, and the TRLGURM, which uses the term PDS. No other standard refers to PDS as repackaging systems. Therefore, introducing a new concept that is not included as a regulatory definition, unlike PDS, which is the name used, is neither appropriate nor technically correct and could lead to confusion.

4.1.23 VÍCTOR BELLVER: It is argued that there is no distinction made between the different systems (their working protocols being very different). Requirements are established that apply only to manual or semi-automatic systems and there is no reference to how this should be done in automated systems (Article 19(4) only specifies the following: 'automated systems, if available, must ensure the traceability of the medicinal products dispensed to each patient and of the devices prepared'). There is a legal vacuum regarding the operation of automated systems. For all these reasons, it is proposed that the articles of this decree recognise the usefulness and proper functioning of these systems, which are already firmly established, provide an excellent service and are constantly evolving and improving.

Not accepted.

It is not the purpose of this regulation to address or pronounce on the different systems that the market offers to carry out this activity, as already mentioned above.

4.1.24 SEFH: It is argued that the reference to the head of the institutional pharmacy within the context of the paragraph as the PDS provider does not seem very consistent with the current legal framework. In addition, it is proposed that the text unify and define the concept of institutional pharmacy (or the different types of institutional pharmacies) for the purposes of this regulation.

Not accepted.

What is to be regulated and its scope have already been defined. General reference is made to institutional pharmacies, and this is so as to accommodate authorised institutional pharmacies in social and healthcare centres or those linked to their in-house dispensaries, which are responsible for pharmaceutical provision in the social and healthcare centre. This means that the draft expressly regulates PDS and not other activities specific to hospital institutional pharmacies.

4.1.25 SEFH: It is suggested that roles and responsibilities in the preparation process should be defined and established in the standard working procedures.

Not accepted.

With regard to roles and activities, the draft decree dedicates Article 16(g) to the delegation of functions and Article 20 establishes the mandatory documentation for the preparation of the devices.

4.1.26 JACINTO VICO: In Article 14(3), it is proposed that an exception be included: 'Pharmacies that have outsourced the preparation of compounded medicines (in their entirety and that therefore do not have a laboratory) to a third-party compounding pharmacy may outsource the PDS preparation service to that pharmacy, if they offer the service, developing a protocol for receiving such medicines at the compounding pharmacy, which would be delivered exclusively and directly, without intermediaries, by the pharmaceutical staff or under their supervision from the dispensing pharmacy.'

Not accepted.

The prohibition on the preparation of PDS by third parties has already been justified without any exceptions.

4.2 Article 15. Declaration of responsibility.

4.2.1 RUBÉN MARTÍN LÁZARO, ADEFARMA: It is proposed that Section 2 be amended and replaced with the following wording:

'*The declaration of responsibility must be updated in the event of amendments to the regulations in force or changes to the conditions initially declared. In order to continue the activity at the end of that period, a new declaration of responsibility must be submitted at least 15 days before its expiry*.'

Accepted.

4.2.2 COFM: It is requested that Points (a), (b) and (c) of Article 15(1) be deleted, leaving the wording as follows:

'*1. The declaration of responsibility must be signed by the owner, owners or manager of the retail pharmacy or, where applicable, by the head of the institutional pharmacy. It shall be submitted using the standard form provided in Annex I, which is available on the website https://www.comunidad.madrid/servicios/salud/farmacias-farmacéuticos, and the standard form on the Digital Administration Portal (E-Office).'*

Accepted.

4.2.3 MARÍA GONZÁLEZ, SEFH: It is requested that institutional pharmacies be excluded from the obligation to submit the declaration of responsibility and that the plans not be attached.

Non-submission of the plans is accepted.

The exemption of institutional pharmacies from the submission of the declaration of responsibility is not accepted. The declaration of responsibility must be submitted in both cases, by retail pharmacies and institutional pharmacies. For the latter, the standard regulates a specific activity: the preparation of PDS intended for institutionalised patients. Nor is it accepted that these provisions apply only to the authorisation of new institutional pharmacies, since the purpose of the decree is not to regulate the requirements for such authorisation.

4.2.4 FARMAINDUSTRIA: It is requested that authorisation be required for the preparation of PDS, without a mere declaration of responsibility being acceptable, as this 'lacks prior checks by the administration.'

Not accepted.

The declaration of responsibility speeds up the administrative procedure, allowing the activity to begin immediately, without having to wait for the processing of an authorisation procedure, which is more cumbersome and time-consuming. Although it is true that there is no prior checking of the activity, there is subsequent and permanent checking. Furthermore, the consequences associated with false declarations under Article 69 of the Law of Common Administrative Procedure act as a deterrent. With regard to the alleged equivalence to compounded medicines, the answer is that this is not the case. In effect, compounded medicines are medicines in the legal sense, whose preparation involves a manufacturing process; for this reason, they must be prepared in accordance with the good manufacturing practices specifically established for them. On the contrary, PDS involve the repackaging of previously dispensed medicines, not a manufacturing process.

4.3 Article 16. Technical and organisational requirements for the provision of the PDS service.

4.3.1 COFM: It is considered necessary to add that, in the event that functions are delegated to an assistant pharmacist (Article 16(g)), the responsibility of the licensed pharmacist, manager or head of service shall not be excluded, with the text reading as follows:

'(g) Delegation of documented functions: in the event that the licensed pharmacist, manager or head of the institutional pharmacy delegates functions to an assistant pharmacist, such delegation must be expressly stated in the standard working procedure, without this excluding the responsibility of the licensed pharmacist.'

Accepted.

4.3.2 COFM: It is proposed that Section (c) '*Definition of functions. The duties of each professional involved in the service must be documented internally in order to ensure the proper organisation of*

the process' be deleted, since this requirement is redundant, as it is already included in the standard working procedure, Article 21(2) of the draft.

Accepted.

4.3.3 COFM: We request the inclusion of a new article requiring specific training for pharmaceutical staff involved in the preparation and delivery of PDS, as well as the minimum content of the training programme, to be included in the standard working procedure.

Not accepted.

There is no regulated training for these functions.

4.3.4 ADEFARMA: It is proposed that Sections (d) to (g) be deleted.

Not accepted.

It proposes removing the requirement for prior informed consent explicitly laid down in Law 13/2022, of 21 December, as well as the records that guarantee traceability, which is a fundamental aspect of service quality and patient safety.

4.3.5 SEFH: The deletion of hospital institutional pharmacies is proposed, with the requirements applying only to retail pharmacies.

Not accepted.

The scope of the regulation of PDS in the field of institutional pharmacies has already been explained.

4.3.6 FARMAINDUSTRIA: It is proposed that it be expressly stated that responsibility for any damage that may arise from the preparation of PDS lies solely with the pharmacist.

This is accepted and incorporated into Article 16(f), indicating who is responsible, but it is not considered necessary to incorporate specific regulations on liability or insurance obligations, given that the preparation of personalised administration devices (PDS) is part of the pharmacist's professional activity within the framework of dispensing and pharmaceutical care, subject to the civil and ethical responsibility inherent to professional practice. Consequently, any potential damages arising from errors in this activity are now covered by the compulsory civil liability policies of pharmacies, in accordance with the provisions of current regulations on professional pharmaceutical practice and liability.

4.3.7 MARÍA GONZÁLEZ: It is suggested that Sections *(g) and (l) should only apply to retail pharmacies.

This is not accepted, as it also applies to institutional pharmacies.

4.3.8 MARÍA GONZÁLEZ: It is suggested that *'when delivery is made to patients at home'* be added to Section (j).

Accepted.

4.4 Article 17. Requirements and standards for the preparation and delivery of PDS.

4.4.1 VÍCTOR BELLVER: The following amendment is proposed: '*Each patient's medicines must be stored in the retail pharmacy in clearly separated areas and under secure conditions*.'

Not accepted.

The current wording refers to separate, clearly identified containers and under safe conditions. The proposed wording lowers the standard by referring to areas rather than containers, which could compromise the traceability of which medicine is intended for each patient. On the other hand, new wording has been adopted since this separation must be assumed by both retail pharmacies and institutional pharmacies.

4.4.2 RUBÉN MARTÍN LÁZARO: It is proposed that its content be deleted as it is considered excessive and redundant and on the grounds that the pharmacist is sufficiently trained.

Not accepted. It is precisely part of the necessary regulatory development to ensure the provision of a quality service.

4.4.3 COFM: Regarding the requirements and standards for the preparation and delivery of PDS, it is suggested that Section (j) of Article 17 be amended to read as follows: 'Suitable information on the use of PDS devices shall be provided.'

Accepted.

4.4.4 MARÍA ÁNGELES MONTERO: In Section (l) concerning the fact that each patient's medicines must be stored in the retail pharmacy in separate, clearly identified containers and under safe conditions, it is proposed that the following be added: '*except in pharmacies that have implemented automated systems which ensure the traceability of each patient's packaging with its updated stock*.'

Not accepted.

The separation and identification of the patient's medication must be guaranteed. As already mentioned, the decree regulates the conditions, requirements and standards that must be met in the preparation of PDS without regulating the different systems used to carry out this activity. It has already been mentioned that traceability must be guaranteed from dispensing until the PDS is delivered to the patient.

4.4.5 MARÍA GONZÁLEZ: It is requested that it be clarified whether Sections (g) and (l) apply only to retail pharmacies.

This is not accepted, as it also applies to institutional pharmacies.

4.4.6 MARÍA GONZÁLEZ: In Section (j), it is suggested that the following be added: 'Where delivery is made to patients at home'.

Accepted, but with different wording.

4.4.7 MARÍA GONZÁLEZ: It should be noted that retail pharmacies must ensure that the professionals who prepare medication have adequate protective measures in place to minimise the risk to their workers of exposure to hazardous medicines.

This is not accepted since the purpose of this decree is not to regulate aspects of occupational health and safety but to regulate technical requirements for the provision and quality of the PDS service.

4.4.8 SEFAC: Clarify that PDS are only prepared with medicinal products previously dispensed in the pharmacy or institutional pharmacy.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities.

4.4.9 FARMAINDUSTRIA: It is proposed that it be required that all original packaging have the unique identifier deactivated.

Not accepted.

The express inclusion of this clarification is not considered necessary, given that retail pharmacies are already required by state regulations (Delegated Regulation (EU) 2016/161 and Royal Decree 717/2019 of 5 December 2019) to verify and deactivate the unique identifier of medicines at the

time of dispensing. This is a directly applicable legal obligation, which is inherent to the dispensing process and does not need to be reiterated in regional legislation.

4.5 Article 18. Requirements for facilities.

4.5.1 COFM: It is requested that the personalised care area not be required to be separated from the dispensing area.

Not accepted.

It focuses on retail pharmacies. However, new wording is given as these requirements also affect institutional pharmacies. The new wording leaves open the possibility of using areas dedicated to other professional services in retail pharmacies.

4.5.2 COFM: It is requested that the requirement to maintain a relative humidity between 40% and 60%, provided for in Article 18(3)(b)(3) be removed, since the requirement for environmental conditions of between 15 and 25 degrees is sufficient to maintain optimal conditions.

Not accepted.

This requirement was assessed by the AEMPS in the document CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES, a document which, although not legally binding, brings together the expert opinion of pharmaceutical technicians from the autonomous communities and the AEMPS in the area of medicines. This document sets out the minimum requirements that have been incorporated into other regional regulations governing PDS.

4.5.3 COFM: With regard to Article 18(3)(c)(1) and (2), it is proposed that the term ‘trays’ be replaced with ‘containers’.

Accepted.

It is also suggested that, in the same paragraph, the conjunction ‘and’ be replaced with ‘or’, as follows:

‘2. *In institutional pharmacies, this area is intended to safeguard and conserve the medicinal products necessary for the preparation of PDS, which are available in clearly identified containers for each patient or residential centre, where appropriate*.’

Not accepted.

This requirement was assessed by the AEMPS in the publication of the document CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES.

4.5.4. MARÍA GONZÁLEZ: In Section (c)(2), the current wording should be amended, as it is interpreted to mean that the medication dispensed by institutional pharmacies is individualised for each patient. Since acquisition in institutional pharmacies is direct, it is essential to specify that it is the medication prepared in a PDS that has to be identified by patient.

Accepted.

4.5.5 VÍCTOR BELLVER: It is proposed that a new article defining the types of PDS (manual, automatic and semi-automatic) be added.

Not accepted.

The proposed amendments to the wording are based on establishing differences in the case of automated systems and what is regulated are the requirements that they must meet for preparation, beyond the type of system they use.

4.5.6 ADEFARMA: It is proposed that it be stated that PDS must be prepared within the pharmacy that has dispensed the medicinal products or the authorised institutional pharmacy that is the reference for the residential centre.

Accepted.

4.5.7 ADEFARMA: It is proposed that it be indicated that an area specifically dedicated to this activity should be enabled, which has only the PDS preparation area.

Accepted.

4.5.8 ADEFARMA: It is proposed that Section (3) be replaced by '*Must have:*

(i) accessible sink or washbasin;

(ii) smooth, waterproof, washable and disinfectable work surface;

iii. *(iii) walls made of smooth, washable and disinfectable materials.*'

This is not acceptable, as it removes the temperature and humidity conditions, which is contrary to the recommendations of the aforementioned AEMPS criteria document.

4.5.9 ADEFARMA: It is suggested that the wording of Point (c) 'Storage area' be replaced by:

'*In retail pharmacies, the storage area must be intended to safeguard and store the medication dispensed in its original packaging, as well as the prepared PDS identified by patient. In the case of institutionalised patients, the name of the corresponding residential centre must also be included*.'

Accepted.

4.5.10 SEFH: It is proposed that Subsection (b), concerning the PDS preparation area, provide for the automation/robotisation of PDS preparation, as it is already a reality today in retail pharmacies.

Not accepted.

This article is expressly dedicated to establishing the necessary areas without entering into the types of systems that may be used for the provision of the service. This matter has already been addressed previously.

4.5.11 SEFH: It is argued that the provisions of Section (2) should not apply to the storage area in institutional pharmacies, since the organisation of the work of preparation and adaptation in these services does not correspond to the provisions of this paragraph.

Accepted.

4.5.12 SEFAC: It is requested that there be flexibility in the temperature and humidity ranges for medicinal products handled outside their primary packaging.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities, and to be taken into account in the regulatory developments carried out by the autonomous communities in this regard.

4.5.13 FEFE, AFIN: In relation to the fact that technical and infrastructure requirements are disproportionate, creating economic barriers and restricting patient access.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following

agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities, and to be taken into account in the regulatory developments carried out by the autonomous communities in this regard.

4.5.14 COELLO DE PORTUGAL: It is argued that there is no criterion in the draft decree for the technical approval of devices that can be used for the implementation of personalised dosage services.

Not accepted.

Personalised dosage systems (PDS) are a healthcare activity specific to pharmacists, integrated into pharmaceutical care and aimed at optimising treatment and rationalising the use of medicinal products.

Far from being a mere material act in the pharmacy, the PDS involves the assessment of the prescribed treatment, the detection of possible problems related to medicinal products and the medication management of the patient, functions requiring the professional intervention of the pharmacist, in accordance with the framework established by Law 13/2022, of 21 December, and the state regulations on pharmaceutical management. It was the state legislator itself that defined the scope of the basic regulation, limiting it to considering the possibility of implementing these systems.

The essential issue is not whether the PDS is prepared manually or automatically, regardless of the practical advantages that the use of automated means may offer, since both when the PDS is prepared manually and when it is prepared using an automated support system (robot or computer support), compliance with the technical health requirements now established is mandatory. Automated processes are a tool, not an end in themselves, and therefore it is not appropriate in this draft decree to either standardise or certify them. Consequently, automated systems must be adjusted and approved in accordance with the specific regulations applicable to them, without this draft being responsible for their regulation or certification.

4.6 Article 19. Requirements for equipment and tools.

4.6.1 COFM: It would be good if, in Article 19(2), compartmentalised trays were listed in a different section, since they are not classified as multi-compartment packaging. The wording could be as follows:

'*2. The packaging material consists of personalised dosage devices, which may be:*

disposable multi-dose (blister pack or similar);

multi-compartment (weekly pill boxes);

compartmentalised trays or automatic preparation PDS (bags) for patients institutionalised in hospitals or healthcare centres.'

Not accepted. Compartmentalised trays are a type of multi-compartment device.

4.6.2 COFM: Deletion of Section (e) of Article 19(3) in relation to waste and SIGRE [integrated management system for waste packaging].

Accepted

4.6.3 MARÍA GONZÁLEZ: In Section (3)(a), it is suggested that 'cutter' be added after 'utility knife'.

In Section (3)(c), it is proposed that 'head coverings' be replaced with 'disposable gowns'.

It is requested that Section (3)(d) only apply to retail pharmacies.

In Section (4), it is proposed that it be indicated that it would apply to all PDS, whether they are prepared using automated systems or manually.

Accepted, except for the suggestion relating to Paragraph (3)(d), given that the scope of this regulation extends in all cases to institutional pharmacies.

4.6.4 ADEFARMA: It is proposed that Points (b), (c) and (e) of Section (3) be deleted.

Not accepted.

This refers to thermometers, hygrometers, single-use clothing and individually identified containers, all of which are necessary requirements.

4.6.5 SEFH: It is pointed out that the requirement of Subsection (3)(d) is very difficult to apply to hospital institutional pharmacies, due to the characteristics and way of working of this type of specialised service.

Not accepted.

The conditions are the same for retail pharmacies and hospital institutional pharmacies. The argument puts the focus on hospital institutional pharmacies. The wording has already been improved to clarify the purpose of the regulation of PDS (retail pharmacy and institutional pharmacy of the residential centres themselves or of institutional pharmacies linked to the in-house dispensaries of these centres, and in both cases the traceability and allocation of medicines to

specific patients must be perfect). Please note that other functions of hospital institutional pharmacies are not being regulated.

4.6.6 SEFH: It is noted that the traceability requirement set out in Section 4 for automated systems must be expressly extended to manually produced PDS.

Accepted.

4.6.7 SEFH: It is noted that there are three systems: manual, semi-automatic and automatic, while Article 19(4) refers only to the automatic system.

Not accepted.

Semi-automatic systems are included in the automatic category.

4.6.8 SEFH: Sections (1) and (5) essentially deal with the same issue, so it would be appropriate to combine them into one.

Not accepted.

It is one thing that equipment and instruments must be kept in a perfectly clean condition, and another that they must be cleaned properly between each preparation, avoiding any risk of cross-contamination between medicines for the same patient or for different patients.

4.6.9 VÍCTOR BELLVER: On the existence of three systems – manual, semi-automatic and automatic – and that only Article 19(4) refers to the automatic system.

Not accepted.

The draft decree does not regulate the different systems that can be used in the preparation of PDS, as they are merely tools for their preparation. Article 19(4) refers to automated systems, including semi-automatic and automatic systems.

With regard to deleting Article 19(3)(d),

This is not accepted as the requirements covered by this regulation apply to all PDS types.

4.6.10 FEFE, AFIN: The fact that technical and infrastructure requirements are disproportionate, creating economic barriers and restricting patient access.

This is not accepted, as already stated in the response to the comment regarding Article 18.

4.7 **Article 20. Mandatory documentation**.

4.7.1 MARÍA GONZÁLEZ: It is proposed that this article be divided into two sections, one for retail pharmacies preparing medication for patients at home, and another for users of residential centres. In the latter case, documentation could be simplified by delegating the management of consent and permission documents to the centre's director. Users shall have the management and administration of medication delegated to the centre. This would avoid high bureaucratic burdens on retail pharmacies or pharmacies services that prepare medication for many users and would reduce the environmental impact. They will probably have automated preparation, so the patient's record and data relating to changes and blister-packable medicines will be stored in the automated system software they use.

Not accepted. The requirements relating to mandatory documentation apply in all cases. The particularities in the case of institutionalised patients are already reflected in the body of the decree.

4.7.2 SEFH: It is proposed that the reference to institutional pharmacies in Section (1) be deleted.

This is not accepted in line with other observations of a similar nature, the purpose of which is to exclude institutional pharmacies, when the requirements established by the decree for the preparation of PDS apply to both retail pharmacies and institutional pharmacies.

4.7.3 SEFAC: They request replacing '*patient record*' with '*medication history*' or '*pharmaceutical history*'.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities, and to be taken into account in the regulatory developments carried out by the autonomous communities in this regard.

4.7.4 COFM: Demarcate the responsibility of the pharmacist, since the data entered into the patient record are those provided by the patient or their legal representative, and the pharmacist cannot verify them in the patient's medical history. In this regard, we request that the following be added to Article 20(1)(b). 2. 'Patient record, signed by the patient'. This argument is related to the content of Article 26(2).

Not accepted (the proposal for Article 26(2) is accepted).

4.8 Article 21. Standard working procedure.

4.8.1 MARÍA GONZÁLEZ: It is proposed that the sections be reordered.

This is not accepted because it is considered that the order in which it is presented is appropriate.

4.8.2 MARÍA GONZÁLEZ: In Section (k), if the preparation is automated, it is proposed that the type of robot and the customised system used be specified. Furthermore, if preparation is automated, there must be a contingency plan in place to ensure delivery within the agreed deadlines and a training plan for retail pharmacy / institutional pharmacy professionals.

Not accepted.

Automated systems are merely a means of support or a tool for the pharmacist's healthcare activities; they are not an end in themselves. What is relevant is the professional practice and compliance with the technical and health requirements of the service, regardless of whether the process is manual or automated. The draft decree does not regulate the automated systems that may be used. On the other hand, the current wording establishes which aspects must be included in the standard working procedure as a minimum, which apply regardless of whether it is an institutional pharmacy or a retail pharmacy. As for the training plan, there is no approved training pathway for this activity.

4.8.3 EAADD: It is requested that the following addition be made to this provision:

'*Standard working procedure*

1. *The PDS preparation and delivery service is carried out in accordance with a standard working procedure approved, dated and signed by the licensed pharmacist or owners, manager or, where applicable, by the head of the institutional pharmacy. In the case of use of automated PDS systems, the aforementioned procedure shall follow the criteria issued by the Council of Europe, through the European Directory for the Quality of Medicines and Healthcare (EDQM)*'.

Not accepted.

It does not comply with European Union regulations requiring traceability for each container. In any case, the requirements agreed upon by the AEMPS and the autonomous communities will be met.

4.8.4 ADEFARMA: In Section (2), it is suggested that a Point (ñ) be added: *'The service must be paid for either by the health administration, by private entities or by the patient.'*

Not accepted.

This decree does not regulate remuneration for services rendered, as has been previously justified in response to arguments put forward in this regard.

4.8.5 FEFE, AFIN: The fact that technical and infrastructure requirements are disproportionate, creating economic barriers and restricting patient access.

This is not accepted, as already stated in the response to the comment regarding Articles 18 and 19,

4.8.6 COFM: The proposal to delete Section (m) '*protocols for the disposal of non-compliant or expired material*' in relation to the argument regarding Article 35 on waste and SIGRE is accepted.

4.9 Article 22. Record of actions.

4.9.1 COFM: The deletion of Point (2) of Article 22 is requested. The reason for this is that the requirements for preparing PDS (conditions for the preparation and traceability of medicines) are already included throughout the document, making it unnecessary to draw up an exhaustive list of the points that must be included in a record, as compliance with these parameters is already established, resulting in a bureaucratic requirement that hinders the professional's practice.

Not accepted.

It is one thing to establish a standard working procedure and set conditions for preparation, but quite another to require records that facilitate verification of the conditions and traceability of preparations. Anything that is not documented does not exist.

4.9.2 COFM: Proposal to delete Section (2)(e) '*Waste management record*' in relation to the argument regarding Article 35 on waste and SIGRE.

Accepted.

4.9.2 MARÍA GONZÁLEZ: It is proposed that in Section (2)(d), in the case of institutional pharmacies and retail pharmacies preparing medication for residential centres, these delivery records should be allowed to be in bulk and signed by a professional from the centre's in-house dispensary to whom this role has been delegated.

Accepted.

4.9.3 ADEFARMA: It is proposed that Section (2) concerning environmental conditions be deleted.

Not accepted.

Nor has the proposal to remove from the text the requirement to have a thermometer and hygrometer as necessary equipment for environmental control during the preparation of PDS been

accepted. The recording of environmental conditions is an essential requirement, as it is for the custody and storage of medicinal products.

4.9.4 SEFH: It should be noted that the requirement for a written standard working procedure does not apply in the field of hospital pharmacies.

Not accepted.

The PDS requirements apply without distinction to institutional pharmacies and retail pharmacies.

4.10 Article 23. Medicinal products suitable for preparation in a personalised dosage system.

4.10.1 COFM. It is requested that the following sentence be removed from Article 23(3): 'either with their own primary packaging material in reusable multi-compartment devices, or without such material, in sealed multi-dose containers.'

Accepted.

4.10.2 COFM: With regard to the medicinal products that may be included in a PDS (Article 23(4)), it should be noted that the draft is particularly restrictive in this regard, requiring that the medicinal products to be included have sufficient information on their suitability in PDS.

Accepted.

4.10.3 COFM: It is requested that Article 23(7) be worded as proposed:

'7. *Medicinal products that professional pharmaceutical staff cannot clearly differentiate from others on the basis of their physical characteristics may not be packaged in the same blister pack or container unless they are in their own immediate packaging material. Medicines that must be individually repackaged shall be identified*.'

Accepted.

It has been amended, and the new wording does not suggest that identification problems affect only the pharmacist.

4.10.4 MARÍA GONZÁLEZ: In Section (6), it is proposed that '*for division or those with information prepared by the marketing authorisation holder for their possible division*' be replaced with '*for division, in homogeneous doses or those with information prepared by the marketing authorisation holder or holder of quality scientific evidence attesting that they can be divided*'.

Accepted.

4.10.5 MARÍA GONZÁLEZ: It is proposed that the provision stating that under no circumstances may leftover fractions be stored should apply only to retail pharmacies, and it should be borne in mind that this could result in the user running out of medication before the next dispensing period, since MUP takes half tablets into account when calculating the period. Especially in cases of infrequent and irregular deliveries. It would not apply to institutional pharmacies, as they follow best practice guidelines and repackaging is common practice. Consider deleting this sentence.

Not accepted.

As stated above, the requirements set out in the draft decree apply to both retail pharmacies and institutional pharmacies.

4.10.6 MARÍA GONZÁLEZ: It is proposed that Section 7 be deleted because, although pharmacists are able to distinguish between them, professionals working in residential care homes may not have the knowledge to identify tablets that have been removed from their blister packs, and pharmacists will not be available at all times. If in doubt, the entire contents should be discarded.

Accepted.

4.10.7 EAADD: It is proposed that a definition of ‘single-dose administration’ be included.

Not accepted.

The PDS is designed for medicines that require regular and repeated dosing. Single-dose or sporadic administration medicinal products do not require daily planning, which is the main objective of the PDS. However, its definition does not apply since it is defined on its own. Nor has emergency administration been defined.

4.10.8 EAADD: It is suggested that Article 23(8) be deleted.

Not accepted.

Allowing narcotics only when they have a fixed repeat prescription ensures that their inclusion is predictable and safe. Without this condition, inclusion could be arbitrary, compromising patient safety and the integrity of the PDS. Furthermore, the text requires that inclusion be properly documented and that packaging be safeguarded, which is consistent with narcotics control regulations.

4.10.9 MARÍA ÁNGELES MONTERO: It is proposed that it be added that, exceptionally, vitamin and functional supplements may be included, provided that they have been dispensed by the retail pharmacy itself and meet the eligibility criteria for inclusion in the PDS.

Not accepted.

PDS are repackaging devices intended for medicines, and this is the scope of this regulation in accordance with the provisions of Royal Legislative Decree 1/2015 and Law 23/2022 (Article 13).

4.10.10 ADEFARMA: It is proposed that Section (1) be replaced with the following: 'Only medicines authorised by the Spanish Agency for Medicinal Products and Medical Devices may be prepared in a PDS. Solid nutritional supplements recommended by a healthcare professional could be included with the patient's prior consent.'

Not accepted, as with the previous argument.

4.10.11 ADEFARMA: In Section (4)(c), replace the current wording with the following: 'Medicinal products prescribed for emergency administration and without a fixed regimen.'

Not accepted.

Also those relating to single-dose administration, as written.

4.10.12 ADEFARMA: It is suggested that Section (6) be replaced by '*Only medicines presented in tablets scored for division or those with information provided by the marketing authorisation holder regarding their possible division may be divided for preparation in PDS.*

Divided tablets must only be used when there are no authorised medicines available with the prescribed dosage or other alternatives available. Under no circumstances may surplus divided units be stored and kept for inclusion in the next personalised dosage preparation. The doctor and the administration should be aware that there will be a loss of the corresponding fraction, so the number of medicine containers should be adjusted accordingly.'

Not accepted.

This was agreed by the AEMPS, given that the medicine has already undergone handling that may affect its chemical stability when exposed to light; similarly, humidity may accelerate degradation, loss of health guarantee affecting expiry, risk of cross-contamination, alteration of the active ingredient, errors and confusion, and unintentional mixing, among other issues.

4.10.13 SEFH: It is requested that it be limited to the area of the pharmacy.

Not accepted.

Also in institutional pharmacies that prepare PDS for patients in residential centres.

4.10.14 SEFAC: It is requested that there be exceptions for thermolabile medicines, more flexible rules on tablet splitting, and the removal of restrictions considered impractical.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities, and to be taken into account in the regulatory developments carried out by the autonomous communities in this regard.

4.10.15 VÍCTOR BELLVER: Proposes to delete Article 23(8) and include narcotics in Point (4) within excluded medicinal products.

Not accepted.

The provisions of Article 23(8) have been established in accordance with the criteria agreed between the AEMPS and the autonomous communities, which provide for its possible repackaging provided that it is a fixed-dose treatment, without prejudice to the assessment of other characteristics of the medicinal product that may make it inadvisable.

4.11 Article 24. Assessment of the patient's suitability for inclusion in the PDS.

4.11.1 COFM: With regard to Article 24(1), it is requested that it be amended to reinforce the requirement for patient assessment and review of their medication. Section (1) would read as follows:

'*1. The inclusion of a patient in an adherence programme using PDS should be based on an individual assessment, following a systematic review of their medication with the patient present whenever possible, carried out by the pharmacist, taking into account objective criteria related to medication adherence, medication management capacity and the specific needs of the patient*.'

Accepted.

4.11.2 MARÍA GONZÁLEZ: It is proposed that it be stated that this article is intended for persons living at home, or to separate it into two sections: persons living at home and persons living in residential centres.

Not accepted.

The assessment of the patient's suitability must be carried out in all cases, regardless of where they live. The article itself introduces the concepts of legal representative and responsible health professional.

4.12 Article 25. Informed consent of the patient.

4.12.1 MARÍA GONZÁLEZ: It is requested that consideration be given to including a commitment to report hospital admissions or prolonged temporary stays.

Accepted.

4.13 Article 26. Patient record.

4.13.1 COFM: Incorporate into Article 26(2) '*The patient record, reviewed and signed by the patient, must be kept...'* If the request for amendment indicated in the previous paragraph is not accepted, we request the deletion of Points (g), (h) and (i) of Article 26(1), since the pharmacist does not have the possibility of verifying the veracity of such information.

Accepted.

4.13.2 EAADD: The deletion of the following requirement is requested:

'*Patient record*

(i) - Relevant health problems'.

Accepted.

4.13.3 ADEFARMA: It is proposed that it be stated in Section (d) '*Medication chart: active substance, dose, posology and duration of treatment*.'

This is accepted, but the trade name of the medicinal product must also be included.

4.13.4 ADEFARMA: It is proposed that Section (2) be replaced with 'The patient record must be kept for a minimum period of three months after leaving the service, ensuring the confidentiality of the data.'

Not accepted.

The requirement of one year is maintained, as a shorter period would be a very short time for control and inspection work.

4.13.5 SEFAC: They reiterate the request to use ‘medication history’ instead of ‘patient record’.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities.

4.14 Article 27. General requirements for preparing PDS.

4.14.1 MARÍA GONZÁLEZ: In Section (2), include ‘after checking for any problems related to the medicines, such as duplications, incorrect dosage guidelines, duration of treatment and interactions.’

Accepted.

4.14.2 MARÍA GONZÁLEZ: It is proposed that it be specified that Section (3) applies only to retail pharmacies.

Not accepted, because it also affects the institutional pharmacies responsible for preparing PDS for institutionalised patients.

4.14.3 ADEFARMA: It is suggested that Section (3) be replaced with the following: Only the medicinal products dispensed to the patient and the necessary utensils and the supporting documentation may be present in the preparation area.’

Accepted.

4.15 Article 28. Preparation and control sheet.

4.15.1 MARÍA GONZÁLEZ: It is considered necessary to divide this section into:

Manual preparation: simplify this form and create a digital version for each day of preparation, including a list of the PDS prepared on a given day, medicines with batch numbers and expiry dates, but with a single record of environmental conditions, type of device, date, signature and incidents. If the same retail pharmacy prepares medicines for many people, this point can be a significant limitation.

Automated preparation: a record and trace of the preparations made are kept in the computer programmes, so it is not necessary to create the form. If a visual quality control system is also in place, further review is not necessary.

Not accepted.

The preparation and control form is mandatory in all cases, regardless of the type of medium used to create the form. What has been regulated is the minimum information required during the preparation of the PDS.

4.15.2 MARÍA GONZÁLEZ: In Point (g), clarify whether the period of validity is the nearest expiry date of the medicines included in the PDS or whether the expiry date is modified when the medicines are removed from their primary packaging.

Accepted.

What is established is the validity of the PDS once it has been prepared. In this regard, the document CRITERIA AGREED BETWEEN THE DIFFERENT AUTONOMOUS COMMUNITIES AND THE AEMPS FOR THE PREPARATION OF PERSONALISED DOSAGE SYSTEMS (PDS) BY RETAIL PHARMACIES, which establishes as a general rule that the validity of a blister pack produced for a PDS system shall be a maximum of two weeks, and other autonomous communities such as Galicia have established the same rule. The wording in this regard is amended in Article 27(5) and in Article 23.

4.16 Article 29. Packaging devices.

4.16.1 COFM: It is proposed that the term '*multi-dose*' be removed.

Not accepted.

Article 29 is devoted exclusively to the types of personalised dosage system (PDS) devices available, which, incidentally, have already been mentioned in Article 19 concerning equipment and tool requirements.

4.16.2 COFM: It is requested that Section (2) be deleted in its entirety, for the reasons indicated in the arguments regarding Article 23.

Not accepted.

This article is dedicated to PDS devices that have previously been referenced in Article 19 dedicated to equipment and tool requirements.

4.16.3 MARÍA GONZÁLEZ: after '*its primary packaging*', include '*or repackaged*'. There are active ingredients in solid oral pharmaceutical forms that are only available in bottles.

Not accepted.

This article is dedicated to device types and therefore there is no place here to include aspects related to packaging based on the presentation of the starting medicinal product.

4.17 Article 30. Verification, labelling and special conditions for preparation.

4.17.1 COFM: The following wording is proposed:

'*4. The service must be suspended during the patient's hospitalisation and resumed once the pharmacological plan or the patient's treatment has been updated and after the pharmacist has reconciled the medication*.'

Accepted.

4.17.2 MARÍA GONZÁLEZ: It is suggested that Sections (1) and (2) refer only to the manual preparation of PDS.

Not accepted.

The preparation requirements apply regardless of the system used. It is not the purpose of the regulation to regulate these systems as such.

4.17.3 SEFH: It is proposed that this article be merged with Articles 32 and 33, which elaborate on these aspects.

Accepted.

Article 30 has been deleted, and its content incorporated into Articles 27, 32 and 33 (now 27, 31 and 32).

4.17.4 VÍCTOR BELLVER: It is proposed that Section (5) be reworded.

Not accepted.

This argument hinges on the need to make a clear distinction between PDS preparation systems (manual, automatic, etc.). What is being regulated are the technical health requirements necessary for PDS preparation, without regulating the characteristics of the different systems offered on the market to carry out this service.

4.18. Article 31. Custody of surplus medication and termination of service (now Article 30).

4.18.1 MARÍA GONZÁLEZ, SEFH: It is proposed that it be specified that this article applies only to retail pharmacies.

Accepted.

4.18.2 VÍCTOR BELLVER: He suggests amending Article 31(1).

Not accepted.

This argument hinges on the need to make a clear distinction between PDS preparation systems (manual, automatic, etc.). What is being regulated are the technical health requirements necessary for PDS preparation, without regulating the characteristics of the different systems offered on the market to carry out this service.

4.19 Article 32. Labelling (now Article 31).

4.19.1 EAADD: It is proposed that it be specified who the responsible doctor is in the social and healthcare centres.

Not accepted, as the doctor responsible for the patient may or may not be the one at the social and healthcare centre.

4.19.2 FARMAINDUSTRIA: Expressly require that the PDS's internal registration number appear on the label.

Not accepted.

The traceability of the device is fully guaranteed through the internal documentary register of the retail pharmacy, in which the assigned number, the content of the device, the patient and the preparation date are recorded. Including this number on the label could also make it difficult to read the relevant clinical information that must appear (dosage, warnings, storage).

4.20. Article 34. Delivery of personalised dosage devices (now Article 33).

4.20.1 COFM: It is requested that, in the case of institutionalised patients, the standard working procedure be sent to the social and healthcare centre, amending Article 34(1) accordingly. Namely:

‘1*. Once the device has been verified, it is delivered to the patient or their legal representative, in accordance with the provisions of the standard working procedure. For institutionalised patients, a standard working procedure* will be sent to the social and healthcare centre.’

Not accepted.

It is not considered necessary to send the standard working procedure to the social and healthcare centre, as it is a standard working procedure that defines the service of preparing and delivering

PDS by the retail pharmacy or institutional pharmacy. A separate issue will be for the social and healthcare centre itself to define its standard working procedure for managing the PDS delivered to them.

4.20.2 MARÍA GONZÁLEZ: Section (6) does not apply exclusively to transport to residential centres; it must also be guaranteed for home delivery. In fact, it is a requirement that must be included in the dispensary management report and is therefore mandatory regardless of whether they are PDS or medicines dispensed to the patient's home. I would move it to Chapter IV, Article 43 or to Point (2) of this article, where dispensing to the patient's home is discussed.

Not accepted.

However, the article has been split into two (now 33 and 34), one dedicated to the delivery of PDS in retail pharmacies, and the other dedicated to the delivery of PDS in the case of institutionalised patients. A different matter is Article 41 relating to pharmacy delivery services (not Article 43, which you cite), now Article 40, which expressly sets out how informed delivery is made to the patient’s home and which, in Point (8), includes a reference to Chapter III on PDS in the event that the PDS are included in pharmacy delivery services.

4.20.3 EAADD: The deletion of Section (6) is requested.

Not accepted.

Once dispensed, medicines belong to the patient. The wording is consistent with Article 25 (3)(g) which states that they are not given to the patient if they have consented to their custody at the pharmacy.

4.20.4 SEFH: It is proposed that the reference to the responsible institutional pharmacy in Section (4)(d) be deleted.

Not accepted.

PDS in social and healthcare centres can be prepared by retail pharmacies, by their own institutional pharmacy, or by an in-house dispensary linked to an institutional pharmacy.

4.20.5 FARMAINDUSTRIA: On the delivery of the ‘updated package leaflet’ in each PDS.

Not accepted.

The proposed amendment is not considered necessary, since Article 34(3) already ensures that the patient receives the essential information by establishing that the package leaflet of the medicinal products included in the PDS will be provided with the first delivery. In their role of

advising and monitoring treatment, pharmacists have a professional duty to keep up to date and inform patients of any relevant changes to the information on medicines. Requiring the physical delivery of the 'updated package leaflet' in each dispensation would be redundant and impractical. Consequently, it is considered that the current wording already ensures the availability of up-to-date information, without the need to impose an unnecessary additional burden on the retail pharmacy.

4.20.6 SEFAC: Add information about the responsible doctor's details and the delivery of signed instruction sheets when collecting the PDS.

Not accepted.

The current wording guarantees safety, traceability and quality in the preparation and delivery of PDS, including the medicines used, storage conditions and associated documentation, following agreed criteria that have been set as minimum requirements by the AEMPS and the autonomous communities, and to be taken into account in the regulatory developments carried out by the autonomous communities in this regard.

4.21 Article 35. Disposal of waste.

4.21.1 COFM: Given that Article 35 sets out the suitability of SIGRE for the collection of PDS waste, the removal of Article 19(e), Article 21(m) and Article 22(e) is requested.

Accepted.

5. Chapter IV. Pharmacy delivery services and dispensing with informed delivery to the patient's home (Articles 36–43).

5.1 Article 36. Declaration of responsibility for the provision of services from the retail pharmacy (now Article 37).

5.1.1 FARMAINDUSTRIA: It argues that it is assumed that, in the absence of delivery by pharmaceutical personnel, the transport of medicinal products will be by an authorised distribution company.

Not accepted.

Delivery by pharmacy delivery services is clearly regulated by Law 13/2022, of 21 December, which states that '*(pharmacy delivery services) must be carried out by qualified staff from the retail pharmacy*'.

5.1.2 FARMAINDUSTRIA: It is suggested that the requirements for retail pharmacies and institutional pharmacies be equivalent.

Not accepted.

They are different areas. In hospital pharmacies, this refers to the non-face-to-face dispensing of hospital medicines, and the draft decree does not seek to change the scope of dispensing.

5.1.3 FARMAINDUSTRIA: It is suggested that the collaboration and coordination mechanism of the retail pharmacy and institutional pharmacy be included in the delivery of hospital-dispensed medicines.

Not accepted.

This aspect is defined in the protocols referred to in Article 40(j) of Law 13/2022, of 21 December.

5.1.4 SEFH: To facilitate understanding, it is proposed that the articles be reordered, combining those that refer to retail pharmacies. The proposed order is as follows: 38, 36, 39, 40, 41, 42 and 37.

Accepted.

5.1.5 RUBÉN MARTÍN LÁZARO: It is proposed that the annual declaration of pharmacy delivery services provided be scrapped.

Not accepted.

Law 13/2022, of 21 December, also states that the procedure to be followed and the necessary control systems will be implemented by regulation. The annual declaration has been included in this context.

5.1.6 COFM: It is proposed that a definition of the service be included.

This is not accepted as it would be a new definition not provided for in the law being implemented.

5.1.7 COFM: In order to verify that the service is provided by retail pharmacies to patients within their Basic Health Zone or neighbouring zones and by hospital institutional pharmacies in their area of influence, the annual activity declaration must detail not only the number of patients to whom the service has been provided and the number of deliveries, but also the postal address for each delivery.

Not accepted.

The content of what must be declared is considered proportionate without the need to extend it to the postal address. However, these aspects may be verified in the control procedures carried out by the body responsible for them.

5.1.8 JOSE MANUEL IZQUIERDO PALOMARES: It is suggested that primary care institutional pharmacy services be explicitly included in pharmacy delivery services.

Not accepted.

Law 13/2022, of 21 December, recognises the fundamental role of pharmacy units in primary care for optimising the quality of the care process in collaboration with other healthcare professionals at this level of care. However, the pharmaceutical care implemented by the decree is that which Article 13(3) of the law established in conjunction with the dispensing of medicinal products with informed delivery to the patient's home and which was conditional on regulatory development. The decree also includes pharmaceutical care from the hospital institutional pharmacy within the framework of the provisions of Article 40(j) of the law and the provisions of the TRLGURM, which incorporates a Section (8) into Article 3 in this regard and which would justify development in this decree. It is precisely this dispensing of medicinal products that exceeds the functions that Law 13/2022, of 21 December, attributes to primary care institutional pharmacy services.

5.1.9 ADEFARMA: Section (2) should be substituted with: '*In the event of a change in ownership of the retail pharmacy, the new owner or owners must, within three months from the day following the effective date of the change, submit a new declaration of responsibility if they wish to continue with this service, or report the cessation of the service*.'

Not accepted. The notification period shall be the same as that established in Article 48 regarding the documentation to be submitted after the transfer decision has taken effect.

5.1.10 ADEFARMA: Section (5) should be substituted with: *'The owner or owners or manager of the retail pharmacy that has provided the pharmaceutical care and dispensing service with informed delivery to the patient's home must submit, before 28 February each year, to the directorate-general with responsibility for pharmaceutical regulation, an annual declaration detailing the number of patients to whom this service has been provided, indicating the number of deliveries made to each of them. It shall be submitted using the standard form provided in Annex III, which is available on the website https://www.comunidad.madrid/servicios/salud/farmacias-farmacéuticos, and the standard form on the Digital Administration Portal (E-Office).'*

Accepted.

5.2 Article 37. Pharmaceutical care provided by the hospital institutional pharmacy (now Article 43).

5.2.1 FARMAINDUSTRIA: It is suggested that the word '*informed*' be added to Point (c).

Not accepted.

The scope of the pharmaceutical care that the decree will regulate for hospital institutional pharmacies has been specified, focusing on the provisions of Article 40(j) of the law. This decree does not regulate any other activity or function performed by hospital institutional pharmacies.

5.2.2 COFM: It is proposed that this annual declaration be submitted to the college, for subsequent forwarding to the relevant regional ministry of the Community of Madrid.

Not accepted.

The Regional Ministry of Health is the competent body for monitoring and control.

5.2.3 COFM: With regard to Article 37 (now 43), clarification is requested that the article refers to 'pharmacy delivery services'.

Not accepted.

What is regulated is the non-face-to-face dispensing of medicines restricted to hospital settings, which may be done at a retail pharmacy or at the patient's home, as established by Law 13/2022. What is provided for is remote pharmaceutical care.

5.2.4 COFM: It is proposed that the term '*domestic*' be added to the title of the article, and we also request clarification as to which medicinal products are covered by the service, indicating that they are hospital-diagnosed, hospital-dispensed medicinal products.

The proposal for the title of the article as set out in the previous argument is not accepted, but it is clarified that dispensing is restricted to the hospital setting.

5.2.5 COFM: A series of requirements is established to ensure that patients receive pharmaceutical care and dispensing services with informed delivery to the appropriate address, but these requirements only apply to retail pharmacies. The COFM considers it necessary that the same guarantees are also required for the provision of this service from hospital institutional pharmacies, in order to offer a service with all patient guarantees, through the corresponding regulatory development.

Not accepted.

In accordance with the provisions of Law 13/2022, of 21 December, this non-face-to-face dispensing by hospital institutional pharmacies will be established through specific protocols

approved by the hospital pharmacies responsible for monitoring these patients, which will include these guarantees, without the need for regulatory development as proposed.

5.2.6 SEFAC: Requests that the regulatory requirements be the same for retail pharmacies as for hospital institutional pharmacies.

Not accepted.

Hospital institutional pharmacies are governed by protocols, as already mentioned.

5.2.7 SEFAC: Section (4) should state that the pharmacist must inform the health authorities of any incident that occurs during the provision of the service that could have clinical significance for patients.

Accepted.

5.2.8 SEFH: It is considered that Section (4) should not be applicable to the institutional pharmacies of public hospitals.

Accepted. It is eliminated for all: public and private.

5.2.9 SEFH: It is proposed that Section (1) of the article be amended to allow diethotherapeutic products to be included as suitable for care and monitoring by the hospital institutional pharmacy. Similarly, the possibility of obtaining hospital-dispensed medicines is excluded. The diversity of cases recommends that, in order to be able to carry out comprehensive pharmaceutical care from the hospital institutional pharmacy, patients should be those who, beyond the scope of dispensing the medicinal products, require attention, treatment and follow-up by a specialist in the hospital field.

Not accepted.

Other functions or activities carried out by hospital institutional pharmacies are not regulated. The draft decree clearly specifies the subject matter of the regulation.

5.2.10 COFARES: It is proposed that Section (1) be amended as follows:

‘*Pharmaceutical care services may include remote assistance provided by pharmacists specialising in hospital pharmacy, aimed at ensuring safe, effective and accessible pharmacotherapy for patients who require hospital-dispensed medicines. It may also include non-face-to-face dispensing with the delivery, if applicable, of medicines to pharmaceutical establishments authorised for dispensing near the patient's home, or to their own home.*

The authorised pharmaceutical establishment, at the patient's request and when the patient meets the legally established requirements, may deliver the medicines to the patient's home, in accordance with the provisions of Articles 38 and 39 of this decree.'

Not accepted.

This article covers the dispensing of hospital medicines by the hospital institutional pharmacy, which is monitored by that pharmacy's manager, and Articles 38 and 39 (now 36 and 38) cited in the draft proposal are dedicated to pharmacy delivery services in the context of retail pharmacies and therefore to the dispensing of medicines not restricted to the hospital setting, which is monitored by the retail pharmacy's pharmacist.

5.3 Article 38. Pharmaceutical care and dispensing with informed delivery to the patient's home from retail pharmacies (now Article 36).

5.3.1 COFARES: It is proposed that control measures be established to ensure that medicinal products arrive at their destination without alterations or loss of quality. To this end, the hospital institutional pharmacy may collaborate with authorised full-range medicine distribution entities, both for delivery to the pharmacy closest to the patient's home and for informed delivery to their home, thus ensuring that the transport and delivery of medicinal products and medical devices comply with the appropriate conditions of storage and custody.

Not accepted.

The means used by the hospital institutional pharmacy for delivery shall be those agreed upon through the hospital institutional pharmacy's protocols established for this purpose, without the text of the draft decree entering into other considerations.

5.3.2 SEFAC: It is proposed that the reference to dispensing with informed delivery to the patient's home be changed to one of the following alternatives: home dispensing, dispensing with home delivery, dispensing with informed delivery.

Not accepted.

The current wording of the draft decree complies with and respects the provisions of Law 13/2022, of 21 December.

5.3.3 COLLEGE OF OPTICIANS AND OPTOMETRISTS: It is proposed that a section be added establishing the exclusion of pharmacy delivery services from its own activities and products that are marketed or adapted in the various sections that may be authorised by the retail pharmacy.

Not accepted.

The proposed text is sufficiently clear, as it precisely defines the scope of the service. It is not considered necessary to incorporate express prohibitions, especially when they are formulated in generic terms that may create legal uncertainty.

5.4 Article 39. General conditions for the provision of pharmaceutical care and dispensing with informed delivery to the patient's home from retail pharmacies (now Article 38).

5.4.1 RUBÉN MARTÍN LÁZARO: It is proposed that it be specified that the service can only be provided by retail pharmacies that have previously dispensed the pharmaceutical products requested by the patient in person or remotely.

Not accepted.

The dispensation is for retail pharmacies, since Article 3(5) TRLGURM prohibits the sale by mail order and telematic procedures of medicinal products and medical devices subject to prescription, with remote sale being limited to medicinal products not subject to prescription.

5.4.2 RUBÉN MARTÍN LÁZARO, EAADD, SEFAC, COFARES: Regarding intermediation in delivery, with the exception of full-range distribution warehouses or the participation of other operators established by the retail pharmacy.

Not accepted.

The possibility of intermediation is not contemplated. Law 13/2022, of 21 December, laid down that home delivery of medicines must be carried out by qualified pharmacy staff, ruling out this possible intermediation.

5.4.3 COFARES: That the pharmaceutical care service may include remote assistance provided by pharmacists from the retail pharmacy, aimed at ensuring safe, effective and accessible pharmacotherapy for patients.

Accepted, but included in Article 39 (now 38).

5.4.4 COFM: It is requested that the article be amended by adding a Point (5), as follows:

'*5. In any case, the retail pharmacy is responsible for the medication management of patients included in this modality, ensuring continuous care and resolving problems related to medication.'*

Accepted.

5.4.5 AFIN, FEFE, EAADD: The rigidity of the criterion in the limitation of pharmacy delivery services to the basic health zone (ZBS) is criticised.

Not accepted.

For reasons of proximity to the homes of patients eligible to receive this service, it seems reasonable to establish the basic health zone as the geographical area in which the retail pharmacy is located. However, there is a caveat that patients may exercise their right to freely choose a retail pharmacy not only in the basic health zone but also retail pharmacies located in other zones.

5.4.6 AFIN: Charging for pharmacy delivery services makes these services unsustainable.

Not accepted.

As was justified for PDS, the autonomous community cannot extend its regulation beyond the planning criteria established in the state regulation. The remuneration would exceed the limits set by the state regulation.

5.5 Article 40. Request for the provision of pharmaceutical care and dispensing with informed delivery to the patient's home from retail pharmacies (now Article 39).

5.5.1 RUBÉN MARTÍN LÁZARO: It is suggested that the wording of Section (1) be changed to the following:

'1*. Any patient may request the service, with priority given to patients who are dependent or disabled who have lost their functional autonomy and with difficulty or an impediment to travelling to the retail pharmacy of their choice. Their legal representatives may also request the service at the retail pharmacy of their choice, provided that it offers this service.'*

Not accepted.

It is not just any patient, as the profile of recipients of delivery services from retail pharmacies is clearly limited in Law 13/2022, of 21 December.

5.5.2 RUBÉN MARTÍN LÁZARO: It is suggested that the wording of Section (3) be changed to the following:

'*The patient or his representative must sign the request, which shall be valid for one year. In any case, the patient or his representative may terminate the continuity of the service at any time. For this purpose, a withdrawal document provided by the retail pharmacy, stating the express wish of the patient to terminate the service, must be signed. This document must be filed with the patient's medical records. The request for the service and the delivery of the consignment must be recorded*.'

Not accepted.

The proposal consists of adding that '*the request for the service and the delivery of the consignment must be recorded*'. This is redundant, given that the service request form already records the request and the delivery receipt documents the delivery, both of which are required to be kept by the pharmacy.

5.5.3 COFM, JACINTO VICO: It is argued that it is necessary to amend Article 40(1), incorporating the following wording:

'*1. Patients who are dependent or disabled who have lost their functional autonomy and with an officially recognised difficulty or impediment to travelling to the retail pharmacy of their choice. Their legal representatives may also request the service at the retail pharmacy of their choice, provided that it offers this service.*'

Not accepted.

There are specific regulations governing the accreditation of such a disability situation. Furthermore, the draft decree establishes in the article dedicated to requesting this service that the dispensation form must include the circumstances justifying the request for the service. It is therefore the pharmacist who must check whether they match the profile of patients for whom they are intended and who are entitled to request such accreditation, even if this is not explicitly stated. In other words, the pharmacist is free to ask the patient for proof of this circumstance.

5.5.4 EAADD: It is suggested that the wording of Sections (1) and (2)(e) be reworded as follows:

'*1. Patients who are dependent or disabled who have lost their functional autonomy and with a difficulty or impediment to travelling to the retail pharmacy of their choice. Their legal representatives may also request the service at the retail pharmacy of their choice, provided that it offers this service. This group includes patients living in social and healthcare centres where the aforementioned circumstances apply.'*

Not accepted.

What is regulated is pharmacy delivery services provided by retail pharmacies to non-institutionalised patients. It is requested that patients living in social and health care centres where the aforementioned circumstances apply be included in this group. This proposal is rejected because the regulation does not regulate pharmaceutical care in residential centres. Chapter IV focuses on pharmaceutical care in accordance with Article 13(3) of Law 13/2022 and does not apply to institutionalised patients.

‘*2. (e) The individual health card code in the case of electronic prescription and, in the case of a prescription for narcotic or psychotropic medicinal products, the patient’s identity number. This criterion shall also apply to patients living in social and healthcare centres, with loss of functional autonomy and with a difficulty or impediment in travelling to the pharmacy*.’

It is not accepted for the reasons expressed in the previous point.

5.5.5 SEFAC: It is suggested that the wording of Section (2) be changed to the following:

‘2*. Once the service request has been received, the retail pharmacy must inform the patient of the available payment methods and complete, in addition to an informed consent form, a dispensing form that includes*…’

Not accepted.

Law 13/2022, of 21 December, establishes that it is at the user's request and, unlike PDS, has not established prior informed consent.

5.5.6 SEFAC: It is suggested that the wording of Section (2)(f) be changed to the following:

‘*The details of the retail pharmacy providing the service (name of the owner and community pharmacy), and a brief description of the conditions of operation of the service, including the cost, if any*.’

Not accepted.

It is considered that the chapter describes in sufficient detail how the retail pharmacy must provide this service.

5.5.7 SEFAC: It is suggested that the wording of Section (7) be changed to the following: ‘*As a general rule, home delivery is carried out exclusively by the licensed pharmacists of the dispensing pharmacy, the pharmaceutical staff or the pharmacy technicians of the same pharmacy, always under the supervision of the pharmacist, and in accordance with established standard operating procedures and applicable regulations. However, when there are justified objective reasons, community pharmacies may provide this service through remote pharmaceutical care and by contracting a transport company for delivery*.’

Not accepted.

Law 13/2022, of 21 December, does not include any type of exception for contracting a transport company. On the other hand, remote pharmaceutical care will be included for medication management, but outside of what could be understood as remote sales.

5.6 Article 41. Dispensing at the retail pharmacy and home delivery of the requested pharmaceutical products (now Article 40).

5.6.1 COFM: It is considered that the verification of the patient's identity should only be carried out at the time of delivery.

Not accepted.

The identification of the patient must be at the time of dispensing, in accordance with Article 9 of Royal Decree 1718/2010 of 17 December 2010.

5.6.2 COFM: It is requested that Section (1) of article 41 be amended and that a Point (9) be added to it, relating to delivery, as follows:

'*Article 41. Dispensing at the retail pharmacy and home delivery of the requested pharmaceutical products.*

Dispensing must be authorised in advance by the patient.'

Not accepted.

Patient authorisation cannot exempt from compliance with the regulation.

5.6.3 COFM: It is proposed that '*Dispensing should be exclusively for prescriptions that have not yet been dispensed that the patient requests (...)*'.

Accepted.

5.6.4 MARÍA GONZÁLEZ: In Section (2), it is proposed that '*that the patient requests*' be changed to '*that the patient or their legal representative requests*'.

Accepted.

5.6.5 RUBÉN MARTÍN LÁZARO: It is proposed that home delivery be carried out preferably by the licensed pharmacists of the dispensing pharmacy, the pharmaceutical staff or the pharmacy technicians of the same pharmacy, always under the supervision of the pharmacist, and in accordance with established standard operating procedures and applicable regulations. All possible delivery methods must be specified in the communication to the Department of Health on an exclusive basis.

Not accepted.

The proposed wording is consistent with the mandate of Law 13/2022, of 21 December, which stipulates that delivery must be carried out by the retail pharmacy's staff in all cases. This exclusivity in delivery by pharmaceutical personnel ensures that the medicinal product does not leave the pharmacist's control until it is received by the patient, preserving the chain of custody and the storage conditions. If delivery is allowed to be made by a third party, the pharmacist loses the ability to ensure compliance with the storage and confidentiality conditions, which in principle infringes the direct responsibility of the professional set out in Royal Legislative Decree 1/2015, of 24 July, and Law 13/2022, of 21 December.

5.6.6 SEFAC: It is proposed that transport for pharmacy delivery services should not be considered to be intermediation.

Rejected for the reasons already stated, given that Law 13/2022, of 21 December, establishes that delivery shall be made by the retail pharmacy's staff.

5.6.7 FARMAINDUSTRIA: It suggests including the concept of 'informed'.

Not accepted.

The title is faithful to the mandate of Law 13/2022, of 21 December, which is being implemented.

5.7 Article 42. Payment to the retail pharmacy of the financial contribution for pharmaceutical products (now Article 41).

5.7.1 COFM: It is proposed that a Point (4) be added to Article 42 of the draft, stating the following:

'*When a public administration or public or private entity wishes this service to be provided specifically to a particular sector or population group, it may arrange for the COFM to provide it*.'

Not accepted.

The provisions of the draft decree comply with the mandate established in Article 13 of Law 13/2022, of 21 December, and the proposals are more in line with health/pharmaceutical policy strategies through agreements. However, what is being proposed was already included in general terms in Article 4 of Law 13/2022, of 21 December, dedicated to institutional cooperation, where this proposal would fit.

5.7.2 RUBÉN MARTÍN LÁZARO: It is suggested that it be stated that under no circumstances may the provision of this service lead to an increase in the price of the medicinal products or medical devices dispensed. Nor an additional cost for the patient or the social and healthcare centre.

Not accepted.

This would represent a greater restriction than that established in Law 13/2022, of 21 December, which expressly states that the price of medicinal products and medical devices may not be increased.

5.7.3 AFIN, TREBOL, SEFAC, FEFE, ADEFARMA: In relation to payment for pharmacy delivery services.

Not accepted.

Law 16/1997, of 25 April, defines retail pharmacies as '... private healthcare establishments of public interest and expressly recognises in Article 1 as basic services to be provided to the population: information and monitoring of pharmacological treatments for patients, collaboration on the control of individualised use of medicinal products in order to detect adverse reactions and report them to the bodies responsible for pharmacovigilance, collaboration on programmes promoted by the health authorities on quality assurance in pharmaceutical care and healthcare in general, health promotion and protection, disease prevention and health education, collaboration with the health administration on training and informing other health professionals and users about the rational use of medicinal products and medical devices. Coordinated action with the healthcare structures of the health services ... without, under any circumstances, taking economic criteria into account. The autonomous community cannot extend its regulation beyond the planning criteria established in the state regulation. The remuneration would exceed the limits set by the state regulation.

5.7.4 ADEFARMA: Regarding subsidies for carrying out this service.

Not accepted.

It is not the subject of this decree to regulate any type of aid or subsidy to ensure the sustainability or not of this service. However, it could fall within the scope of Article 4 of Law 13/2022 on institutional cooperation.

5.7.5 SEFAC. It is proposed that the term *community pharmacy*' be used instead of '*retail pharmacy*'.

Not accepted.

The term 'retail pharmacy' is used uniformly in Spanish legislation (Law 16/1997, of 25 April; Royal Legislative Decree 1/2015, of 24 July; Law 13/2022, of 21 December) to refer to the authorised pharmaceutical establishment, ensuring terminological consistency, legal certainty and linkage with administrative procedures and official registers.

5.7.6 ADEFARMA. It is proposed that Section (3) be replaced with the following: '*Under no circumstances may the provision of this service lead to an increase in the price of the medicinal products or medical devices dispensed. In order for this service to be sustainable for all retail pharmacies, the regional or municipal administration will reach agreements with the official college of pharmacists to subsidise this service*.'

Not accepted.

It is not the subject of this decree to regulate any type of aid or subsidy to ensure the sustainability or not of this service. However, it could fall within the scope of Article 4 of Law 13/2022 on institutional cooperation.

5.8 Article 43. Obligations of the retail pharmacy in providing the service (now Article 42).

5.8.1 COFM: It is requested that retail pharmacies be prohibited from using the service to attract patients:

'*5. In order to promote the rational use of medicinal products and patient safety, the use of this service as a means of attracting patients is prohibited in order to avoid possible incentivisation of the use of medicinal products, in accordance with Article 80 of Royal Decree 1/2015*.'

Not accepted for the reasons already stated in relation to PDS.

5.8.2. ADEFARMA: It is proposed that the original delivery receipts be kept for a period of three months and made available to the health authorities when requested.

Not accepted.

The two-year period is considered necessary in order to protect safety.

5.8.3 SEFAC: It is requested that the obligation to inform the health authorities about incidents be specified, proposing more precise criteria or a digital register of incidents in the community pharmacy in order to facilitate compliance.

Not accepted.

The current wording of Article 43(4) is sufficient to ensure that incidents are reported to the health authorities. Introducing digital records or additional criteria would entail obligations not provided for by law and an unnecessary increase in administrative burdens, without adding any significant value. The regulations allow each pharmacy to manage its procedures internally, while always complying with the legal obligation.

5.8.4 MARÍA GONZÁLEZ: Suggests including '*Ensure conditions during transport that prevent any deterioration in the quality of the medicinal products, medical devices and dietetic products dispensed*.'

Not accepted.

This would establish a new obligation and is already implicitly included in Article 41(6) (now 40(6)).

6. CHAPTER V. TRANSFERS (ARTICLES 44–47).

6.1 AFIN: General comment on Chapter V: It is argued that this regulation infringes the principle of legal certainty; it contradicts the law it implements and is detrimental to the viability of pharmacies.

Not accepted.

The draft decree does not distort the mandate of Article 31 of Law 13/2022 and does not create uncertainty about the transfer of ownership of retail pharmacies. The procedure is simplified and streamlined by reducing administrative burdens through the use of declarations of responsibility, allowing the transfer of ownership to be carried out more efficiently, and ensuring the continuity of authorised pharmaceutical services during the process of change of ownership. Legal coverage is provided against possible time gaps between the accreditation of the legal act and the effectiveness of the health authorisation, by establishing a certain date for the entry into force of the new owner in the authorisation, complying with the objectives of Law 13/2022, of 21 December.

With regard to the argument that Articles 44 to 48 present 'confusing and cumbersome wording' and calls for the entire chapter to be deleted, it is stated that this claim is not in line with reality. The wording of these provisions is clear and systematic, structuring the procedure for transferring ownership in an orderly manner, including deadlines, the necessary documentation and the obligations of the owners.

6.2 Article 44. Authorisation of the transfer.

6.2.1 COFM. It is proposed that a section be added as follows:

'*It is strictly prohibited, in the transfer of a retail pharmacy, for a third party or the financier of the new owner to participate, directly or indirectly, in the management, administration, organisation or operation of the retail pharmacy, or exercise control powers over the new owner, or in any way limit management autonomy, which corresponds solely and exclusively to the acquiring owner*.'

This is not accepted for the following reasons:

1. Regulation of this matter exceeds the objective scope of the draft, which is the management of the activities of retail pharmacies.

2. The status of the regulation is insufficient to amend a law, the Commercial Code, which governs this contract.

3. The introduction of a restriction on entering into this contract would constitute an infringement of the principle of freedom of contract under Article 1255 of the Civil Code (applicable to commercial contracts by reference to Article 50 of the Civil Code), since this is a commercial transaction that is not contrary to the law, morality or public order. It should be noted that, without prejudice to their status as healthcare establishments, retail pharmacies are also businesses insofar as they carry out an economic activity aimed at the retail distribution of goods and the provision of services.

Without prejudice to the above, the wording of the text has been improved in the sense of referring to Article 31 of Law 13/2022, of 21 December, which provides that the transfer of the retail pharmacy may only be made in favour of one or more other pharmacists.

6.2.2 COFM: In relation to Article 44(4), which provides for the feasibility of processing the request for the exchange of two retail pharmacies open to the public in a single file, it is considered important that provision is also made for the possibility of processing the request in a single file when the pharmacy to be exchanged has more than one owner, in order to avoid a situation of incompatibility of the co-owner. It is proposed that a Section (4) be added to Article 44 of the draft, stating the following:

'*4. In the event that the owners of two retail pharmacies located in the Community of Madrid request the exchange of their respective pharmacies, the request shall be processed in a single file.*

Likewise, the application will be processed in a single file when the pharmacy to be exchanged has more than one owner and undivided shares are exchanged.'

Accepted.

6.3 Article 45. Request for authorisation.

6.3.1 COFM. With regard to Article 45(3), it is argued that it is considered absolutely necessary to require a certificate of membership from the purchaser or purchasers, subjecting this certificate of membership to the condition precedent that the Regional Ministry of Health authorise the transfer of the pharmacy in question to the new owner/pharmacist.

The requirement to submit the membership certificate is accepted.

The incorporation in the regulation of the reference to the above-mentioned 'condition precedent' is not accepted, as it does not constitute a legal ground for suspending the administrative procedure. On the other hand, the conditions relating to compatibility or incompatibility are subject to verification by the Regional Ministry of Health during the transfer procedure, as is already the case.

6.3.2 ADEFARMA: It is proposed that the following be added:

'5. In cases of transfers to a co-owner due to the death of another co-owner of the same retail pharmacy, only the documentation referred to in point (4) of this article will be required, as it will not be necessary to justify anything that has already been accredited previously in order to be a co-owner (unless any changes are made that do need to be declared). '

Accepted.

6.3.3 ADEFARMA: It is proposed that, in cases of sale to one or more co-owners of the share of another co-owner of the same retail pharmacy, it will not be necessary to provide any documentation other than the updated declaration of the owners.

Accepted.

6.4 Article 46. Decision and effectiveness of the same.

6.4.1 COFM: With regard to Article 46(1), it is requested that the COFM also be notified of the decision.

Not accepted.

The notification that has been maintained so far will be maintained, not the notification of the health authorisation decision relating to a legal act between individuals.

6.4.2 FEFE: It is argued that separating civil transfer from health authorisation creates a 'legal limbo', generating serious uncertainty regarding health liability and hindering access to financing, thereby jeopardising the continuity of the service.

Not accepted for the reasons set out in Heading 6.1.

6.5 Article 48. Requirements to be met by the purchasing pharmacist.

6.5.1 SEFAC. It is proposed that an additional requirement consisting of the requirement for accreditation of a minimum of years of experience, as well as minimum training, beyond the higher degree in pharmacy, be included.

Not accepted.

The scope of the draft decree is limited to regulating the procedure for transferring a retail pharmacy. The incorporation of new requirements, such as years of experience or additional training, is not considered, as this would exceed the scope of the regulation and restrict the general nature established in state legislation, which only requires that the transfer be made to a pharmacist, without imposing any other conditions.

7.CHAPTER VI. PENALTY SYSTEM (Article 49):

7.1 FEFE, AFIN: In general, this chapter is objected to, it being considered null and void for referring generically to the law without defining specific offences, thus infringing the constitutional principles of legality and the legal definition of penalties.

Not accepted for the reasons set out in Heading 1.3 of this annex regarding the infringement of the principles of good regulation.

7.2 FEFE, AFIN: With regard to the argument concerning hidden penalties in various articles of the draft regulation, please refer to the comments in Heading 1.3 (Subheading 1.3.3) above concerning the principle of legal certainty.

ADDITIONAL, TRANSITIONAL AND FINAL PROVISIONS. AFIN, FEFE.

8.1 First additional provision:

The inclusion of a ‘blank’ regulatory delegation is objected to.

Not accepted.

This provision does not delegate any powers, but merely indicates how the relevant forms are to be updated.

8.2. First and second transitional provisions.

It is argued that they set unreasonable adaptation deadlines that are contrary to due proportionality.

This is not accepted for the reasons set out in Heading 1.3 (Subheading 1.3.1) of this annex.

8.3 Second final provision.

It is argued that the lack of provision for a period of *vacatio legis* undermines legal certainty.

Rejected, as the transitional provisions of the draft regulation establish reasonable deadlines for the various adjustments to be made (e.g. in relation to PDS, personnel, etc.).