PRELIMINARY DRAFT LAW

Draft law containing various provisions concerning medicines and health products

PHILIPPE,
KING OF THE BELGIANS
To all those present and to come,

GREETINGS,

On the proposal of the Minister for Public Health,
WE HAVE DECREED AND HEREBY DECREE:
The Minister for Public Health shall be responsible for presenting, in Our Name, before the Chamber of Representatives, the draft law to read as follows:

Chapter 1 — General provision

Article 1. This law regulates a matter referred to in Article 74 of the Constitution.

Chapter 2 – Amendments to the Law of 25 March 1964 on Medicinal Products for Human Use
Section 1 – Amendments to the Law of 25 March 1964 on Medicinal Products for Human Use
Art. 2. In Article 2, Paragraph 2, of the Law of 25 March 1964 on Medicinal Products for Human Use, replaced by the Law of 11 July 2023, the words ", in the Therapeutic Magistral Form" are repealed.

Art. 3. In Article 3, Section 4, Paragraph 3, of the same law, inserted by the Law of 18 May 2022, the word "approved" is replaced by the words "referred to in Article 15".

Art. 4. Article 6, Section 1, Paragraph 3, of the same law, as amended by the Law of 3 August 2012, in the last sentence, the following amendments are made:

1. the words "recognised by it" are replaced by the words "referred to in Article 15";

2. the words “by a laboratory designated for this purpose” are inserted between the words “or” and “by the competent authority”;

3. the words "with an equivalent legislation" are repealed.
Art. 5. In Article 6 of the same law, as last amended by the Law of 5 May 2022, Paragraph 2 is supplemented by a subparagraph, worded as follows:

"The hospital pharmacist may dispense medicinal products to outpatients as part of measures taken in accordance with or under Article 12f, Subparagraph 3. ”.

Art. 6. In Article 6c of the same law, the following amendments are made:

1. Paragraph 1, Subparagraph 1, Point 1, is supplemented by the following sentence: "The King may subject the application of this provision for a medicinal product to the prior agreement of the minister or their delegate. ”;
2. in Paragraph 3, Subparagraph 1, Point 2, the words "or of the Therapeutic Magistral Form" are repealed.

Art. 7. In Article 12a of the same law, the following amendments are made;

1. in Paragraph 1/1, Subparagraph 1, Point 1, of the same law, as amended by the Law of 5 May 2022, the words "Article 6c, Section 1, Paragraph 1, Point 1” are replaced by the words “Article 6c, Section 3, Paragraph 1, Point 1”;
2. in Paragraph 3, Subparagraph 1, inserted by the Law of 23 December 2009 the words ", or whose primary packaging is modified, or whose packaging or presentation is modified or divided," are inserted between the words "one or more medicinal products are removed from their primary packaging" and the words "and then, where appropriate, grouped";
3. in Paragraph 3, Subparagraph 1, the words "a single closed individual administration

package, intended" are replaced by the words "in a single or several closed individual administration package(s), intended".

Art. 8. Article 12b, Section 1, Paragraph 3, of the same law, last amended by the Law of 7 April 2019, in the last sentence, the word "fulfils" is replaced by the words "and the parallel distributor fulfils".

Art. 9. In Article 12f of the same law, inserted by the Law of 1 May 2006 and amended by the Law of 20 December 2019, the following amendments are made:

1. Paragraph 2 is supplemented by the following words: ", or when the FAMHP finds that the stock available on the Belgian market of a medicinal product is insufficient to cover the needs of patients or that such a shortage is imminent or probable. ”

2. the article is supplemented by three paragraphs, worded as follows:

"If a judgement has been notified or recorded in accordance with Article 6, Section 1e, or when the FAMHP finds that the stock available on the Belgian market of a medicinal product is insufficient to cover patients' needs or that such a shortage is imminent or probable, the Minister or their delegate may take the following measures with regard to individual actors, a group of actors or all persons concerned:

1. order that the remaining stock be redistributed, that it be held by the authorisation holders referred to in Article 12a, by the authorisation holders referred to in Article 12b or by persons authorised to dispense medicinal products to the public;

2. order that stocks be made available primarily to hospitals or specific healthcare professionals and, where appropriate, that hospital pharmacies be authorised to supply outpatients;

3. order that the wholesaler-distributor and/or persons authorised to dispense medicinal products to the public may only be supplied up to a certain quantity, or that only a certain percentage of the available stock may be supplied to the actors mentioned, or otherwise order the proportional distribution between the different actors.

The measures referred to in Paragraph 3 shall only be taken to the extent necessary to protect public health, life or the health of persons. The King may lay down the conditions, procedure and methods of notifying the measures referred to in Paragraph 3, and may empower the minister or their delegate to take measures other than those referred to in Paragraph 3.

If the measures referred to in Paragraph 3 or taken pursuant to Paragraph 4 result in a market participant being unable to meet their contractual obligations, no compensation may be claimed from that participant, nor may any penalty clause be enforced, insofar as the failure to meet the obligations is attributable to the measures referred to in Paragraph 3 or provided for on the basis of Paragraph 4. ”

Art. 10. In Article 13, Paragraph 2, of the same law, amended by the Law of 20 October 2008, the following amendments are made:

1. the words "The minister who has public health in their responsibilities is authorised to approve one or more" are replaced by the word "The";

2. Paragraph 2 is supplemented by the words "are the laboratories referred to in Article 15, Section 4. ”.

Art. 11. In Article 15, Section 4, of the same law, the following amendments are made:

1. A paragraph worded as follows is inserted before Paragraph 1:

"The control of medicinal products is reserved for laboratories holding an authorisation referred to in Article 12a, Section 1, at least with regard to quality control, or to the official medicinal product control laboratories designated for this purpose by the Minister or their delegate. The King can specify what the authorisation must cover at a minimum. He can also determine the conditions and procedure for appointment. ”.;

2. in Paragraph 1, former becoming Paragraph 2, the words "as well as the organisation and operation of laboratories recognised for their analysis" are repealed.

Section 2 - Transitional Provision

Art. 13. Articles 3, 4, 10 and 11 shall enter into force on the first day of the 13th month following that of the publication of this law in the Belgian Official Gazette.

Chapter 3. – Amendments to the Law of 5 July 1994 relating to blood and blood products of human origin

Art. 14. The following amendments are made to Article 15, Point 2, of the Law of 5 July 1994 relating to blood and blood products of human origin:

1. the word “cardiovascular” is replaced by the word “clinical”;
2. the words "including at least the control of heart rate and blood pressure as well as" are replaced by the word "of which".

Art. 15. In Article 17, Section 2, Paragraph 1, of the same law, replaced by the Royal Decree of 1 February 2005, the words "may not exceed 500 ml with a maximum value of 13 % of the estimated total blood volume of the donors" are replaced by the words "may not exceed 500 ml, excluding the sample volume for laboratory tests and archive samples. The total amount of blood taken cannot exceed a maximum value of 15 % of the estimated total blood volume.

Art. 16. In the annex to the same law, as last amended by the Law of 11 July 2023, the following amendments are made:

1. in Point 2(d), the provision worded as follows:

People with hypertension and a diastolic blood pressure greater than 100 mmHg	Exclusion for as long as the situation has not improved

is repealed;

2. in Point 2(d), the provision worded as follows:

People with hypotension and a systolic blood pressure below 100 mmHg	Exclusion for as long as the situation has not improved

is repealed.

Chapter 4 - Amendments to the Law of 7 May 2004 relating to experimentation on human subjects

Art. 17. In Article 2 of the Law of 7 May 2004 relating to experimentation on human subjects, as last amended by the Law of 26 December 2015, Point 15(a) is replaced by the following:

“(a) The sponsor is either a university or college, or a hospital referred to in Article 4 of the Law of 10 July 2008 on hospitals and other healthcare establishments, or a hospital referred to in Article 7, Point 2(g), Sub-point 2, of the Royal Decree of 25 April 2002 on the establishment and liquidation of the budget for the financial resources of hospitals, where both surgical and medical services are provided, exclusively for children or related to tumours, or the National Fund for Scientific Research (FNRS), or the Research Foundation (FWO) or a research fund that depends on one of these two bodies, or a department of a hospital that is accredited for this purpose according to the procedures laid down by the King if that department is, in its field of activity, a centre of excellence or a centre of expertise, or a non-profit institution whose corporate purpose is primarily focused on research, or the equivalent of one of these entities in another Member State;”.

Art. 18. Article 11/2, Section 3, of the same law, as last amended by the Law of 10 April 2014, Paragraph 3 is repealed.

Art. 19. Article 31 of the same law, as last amended by the Law of 10 April 2014, Paragraph 1 is repealed.

Chapter 5. - Amendments to the Law of 20 July 2006 on the establishment and operation of the Federal Agency for Medicines and Health Products

Art. 20. Article 2, Section 1 , Paragraph 3, Point 1 of the Law of 20 July 2006 relating to the creation and operation of the Federal Agency for Medicines and Health Products, inserted by the Law of 8 February 2022, the words "or of the Therapeutic Magistral Form" are repealed each time.

Art. 21. Article 4, Section 1, Paragraph 3, Point 8, of the same law, inserted by the Law of 11 July 2023, the c. is repealed.
Art. 22. Article 7 of the same law is supplemented by a paragraph, worded as follows:

"Within the framework of the missions referred to in Paragraph 1 or 2, and provided that the subcontracting relates to the exercise of supervisory and control powers, the FAMHP may exercise the powers of the subcontracting authority. The provisions of Article 14/21 are applicable in this case. ”
Art. 23. Article 7a of the same law is supplemented by a paragraph, worded as follows:

"Within the framework of the missions referred to in Paragraph 1, the FAMHP may subcontract the surveillance and control referred to in Article 4, Section 1, Paragraph 3, Point 6(a) to another authority, and the officials or contract staff members designated by the King of that authority may make use of the powers conferred by law on the inspectors and controllers of the FAMHP. ”
Art. 24. In Article 8, Section 2, of the same law, as amended by the Law of 10 December 2009, the following amendments are made:
1. Paragraph 1 is completed by the following sentences: "The Director-General may, in the event of incapacity or absence, be replaced by the holder of another senior management position referred to in Article 8, Paragraph 1, Subparagraph 2, in order to exercise the powers referred to in or under this Article. If the Director-General is unable to appoint a replacement, the management committee referred to in Subparagraph 2 shall appoint a replacement." ”
2. in Paragraph 2, the words “The Minister shall determine whether the members thus appointed shall also sit as members of the management board referred to in Article 16, Section 2, of the Royal Decree of 8 January 1973 establishing the staff regulations of certain bodies of public interest, or whether their appointment shall be limited to the members of the Management Committee, as referred to in this paragraph. ” are inserted between the words "of the management committee. ” and the words "The management committee drafts".
3. Paragraph 2 is supplemented by the following sentence: "Members of the management committee may be replaced, in case of absence or impediment, by an FAMHP official of class A4 or higher. ”
Art. 25. In Article 11 of the same law, as amended by the Law of 30 October 2018, the following amendments are made:
1. Paragraph 3 is repealed;
2. In Paragraph 4, the words “, by decree deliberated in the Council of Ministers,” are repealed.
Art. 26. Sec. 1. In Article 14/4, Paragraph 1 of the same law, inserted by the Law of 11 March 2018 and amended by the Law of 22 December 2023, the words "15 days after receipt" are replaced by the words "30 days after sending".

Sec. 2. In Article 14/7, Paragraph 3 of the same law, inserted by the Law of 11 March 2018, the words "15 days after receipt" are replaced by the words "30 days after sending".

Sec. 3. In Article 14/9, Section 2, of the same law, inserted by the Law of 11 March 2018, the words "15 days after receipt" are replaced by the words "30 days after sending".

Sec. 4. In Article 14/13, Paragraph 2, of the same law, inserted by the Law of 11 March 2018 and amended by the Law of 8 February 2022, the words "15 days after receipt" are replaced by the words "30 days after sending"

Sec. 5. In Article 14/15 of the same law, inserted by the Law of 11 March 2018, amended by the Law of 7 April 2019, and replaced by the Law of 22 December 2023, the words "15 days from receipt" are replaced by the words "30 days after sending".

Art. 27. Sec. 1. In Article 14/17 of the same law, inserted by the Law of 11 March 2018 and amended by the Law of 7 April 2019, the following amendments are made:

1. in Section 1, Paragraph 1, the words "the tax is not paid within the applicable payment period provided for in accordance with Articles 14/4, 14/7, Paragraph 2, 14/9, Section 2, or 14/13. ”

are replaced by the words

“the taxes or fees due under this law have not been paid within the applicable payment period.”

2. in Section 1, Paragraph 2, of the same law, the words "of the tax" are replaced by the words "of taxes and fees".

3. Section 1, Paragraph 3, is replaced as follows:

"Interest due will only be claimed when it reaches at least 2.50 euro. ”

4. Sections 2 and 3 are repealed.

5. In Section 4, the words "the interest rates referred to in Sections 1 and 2" are replaced by the words "the interest rate referred to in Section 1 "

Art. 28. In Article 14/19 of the same law, most recently amended by the Law of 22 December 2023, the following amendments are made:

2. in Section 1, Paragraph 1, the words ", by right to 1 January of the year to which they relate," inserted between the words "adapted" and "each year";
2. in Section 1, Paragraph 1, the words "The indexed amounts are published in the *Belgian Official Gazette* and are payable from the 1st January of the year following the one in which the adaptation was carried out. ” are repealed;

3. in Section 1, Paragraph 2 is repealed;

4. in Section 2, Paragraph 2 is repealed;

5. a new Section 3 is inserted, worded as follows:

"Sec. 3. The Agency publishes the indexed amounts on its website within 30 days from the day on which the adjustment, amendment or introduction referred to in Sections 1 and 2 enters into force.

Art. 29. In Article 14/20 of the same law, inserted by the Law of 11 March 2018 and most recently amended by the Law of 22 December 2023, the following amendments are made:

1. in Section 1, Paragraph 1, the words "or fee" are inserted between the words "the tax" and the word "becomes";

2. in Section 1, Paragraph 3, the words "or fee" are inserted between the words "the tax" and the words "in a";

3. in Section 2, the words "or fee" are inserted between the words "the tax" and the word "becomes";

4. in Section 2, in Point 2, the words "or fee" are inserted between the words "the tax" and the words "has been".

Art. 30. In Article 14/22, Section 8 of the same law, inserted by the Law of 22 December 2023, the words "to the debtor, as well as to persons related within the meaning of Article 1:20, Point 2 of the Companies and Associations Code," are inserted between the words "the provision of service" and the words "in the event of non-payment".

Art. 31. In Article 14/24, Paragraph 2 of the same law, inserted by the Law of 11 March 2018 and amended by the Law of 22 December 2023, the following amendments are made:

1. the words ", as the case may be, interrupted or suspended" are repealed;

2. in Point 1, the words "as the case may be, interrupted or suspended" are inserted before the words "in the forms";

3. in Point 2, the word "interrupted" is inserted before the words "by sending".

Art. 32. In Article 14/28, inserted by the Law of 18 July 2025, the words "fifteen days, referred to in Article 14/18, Section 1, after receipt" are replaced by the words "thirty days after sending".

Chapter 6 - Amendments to the Law of 19 December 2008 relating to the obtaining and use of human bodily material intended for human medical applications or for scientific research purposes

Article 33. In Article 3, Section 3(f), of the Law of 19 December 2008 relating to the obtaining

and use of human bodily material intended for human medical applications or for scientific research purposes, inserted by the Law of 30 October 2018 and amended by the Laws of 23 February 2022 and 18 May 2022, the following amendments are made:

1. in the French text, the words ", as referred to in Article 2, Point 7, of the Law of 7 May 2004 relating to experiments on human persons or as referred to" are replaced by the words "as referred to";
2. in the Dutch text, the words “als bedoeld in Article 2, Point 7, van de wet van 7 mei 2004 inzake experimenten op de menselijke persoon of” are repealed;
3. The words "in the context of clinical investigations referred to in Article 2(45) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC or in the context of performance studies referred to in Article 2(42) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU" are inserted between the words “and repealing Directive 2001/20/EC,” and the words “insofar as human bodily material”;
4. the words ", clinical investigation or performance study" are inserted between the words "used for purposes other than the clinical trial" and the words "in question".

Chapter 7. – Amendments to the Law relating to the exercise of healthcare professions, coordinated on 10 May 2015

Art. 34. In Article 9, Section 4, of the Law of 10 May 2015 relating to the exercise of healthcare professions, coordinated on 10 May 2015, last amended by the Law of 30 October 2018, the following amendments are made:

1. In the first sentence, the words "more than sixty days" are inserted between the words "definitive or temporary closure" and "of a dispensing pharmacy";
2. The paragraph is supplemented by a second subparagraph, worded as follows:

"Exceptionally, a temporary closure authorisation may be granted after the closure if, due to circumstances beyond the control of the holder of the operating authorisation referred to in Article 18, it was impossible to apply for the authorisation in time or if, due to unforeseen circumstances, a temporary closure of a maximum duration of 60 days must be extended."

Art. 35. In Article 16 of the same law, most recently amended by the Law of 11 July 2023, the following amendments are made:

1. in Paragraph 1, the Point 1 is supplemented by the words ", without prejudice to Section 2, Point 2";
2. in Paragraph 2, the Point 2 is supplemented by the words "as well as the dispensing, by the pharmacist themself or via a courier service, of these preparations and any other product included in the administration schedule to persons living in the community within the meaning of Article 6, Section 2, Paragraph 1, of the Law of 25 March 1964 on medicinal products for human use as well as to persons who are treated in a day care centre, a home for disabled persons, a children's placement home and a forensic psychiatric centre. ”;
3. Paragraph 2 is supplemented by a paragraph worded as follows: "The King may determine the modalities for the application of this paragraph, and may in particular specify which courier services may be used."

Chapter 8. – Amendments to the Law of 7 May 2017 relating to clinical trials of medicinal products for human use

Art. 36. The following amendments are made to Article 6, Section 4, of the Law of 7 May 2017 relating to clinical trials of medicinal products for human use:

1. in Paragraph 1, the words "or their delegate" are inserted between the words "the minister" and the words "for a period";

2. In Paragraph 2, the words "or their delegate" are inserted between the words "The Minister" and the words "refuses approval".

Art. 37. In the same law, a Chapter 9/2 entitled "Chapter 9/2. Dispensing of investigational

medicinal products and ancillary medicinal products.”

Art. 38. In Chapter 9/2, inserted by Article 37, Article 40/2 is inserted as follows:

"**Art. 40/2. Sec. 1.** Investigational medicinal products and ancillary medicinal products may be dispensed in person, where appropriate to the participant's address, where the medicinal products will be stored and administered, by:

1. An investigator of the clinical trial in question;
2. A hospital pharmacist working in a hospital pharmacy approved in accordance with Article 66 of the Law on Hospitals and other healthcare establishments, coordinated on 10 July 2008, at a clinical trial site, or at a hospital operated by the Ministry of Defence, if it is a clinical trial site; or

3. a pharmacist practising in a pharmacy open to the public, who has an operating license in accordance with Article 18 of the law relating to the practice of healthcare professions, coordinated on 10 May 2015.

Investigational medicinal products and ancillary medicinal products may be dispensed remotely, via a delivery service, at the participant’s address, where the medicinal products will be stored and administered, by:

1. an investigator of the clinical trial in question; or
2. a hospital pharmacist working in a hospital pharmacy approved in accordance with Article 66 of the Law on Hospitals and other healthcare establishments, coordinated on 10 July 2008, at a clinical trial site, or at a hospital operated by the Ministry of Defence, if it is a clinical trial site.

By way of derogation from Paragraph 1, an investigator working in a healthcare establishment shall not dispense an authorised ancillary medicinal product bearing a unique identifier within the meaning of Article 3(2)(a) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down details of safety features appearing on the packaging of medicinal products for human use, unless additional information is included on the outer packaging and the primary container, in accordance with Article 67, Paragraph 2 of the Regulation.

Sec. 2. The investigator may delegate in-person dispensing, where appropriate to the participant’s address, where the medicinal products will be stored and administered, to the following persons:

1. another investigator;

2. a nurse holding the approval referred to in Article 10 of the Law of 22 April 2019 on the quality of healthcare practice; or

3. a coordinator of the study, namely an associate of the principal investigator to whom the latter has delegated (part of) the practical organisation of the clinical trial and the tasks related to the clinical trial, who is neither investigator nor nurse.

The investigator may delegate remote dispensing, via a delivery service, to the address of the participant, where the medicinal products will be stored and administered, to the following persons:

1. the holder of the manufacturing or import authorisation for an authorised investigational medicinal product or authorised ancillary medicinal product, as referred to in Article 12*a* of the Law of 25 March 1964 on medicinal products for human use, in the case of such a medicinal product;

2. the holder of the manufacturing or import authorisation for an unauthorised investigational medicinal product, an unauthorised ancillary medicinal product or an authorised ancillary medicinal product subject to a change that is not covered by a marketing authorisation, referred to in Article 38 of the Law, in the case of such a medicinal product;

3. a wholesale distributor referred to in Article 12b of the Law of 25 March 1964 on

medicinal products for human use, when distributing an authorised investigational medicinal product or authorised ancillary medicinal product;

4. the holder of a distribution authorisation meeting the conditions laid down by the King, referred to in Article 40/1, in the case of an unauthorised investigational medicinal product, an unauthorised ancillary medicinal product or an authorised ancillary medicinal product subject to an amendment that is not covered by a marketing authorisation.

Sec. 3. In-person dispensing or remote dispensing, via a delivery service, to the participant's address, where the medicinal products will be stored and administered, may take place at the address of a participant in Belgium, where that participant participates in a clinical trial authorised in one or more other Member States, even if it is not authorised in Belgium.

Where in-person dispensing or remote dispensing, via a delivery service, to the participant's address, where the medicinal products will be stored and administered, takes place in another Member State, the person referred to in Paragraph 1, Subparagraph 1, Points 1 to 3, or Subparagraph 2, Point 1 or 2, or their delegate, referred to in Paragraph 2, shall comply with the legal and administrative provisions in force in the Member State concerned.

Sec. 4. The King may impose conditions and procedures relating to the dispensing of investigational medicinal products and ancillary medicinal products'. ".

Art. 39. In Article 48 of the same law, the following amendments are made:

1. in Paragraph 2, Subparagraph 2, the words "of one month" are replaced by the words "of two months";

2. Paragraph 3 is replaced by the following:

"Sec. 3. The minister or their delegate shall make a decision within three months of receiving the appeal referred to in Paragraph 1.
The clinical trial or substantial modification can only be authorised if both the Commission for Medicinal Products for Human Use and the Ethics Committee have issued a favourable opinion to that effect.

The clinical trial or substantial modification can only be authorised under conditions if both the Commission for Medicinal Products for Human Use and the Ethics Committee have issued one or more conditions in their opinions. If the conditions issued respectively, following their review, by the Commission for Medicinal Products for Human Use and by the Ethics Committee are incompatible with each other, the clinical trial or substantial modification cannot be authorised.

Chapter 9 – Amendments to the Law of 22 December 2020 on Medical Devices
Art. 40. Article 55 of the Law of 22 December 2020 on Medical Devices is amended as follows:

1. in Paragraph 2, Subparagraph 2, the words "of one month" are replaced by the words "of two months";
2. Paragraph 3 is replaced by the following:

"Sec. 3. The minister or their delegate shall make a decision within three months of receiving the appeal referred to in Paragraph 1.
Clinical investigations may only be authorised if both the FAMHP and the Ethics Committee have issued a favourable opinion.
Clinical investigations may only be authorised conditionally if one or more conditions have been issued by the FAMHP and the Ethics Committee. In the event that the conditions issued respectively, following their examination, by the FAMHP and by the Ethics Committee are incompatible with each other, the clinical investigation cannot be authorised. ".

Chapter 10 – Amendments to the Law of 5 May 2022 on veterinary medicinal products

Section 1. Amending provisions

Art. 41. Article 10 of the Law of 5 May 2022 on Veterinary medicinal products is replaced by the following:

"Art. 10. The control of veterinary medicinal products referred to in Article 29, Paragraph 1, in Article 123, Paragraph 6, Point (b) and Article 128, Paragraph 3 of Regulation 2019/6 are reserved for laboratories holding a manufacturing authorisation referred to in Article 88, Paragraph 1 of Regulation 2019/6, at least with regard to the quality control part, or for official laboratories for the control of medicinal products designated for this purpose by the Minister or their delegate. The King can specify what the authorisation must cover at a minimum. He can also determine the conditions and procedure for appointment. ”.

Art. 42. Article 29/1 is inserted into the same law, worded as follows:

"Art. 29/1. The King may stipulate that the FAMHP establishes and applies a quality system during inspections relating to compliance with good manufacturing practices for veterinary medicinal products. The King can determine the procedures in this matter. The King can determine the content and minimum requirements of this quality system. ”.

Art. 43. Article 33/1 is inserted into the same law, worded as follows:

"Art. 33/1. In accordance with Article 101, Paragraph 2, of Regulation 2019/6, the wholesale distributor may only supply authorised veterinary medicinal products for the manufacture of medicated animal feed to manufacturers of medicated animal feed authorised in accordance with the provisions of Article 3a, Paragraph 1, of the Royal Decree of 22 February 2001 organising the controls of the Federal Agency for the Safety of the Food Chain and amending various legal provisions, confirmed by the Law of 19 July 2001 confirming and amending the Royal Decree of 22 February 2001 organising the controls carried out by the Federal Agency for the Safety of the Food Chain and amending various legal provisions and confirming the Royal Decree of 22 February 2001 relating to the financing of the Federal Agency for the Safety of the Food Chain, and the implementing decrees. The approved manufacturer of medicated animal feed does not need to hold a wholesale distribution license. ”.

Art. 44. Article 33/2 is inserted into the same law, worded as follows:

"Art. 33/2. In accordance with Article 101, Paragraph 2, of Regulation 2019/6, the King may authorise other persons to supply veterinary medicinal products that are not subject to prescription and that, due to their characteristics, are not suited to follow exclusively the normal pharmaceutical distribution circuit.
The King sets the conditions and procedures for this authorisation. ”.

Art. 45. In Article 40 of the same law, a Paragraph 3 is inserted as follows:

"Sec. 3. The King may determine additional conditions and additional measures concerning the remote retail sale of veterinary medicinal products. ”.

Art. 46. Article 41 of the same law is supplemented by two subparagraphs as follows:

"In accordance with Article 105, Paragraph 5, introductory sentence, of Regulation 2019/6, the King may determine additional elements that the veterinary prescription must contain.

In accordance with Article 105, Paragraph 12, of Regulation 2019/6, the King may decide that a veterinary medicinal product classified as subject to veterinary prescription but administered by the veterinarian themself, still requires a veterinary prescription. ”.

Art. 47. Article 50, Section 1, Paragraph 2, of the same law, the words ", in the Therapeutic Magistral Form" are repealed.

Art. 48. In Article 61, Point 33, of the same law, the number "35," is inserted after the words "Paragraph 1 or 2 of Regulation 2019/6, in Article 2.

Section 2. Transitional provision and entry into force

Art. 49. Pending the implementation of Article 29/1 of the Law of 5 May 2022 on veterinary medicinal products by the King, the FAMHP's quality system is based on the framework referred to in Annex IV*a* of the Royal Decree of 14 December 2006 relating to medicinal products for human use.

Art. 50. Article 41 enters into force on the first day of the 13th month following the month of publication of this law in the Belgian Official Gazette.

Chapter 11 – Amendments to the Law of 15 June 2022 on in vitro diagnostic medical devices

Art. 51. The following amendments are made to Article 52 of the Law of 15 June 2022 relating to in vitro diagnostic medical devices:
1. in Paragraph 2, Subparagraph 2, the words "of one month" are replaced by the words "of two months";
2. Paragraph 3 is replaced by the following:
"Sec. 3. The minister or their delegate shall make a decision within three months of receiving the appeal referred to in Paragraph 1.
Performance studies may only be authorised if both the FAMHP and the Ethics Committee have issued a favourable opinion.
Performance studies may only be authorised conditionally if one or more conditions have been issued by either the FAMHP and the Ethics Committee. If the conditions issued respectively by the FAMHP and the Ethics Committee following their review are incompatible with each other, the performance study cannot be authorised."

Chapter 12 – Amendments to the Law of 29 February 2024 relating to raw materials used by pharmacists

Art. 52. In Article 13, Paragraph 2, of the Law of 29 February 2024 relating to raw materials used by pharmacists, the words ", where appropriate, on the advice of the Pharmacopoeia Commission," are replaced by the words "on the advice of the Commission for medicinal products for human use on the public health reasons invoked."

Art. 53. In Article 15, Section 3, Paragraph 1, in the same law, the words ", where appropriate, on the advice of the Pharmacopoeia Commission," are replaced by the words "on the advice of the Commission for medicinal products for human use on the public health reasons invoked."

Art. 54. In Article 18, Paragraph 1, of the same law, Point 7 is supplemented by the words: "This is confirmed by the attending physician."

Art. 55. In Article 19 of the same law, the following amendments are made:

1. in Paragraph 1, the words "in a hospital operated by the Ministry of Defence," are inserted between the words "10 July 2008," and "in a multidisciplinary centre."

2. a paragraph worded as follows is inserted between Paragraphs 2 and 3:

"When the raw material for which the pharmacist submits the application is not described in an analytical reference referred to in Article 11, Section 1, Paragraph 1, Points 1 to 3, but is the subject of a monograph in the hospital or centre referred to in Paragraph 1 to which it is attached, the application referred to in Paragraph 1 is in any case admissible only if the copyright holder(s) of the monograph agree to assign their copyright on the monograph to the FAMHP, exclusively and free of charge, for an indefinite period, so that the FAMHP can draw up the minimum analytical reference in accordance with Article 22, Section 3";

3. in Paragraph 3, which becomes Paragraph 4, the words "and Point 7" are repealed.

Art. 56. In Article 22 of the same law, the following amendments are made:

1. in Paragraph 1, the words "Subparagraph 2" are replaced by the words "Paragraph 1, Subparagraph 2";

2. Paragraph 2 is repealed;

3. Paragraph 3 is replaced by the following:

"Sec. 3. When a raw material with limited use is not described in an analytical reference referred to in Paragraph 1, the FAMHP draws up a minimum analytical reference for the raw material concerned, on the advice of the Pharmacopoeia Commission. The FAMHP (Federal Agency for Medicines and Health Products) may delegate the drafting of the minimum analytical reference to a laboratory.

If the raw material for limited use is the subject of a monograph in accordance with Article 19, Paragraph 3, the FAMHP and the holder(s) of the copyright of the monograph shall conclude a contract for the assignment of rights prior to the drafting of the minimum analytical reference. The copyright holder(s) of the monograph shall communicate it to the FAMHP after the conclusion of the contract.

The FAMHP publishes the minimum analytical reference in the Belgian Pharmacopoeia.

The minimum analytical reference published in the Belgian Pharmacopoeia is used as the analytical reference for the raw material for limited use in question.

The King defines the criteria that a minimum analytical reference must meet. The King may define different criteria depending on the categories of raw materials that He defines. The King may set the time limits and procedures for the process referred to in Sections 1 and 2. ”.

Art. 57. Article 50/1 is inserted into the same law, worded as follows:

“ **Art. 50/1.** Before their first use, the pharmacist checks the conformity of the raw materials that they intend to use for the preparation of a magistral or officinal preparation, to this law and its implementing decrees. ”.

Art. 58. Article 50/2 is inserted into the same law, worded as follows:

“ **Art. 50/2.** The pharmacist may use a raw material for limited use that does not meet the analytical reference applicable to it in accordance with Article 22, if each of the following conditions is met:

1. the raw material is used to prepare a magistral preparation;

2. it is not reasonably possible for the pharmacist to obtain an authorised raw material or a raw material for limited use that meets the applicable analytical reference; the pharmacist informs the prescribing physician;

3. the pharmacist has the declaration from the prescribing physician that the magistral preparation based on this limited-use raw material is absolutely necessary in order to treat a patient in a life-threatening situation or to prevent a significant and irreversible deterioration of their condition.

The King may determine the form and content of the prescribing physician's declaration, referred to in Paragraph 1, Point 3. The King may determine the conditions for the preservation of this declaration, as well as any document that provides supports that the condition referred to in Paragraph 1, Point 2, is fulfilled. ”.

Art. 59. Article 50/3 is inserted into the same law, worded as follows:

"Art. 50/3. By way of derogation from Article 11, Section 1, Paragraph 1 and in Article 50, Paragraph 1, the hospital pharmacist may use a raw material that does not have a raw material authorisation as referred to in Article 13, whether supplied by a manufacturer, distributor or other supplier, under the following conditions:

1. The hospital pharmacist submits an application for the status of limited use raw material to the FAMHP in accordance with Article 19 unless another hospital pharmacist has submitted such an application;

2. When the raw material is not accompanied by a certificate of analysis and the pharmacist cannot obtain this certificate of analysis from another pharmacist, the pharmacist delegates the analysis of the raw material to a laboratory that provides them with the certificate of analysis;

3. The pharmacist shall use the raw material in question only:

a. until a period to be fixed by the King after the decision of the Minister or their delegate in accordance with Article 20, if the raw material concerned is described in one or more analytical

reference(s) referred to in Article 11, Section 1, Paragraph 2, Points 1 to 3, in accordance with Article 22, Section 1, or **until a deadline to be set by the King** after the minister or their delegate has refused to grant the status of limited-use raw material;
b. until a period to be set by the King after the publication of the minimum analytical reference in the Belgian Pharmacopoeia, in accordance with Article 22, Section 3, Paragraph 3, when the raw material in question was not described in a reference referred to in Article 22, Section 1. ".

Art. 60. Article 65 of the same law is replaced as follows:
"Art. 65. By way of derogation from Article 50/3, Point 1, the pharmacist may use a raw material not having a raw material authorisation as referred to in Article 13, whether supplied by a manufacturer, distributor or other supplier, that they were already using at the time of entry into force of the Law, provided that the application for the allocation of the status of raw material for limited use, as referred to in Article 50/3, Point 1, is submitted within a period to be set by the King and at the latest three years after the entry into force of this law. ".

Art. 61. In Article 72 of the same law, the words "first day of the twenty-fifth month after its publication in the Belgian Official Gazette" are replaced by the words "1st January 2027.

Art. 62. This chapter shall enter into force on 30 May 2026.

... (place), on... (date).

By the King:
The Minister for Public Health,

Frank VANDENBROUCKE