KINGDOM OF BELGIUM

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Royal Decree implementing the Law of 29 February 2024 on raw materials used by pharmacists

PHILIPPE, King of the Belgians,

To all present and to come, greetings.

Having regard to Article 108 of the Constitution;

Having regard to the Law of 29 February 2024 on raw materials used by pharmacists, Articles 2, § 2, subparagraph 3, 5, 6, subparagraphs 2 and 3, 7, subparagraph 2, 8, subparagraphs 2 and 3, 9, subparagraph 3, 10, § 3, 11, § 3, subparagraphs 1 and 2, 12, subparagraph 2, 13, subparagraphs 1 and 2, 14, subparagraphs 3 and 4, 15, § 4, 16, 17, § 5, 19, subparagraphs 2 and 3, 21, 22, § 3, subparagraph 5, 23, 24, § 3, 25, § 1, subparagraph 4 and § 2, subparagraphs 1 and 2, 26, subparagraphs 2 and 3, 28, subparagraph 2, 29, subparagraph 2, 30, § 3, 34, 36, § 3, subparagraph 1, 37, § 2, subparagraphs 1 and 2, 38, subparagraphs 2 and 3, 39, subparagraph 2, 40, subparagraph 2, 41, § 3, 44, 46, 47, subparagraph 4, 50, subparagraph 2, 50/2, subparagraph 1, inserted by the Law of 30 May 2026, 50/3, point 3(a) and (b), inserted by the Law of 30 May 2026, 51, subparagraphs 1 and 2, 52, § 1, subparagraph 2, 63, § 1, subparagraph 2 and § 2, subparagraph 2, 64, § 1, 65, 67 and 72;

Having regard to the Law on the practice of healthcare professions, coordinated on 10 May 2015, Article 7, subparagraph 6;

Having regard to the Law of 20 July 2006 on the establishment and operation of the Federal Agency for Medicines and Health Products, Article 4, § 1, subparagraph 1, as amended by the Law of 22 December 2008, and subparagraph 3, point 4(c) and (d), as amended by the Law of 8 February 2022;

Having regard to the Law of 25 March 1964 on medicinal products for human use, Articles 3, § 1, subparagraph 2, amended by the Law of 1 May 2006, and § 2, amended by the Law of 5 May 2022, 6*quater*, § 1, subparagraph 1, point 4, inserted by the Law of 29 March 2012 and last amended by the Law of 5 May 2022, and 12*bis*, § 1, subparagraph 3, inserted by the Law of 1 May 2006 and last amended by the Law of 17 July 2015, and § 1/1, subparagraph 3, inserted by the Law of 26 December 2013;

Having regard to the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists, as amended by the Royal Decrees of 10 August 2001 and 8 July 2002;

Having regard to the communication to the European Commission on … (date), pursuant to Article 5(1) 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;

Having regard to the opinion of the Inspector of Finance, given on xx/xx/xxxx;

Having regard to the approval of the Minister for the Budget, given on XX XX XXXX;

Having regard to Opinion No [...] of the Data Protection Authority, given on [...] ;

Having regard to Opinion No XX.XXX/X of the Council of State, given on XX XX XX, pursuant to Article 84, § 1, subparagraph 1, point 2, of the Laws on the Council of State, coordinated on 12 January 1973;

On the proposal of the Minister for Public Health;

We have decreed and hereby decree:

Chapter 1. General provisions

Article 1. For the purposes of this Order and the orders implementing it, the following definitions shall apply:

1. 'Law' means the Law of 29 February 2024 on raw materials used by pharmacists;

2. 'active substance' means a substance that exerts a pharmacological, immunological or metabolic action for the purpose of restoring, correcting or modifying physiological functions or making a medical diagnosis;
3. 'excipient' means any substance other than the active substance;

4. 'batch number' means a characteristic combination of digits and/or letters that specifically identifies a production or manufacturing batch;

5. 'test report' means a document setting out the results of the identity and quality checks on the batch of the raw material, carried out by a producer or manufacturer holding a certificate of good manufacturing practices as referred to in Article 12*bis*, § 1, subparagraph 8, of the Law on medicinal products or of the national provisions transposing Article 111(6) of Directive 2001/83/EC, for tests carried out using methods corresponding to the current state of scientific and technical knowledge;

6. 'editorial change to the monograph' means a change in the form of the monograph;

7. 'substantive change to the monograph' means any amendment to the monograph other than an editorial change;

8. 'primary distributor' means either the manufacturer itself, where it distributes the raw materials that it manufactures, or a distributor designated by the manufacturer to distribute the manufactured raw materials on its behalf;

9. ‘temporary suspension of placing on the market’ means suspension of the placing on the market of a raw material for 90 days or more;

Article 2. The reassignment referred to in Article 2, § 2, subparagraph 3, of the Law may take place only if the manufacturer or distributor demonstrates that a full analysis, in accordance with the analytical specification set out in the raw material authorisation, has been carried out on the production batch packaged for the purposes of reassignment. The production batch shall be accompanied by the certificate of analysis or the test report.

Compliance with the provisions of the Law on medicinal products or the national provisions transposing Directive 2001/83/EC in the case of reassignment of the substances referred to in Article 2, § 2, subparagraph 3, of the Law shall be demonstrated as follows:

1. with regard to the import and/or manufacture of active substances, those operations were carried out:

a) by a manufacturer of active substances registered with the FAMHP in accordance with Article 12*bis*, § 4, of the Law on medicinal products or with the competent authority of the Member State in which it is established in accordance with the national provisions transposing Article 46(h) of Directive 2001/83/EC; and

b) in accordance with Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to the principles and guidelines of good manufacturing practice for active substances in medicinal products for human use;

2. with regard to the manufacture of excipients, those operations were carried out in accordance with the appropriate good manufacturing practices determined in accordance with the Guidelines on the formalised risk assessment to determine the appropriate good manufacturing practices for excipients used in medicinal products for human use, set out in Annex IV*ter* to the Royal Decree of 14 December 2006 on medicinal products for human use, or in accordance with the national provisions transposing the Guidelines of 19 March 2015 on the formalised risk assessment to determine the appropriate good manufacturing practices for excipients used in medicinal products for human use, or directly in accordance with those guidelines if they are directly applicable in the Member State concerned.

Compliance with the provisions of Regulation (EU) 2019/6 in the event of reassignment of the substances referred to in Article 2, § 2, subparagraph 3, of the Law shall be demonstrated, with regard to the import and/or manufacture of active substances, by showing that those operations were carried out:

1. by a manufacturer of active substances registered with the FAMHP or with the competent authority of the Member State in which it is established in accordance with point (j) of Article 93(1)(j) of Regulation (EU) 2019/6; and
2. in accordance with good manufacturing practice for active substances, as referred to in Article 93(1)(j) of Regulation (EU) 2019/6 and adopted by the European Commission in accordance with Article 93(2) of that Regulation.

Chapter 2. Monographs, raw material authorisations and limited-use raw materials

Section 1. Monographs

Subsection 1. Approval of a new monograph

Article 3. In order to be approved in accordance with Article 7 of the Law, a monograph must meet the following criteria:

1. : the monograph contains the validated test methods and corresponding specifications necessary to ensure the quality of the raw material in question;

2. for that purpose, the monograph shall contain at least the elements laid down by the Minister, on the advice of the Pharmacopoeia Commission, according to the category of raw material concerned:

a) simple chemical substances;

b) compound chemical substances;

c) herbal drugs (whether or not intended for herbal teas) and herbal drug powders;

d) tinctures and fluid extracts;

e) dry extracts;

f) herbal drugs and herbal drug powders for homeopathic preparations;

g) mother tinctures for homeopathic preparations;

h) essential oils;

i) phages;

j) semi-solid bases;

k) liquid bases;

l) liquid bases for parenteral preparations;
m) flavourings;

3. the monograph reflects the current state of scientific and technical knowledge.

On the advice of the Pharmacopoeia Commission, the Minister may lay down additional criteria that a monograph must meet. Where appropriate, the Minister may lay down criteria according to the category of the raw material concerned.

Article 4. § 1. Any application for approval of a monograph, as referred to in Article 6, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Article 49, subparagraph 1, of the Law, the application must include the following information and documents:

1° 1. the category of raw material covered by the monograph;

2° the draft monograph;

3° the validation data for the relevant analytical methods;

4° if the raw material is a mixture of substances:

a) the analytical reference of each of the substances forming part of the mixture; if that reference is not one of the analytical references referred to in Article 11, § 1, subparagraph 2, points 1 to 3, of the Law, the draft monograph(s) for the substance(s) concerned;

b) the qualitative and quantitative composition of that mixture and the method of production of the mixture.

The Minister may lay down additional information, details or statements to be included in the application, according to the category of the raw material to which the monograph relates, in accordance with Article 3, point 2.

§ 2. A sufficient quantity of raw material, as referred to in Article 6, subparagraph 2, of the Law, corresponds to two samples taken from two different production batches. The quantity of each of these samples must be sufficient to enable each of the analyses prescribed by the monograph to be carried out three times, in accordance with the principles of good laboratory practice referred to in the Royal Decree of 6 March 2002 laying down the principles of good laboratory practice and the verification of their application for tests carried out on chemical substances. Each sample and each reference material shall be accompanied by the relevant test report or certificate of analysis.

The applicant shall ensure that samples and reference materials are sent to the FAMHP under conditions that ensure their proper preservation and integrity. The applicant shall also ensure that those samples and reference materials have a shelf life of at least one year from the date of their dispatch.

The applicant shall ensure that the samples and reference materials are submitted to the FAMHP no later than seven days after the submission of the application referred to in paragraph 1.

Article 5. The FAMHP shall notify the applicant(s), within 30 days from receipt of the application, whether their application for approval of a monograph contains all the elements referred to in Articles 3 and 4, § 1, paragraph 2, and, where applicable, paragraph 3, and § 2.

If the application does not contain all the elements referred to in Articles 3 and 4, § 1, paragraph 2, and, where applicable, subparagraph 3, and § 2, the FAMHP shall notify the applicant(s) thereof, specifying the missing or incorrect elements. Under penalty of inadmissibility, the applicant(s) shall have 90 days from the date of that notification to complete and/or correct their application.
The FAMHP shall notify the applicant(s) who have completed and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional elements and/or the correction to the application, whether it contains all the elements referred to in Articles 3 and 4, § 1, subparagraph 2, and, where applicable, subparagraph 3,and § 2. If the application still does not contain all the elements referred to in Articles 3 and 4, § 1, subparagraph 2, and, where applicable, subparagraph 3, and § 2, the FAMHP shall declare the application inadmissible.

Article 6. Within 30 days following notification to the applicant(s) that the application for approval of a monograph contains all the elements referred to in Articles 3 and 4, § 1, subparagraph 2, and, where applicable, subparagraph 3, and § 2, in accordance with Article 5, subparagraph 1 or 3, the FAMHP shall forward to a laboratory, in accordance with Article 6, subparagraph 2, of the Law, the monograph and the raw material produced in accordance with the monograph, where applicable accompanied by the reference material(s) necessary for its analysis.

The time limit referred to in Article 7, § 1, shall be suspended from the date on which the monograph and the raw material produced in accordance with the monograph, where applicable accompanied by the reference material(s) necessary for its analysis, are sent to the laboratory until the date on which the laboratory’s report is provided.

Article 7. § 1. The Pharmacopoeia Commission and the FAMHP shall each issue their opinion, in accordance with Article 7, subparagraph 1 of the Law, within 450 days of notification to the applicant(s) that the application contains all the elements referred to in Articles 3 and 4, § 1, subparagraph 2, and, where applicable, subparagraph 3, and § 2, in accordance with Article 5, subparagraph 1 or 3.

The opinions referred to in subparagraph 1 shall be based on the results of the experimental testing carried out by a laboratory in accordance with Article 6, subparagraph 2, of the Law.
§ 2. If the FAMHP and the Pharmacopoeia Commission deem it necessary, they shall, stating their reasons and at most twice, request the applicant(s) to supplement or amend the draft monograph or provide additional information. To that end, the Pharmacopoeia Commission shall validate the complete list of questions to be sent to the applicant(s).

If the FAMHP and the Pharmacopoeia Commission consider that a second experimental testing of the monograph will be necessary following the first supplementation or amendment of the draft monograph or the first submission of additional information, in accordance with subparagraph 1, they shall require the applicant(s), at the same time as the request referred to in subparagraph 1, to resubmit to the FAMHP a sufficient quantity of the raw material produced in accordance with the monograph and, where applicable, the reference material(s) necessary for its analysis. Article 4, § 2, subparagraphs 1 and 2 shall apply. The applicant(s) shall ensure that the samples and reference materials are submitted to the FAMHP no later than 7 days after submission of the amended or supplemented draft monograph.

At the request of the applicant(s) or if the FAMHP and the Pharmacopoeia Commission consider that the applicant(s)' arguments require detailed explanation, they shall invite the applicant(s) to present their arguments in writing or orally.

Where use is made of the option referred to in subparagraph 1, and, where applicable, in subparagraph 2, the time limit referred to in paragraph 1, subparagraph 1, shall be suspended, in addition to any suspension referred to in subparagraph 5, from the date of the request for supplementation or amendment of the draft monograph or supplementary elements until the date on which all those elements are provided, including the requested samples and reference materials. The duration of this period, or of the two periods in the case of two requests for supplementation or amendment of the draft monograph or supplementary elements, shall not exceed 180 days, except in exceptional cases for which detailed reasons are given by the applicant(s) and accepted by the FAMHP.

Where the option referred to in subparagraph 3 is exercised, the time limit referred to in paragraph 1, subparagraph 1, shall be suspended, in addition to any suspension referred to in subparagraph 4, from the date of the invitation to the applicant(s) to present their arguments until the date on which those arguments are received, for a maximum period of 90 days, except in exceptional cases for which detailed reasons are given by the applicant(s) and accepted by the FAMHP.

§ 3. If the applicant(s) have still not supplemented or amended the draft monograph in a satisfactory manner or have still not provided a satisfactory response to the questions asked after two requests within the time limits referred to in paragraph 2, subparagraphs 4 and/or 5, the Pharmacopoeia Commission and the FAMHP shall issue an unfavourable opinion. The Pharmacopoeia Commission and the FAMHP shall also issue an unfavourable opinion if the applicant(s) do not submit the requested samples in accordance with paragraph 2, subparagraph 2, within the applicable deadline.

§ 4. The FAMHP shall forward the opinion of the Pharmacopoeia Commission and its own opinion to the Minister or the Minister's delegate within 10 days of their issue.

Article 8. The Minister or the Minister's delegate shall approve the monograph or refuse its approval, in accordance with Article 7, subparagraph 1 of the Law, within 20 days of receipt of the opinion of the Pharmacopoeia Commission and that of the FAMHP, in accordance with Article 7, § 4.

Subsection 2. Amendment of an approved monograph

Article 9. § 1. Any request for a substantive amendment to a monograph, as referred to in Article 8(1) of the Law, must be submitted electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Article 49, subparagraph 1, of the Law, the request must include the following elements:

1. the draft amended version of the approved monograph, together with a version of the draft clearly indicating each amendment made;

2. the justification for each amendment;

3. the validation data for the relevant analytical methods;

4. if the raw material is a mixture of substances:

a) the updated draft monograph(s) for the substances forming part of the mixture, together with, where applicable, a version of the documents clearly indicating each amendment made;

b) the modified qualitative and quantitative composition of that mixture, the updated production method for the mixture and, where applicable, a version of the documents clearly indicating each change made.

The Minister may lay down additional information, details or statements to be included in the application, according to the category of the raw material to which the monograph relates, in accordance with Article 3, point 2.

§ 2. In order to be approved in accordance with Article 8, subparagraph 2, of the Law, a request for a substantive amendment to an approved monograph must ensure that the monograph continues to meet the criteria set out in Article 3.

§ 3. The FAMHP shall notify the holder(s) of the monograph, within 30 days from receipt of the application, whether their application for a substantive amendment to the approved monograph contains all the elements referred to in paragraph 1, subparagraph 2, and, where applicable, subparagraph 3. The FAMHP shall also inform the holder(s) of the monograph whether the application for a substantive amendment requires experimental testing by a laboratory.

If the application does not contain all the elements referred to in paragraph 1, subparagraph 2, and, where applicable, subparagraph 3, the FAMHP shall notify the holder(s) of the monograph, specifying the missing or incorrect elements. Under penalty of inadmissibility, the holder(s) of the monograph shall have 90 days from the date of that notification to complete and/or correct their application and/or submit a sufficient quantity of the raw material produced in accordance with the monograph and the reference material(s) necessary for its analysis. In this case, Article 4, § 2 applies.

The FAMHP shall notify the holder(s) of the monograph who have completed and/or corrected their application and/or submitted samples in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application and/or the samples, whether it contains all the elements referred to in paragraph 1, subparagraph 2, and, where applicable, subparagraph 3, and/or whether the samples have been submitted in accordance with subparagraph 2. If the application still does not contain all the elements referred to in paragraph 1, subparagraph 2, and, where applicable, subparagraph 3, the FAMHP shall declare it inadmissible. The application shall also be declared inadmissible if the holder(s) of the monograph do not submit the samples requested in accordance with subparagraph 2.

Article 10. § 1. The Pharmacopoeia Commission and the FAMHP shall each give their opinion, in accordance with Article 8, subparagraph 2, of the Law, within 450 days of notification to the holder(s) that the application for a substantive amendment of the approved monograph contains all the elements referred to in Article 9, § 1, subparagraph 2, and, where applicable, subparagraph 3, in accordance with Article 9, § 3, subparagraph 1 or 3.

Where the application for a substantive amendment involves experimental testing by a laboratory, in accordance with Article 9, § 3, subparagraph 1, the opinions referred to in subparagraph 1 shall be based on the results of the experimental check carried out by that laboratory.

§ 2. Where the application for a substantive amendment involves experimental testing by a laboratory, in accordance with Article 9, § 3, subparagraph 1, the FAMHP shall submit to a laboratory for testing, in accordance with Article 6, subparagraph 2, of the Law, the amended monograph and the raw material produced in accordance with the amended monograph, where applicable accompanied by the reference material(s) necessary for its analysis, within 30 days following notification to the holder(s) of the monograph that the application to amend an approved monograph contains all the elements referred to in Article 9, § 1, subparagraph 2, and, where applicable, subparagraph 3, in accordance with Article 9, § 3, subparagraph 1 or 3.

The time limit referred to in paragraph 1 shall be suspended from the date on which the amended monograph and the raw material produced in accordance with the amended monograph, where applicable, together with the reference material(s) necessary for its analysis, are sent to the laboratory until the date on which the laboratory's report is provided.

Article 7, §§ 2 to 4, applies to applications for a substantive amendment where that application involves experimental testing by a laboratory, in accordance with Article 9, § 3, subparagraph 1.

Article 7, § 2, subparagraphs 1 and 3 to 5, §§ 3 and 4, shall apply to the application for a substantive amendment in the event that the application for a substantive amendment does not involve any experimental testing by a laboratory, in accordance with Article 9, § 3, subparagraph 1.

§ 4. The Minister or the Minister's delegate shall approve the amended monograph or refuse its approval, in accordance with Article 8, subparagraph 2, of the Law, within 20 days of receipt of the opinion of the Pharmacopoeia Commission and that of the

FAMHP, in accordance with Article 7, § 4.

Article 11. § 1. Any request for editorial amendments to an approved monograph, as referred to in Article 8, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.

The request shall include, in addition to the personal data referred to in Article 49, subparagraph 1, of the Law:

1. the amended draft monograph, together with a version of the draft clearly indicating each change made;

2. if the raw material is a mixture of substances:

a) the updated draft monograph(s) for the substances forming part of the mixture, together with, where applicable, a version of the documents clearly indicating each change made;

b) the modified qualitative and quantitative composition of that mixture, the updated production method for the mixture and, where applicable, a version of the documents clearly indicating each change made.

The Minister may lay down additional information, details or statements to be included in the application, according to the category of the raw material to which the monograph relates, in accordance with Article 3, point 2.

§ 2. In order to be approved in accordance with Article 8, subparagraph 2, of the Law, a request for editorial change to an approved monograph must ensure that the monograph continues to meet the criteria set out in Article 3.

§ 3. The FAMHP shall confirm to the holder(s) of the monograph that their request to amend the approved monograph is of an editorial nature. If the FAMHP considers that the changes made constitute a substantive amendment to the approved monograph, it shall declare the application inadmissible within 30 days from receipt of the application.

§ 4. The FAMHP shall notify the holder(s) of the monograph, within 30 days from receipt of the request, whether their request for an editorial change to the approved monograph contains all the elements referred to in paragraph 1, subparagraph 2 and, where applicable, subparagraph 3.

If the application does not contain all the elements referred to in paragraph 1, subparagraph 2, and, where applicable, subparagraph 3, the FAMHP shall notify the holder(s) of the monograph, specifying the missing or incorrect elements. Under penalty of inadmissibility, the holder(s) of the monograph shall have 90 days from the date of that notification to supplement and/or correct their application to amend the approved monograph.

The FAMHP shall notify the holder(s) of the monograph who have supplemented and/or corrected their application to amend the approved monograph in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the

correction to the application, whether it contains all the elements referred to in Article 3 and paragraph 1, subparagraph 2 and, where applicable, subparagraph 3. If the application still does not contain all the elements referred to in Article 3 and paragraph 1, subparagraph 2, and, where applicable, subparagraph 3, the FAMHP shall declare it inadmissible.

§ 5. The Pharmacopoeia Commission and the FAMHP shall each issue their opinion, in accordance with Article 8, subparagraph 2, of the Law, within 30 days of notification to the holder(s) that the request for an editorial change to the approved monograph contains all the elements referred to in Article 3 and paragraph 1, subparagraph 2, and, where applicable, subparagraph 3, in accordance with paragraph 4, subparagraph 1 or 3.

The FAMHP shall forward the opinion of the Pharmacopoeia Commission and its own opinion to the Minister or the Minister's delegate within 10 days of their issue.

§ 6. The Minister or the Minister's delegate shall approve the amended monograph or refuse its approval, in accordance with Article 8, subparagraph 2, of the Law, within 20 days of receipt of the opinion of the Pharmacopoeia Commission and that of the FAMHP, in accordance with paragraph 5, subparagraph 2.

Subsection 3. Approval of the report on the five-year reasoned assessment of the monograph

Article 12. Any application for approval of the report on the reasoned assessment of the monograph, as referred to in Article 9, subparagraph 1, of the Law, must be submitted using the form published on the FAMHP website.

In addition to the personal data referred to in Article 49, subparagraph 1, of the Law, the application must include the detailed report on the assessment of the monograph. This assessment shall consist of verification of the compliance of the monograph with the criteria referred to in Article 3. It refers to any analytical method included in the monograph, as well as any analytical method that may be missing, on the basis of the approval criteria referred to in Article 3.

Article 13. The FAMHP shall notify the holder(s) of the approved monograph, within 30 days from receipt of the application, whether their application for approval of the report on the reasoned assessment of the monograph contains all the elements referred to in Article 12, subparagraph 2.

If the application does not contain all the elements referred to in Article 12, subparagraph 2, the FAMHP shall notify the holder(s) of the approved monograph, specifying the missing or incorrect elements. Under penalty of inadmissibility, the holder(s) shall have 30 days from the date of that notification to supplement and/or correct their application.

The FAMHP shall notify the holder(s) of the monograph who have completed and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it contains all the elements referred to in Article 12, subparagraph 2. If the application still does not contain all the elements referred to in Article 12, subparagraph 2, the FAMHP shall declare

it inadmissible.

Article 14. § 1. If the FAMHP deems an opinion of the Pharmacopoeia Commission to be unnecessary, it shall carry out the assessment of the application for approval of the report on the reasoned assessment of the monograph, in accordance with Article 9, subparagraph 2, of the Law, within 120 days of notification to the holder(s) of the monograph that the application is complete and correct, in accordance with Article 13, subparagraph 1 or 3.

§ 2. If the FAMHP deems an opinion of the Pharmacopoeia Commission to be necessary, it shall carry out the assessment of the application for approval of the report on the reasoned assessment of the monograph and the Pharmacopoeia Commission shall issue its opinion, in accordance with Article 9, subparagraph 2, of the Law, within 240 days of notification to the holder(s) of the monograph that the application is complete and correct, in accordance with Article 13, subparagraph 1 or 3.

§ 3. If the FAMHP and, where applicable, the Pharmacopoeia Commission deem it necessary, they shall, stating their reasons and at most once, require the holder(s) of the monograph to supplement or amend the draft report on the reasoned assessment of the monograph or provide additional information. When the Pharmacopoeia Commission issues its opinion in accordance with paragraph 2, it shall validate the complete list of questions to be sent to the holder(s) of the monograph.

At the request of the applicant(s) or if the FAMHP and, where applicable, the Pharmacopoeia Commission consider that the applicant(s)' arguments require detailed explanation, they shall invite the applicant(s) to present their arguments in writing or orally.

Where the option referred to in subparagraph 1 is exercised, the time limit referred to in paragraph 1 or 2 shall be suspended, in addition to any suspension referred to in subparagraph 4, from the date of the request for supplementation or amendment of the draft report on the reasoned assessment of the monograph or for additional information until the date on which those elements are provided. This period shall not exceed 180 days, except in exceptional cases for which detailed reasons are given by the applicant(s) and accepted by the FAMHP.

Where the option referred to in subparagraph 2 is exercised, the time limit referred to in paragraph 1 or 2 shall be suspended, in addition to any suspension referred to in subparagraph 3, from the date of the invitation to the applicant(s) to present their arguments until the date on which those arguments are received, for a maximum period of 90 days, except in exceptional cases for which detailed reasons are given by the applicant(s) and accepted by the FAMHP.

Article 15. The FAMHP shall approve or refuse to approve the reasoned assessment report in accordance with Article 9, subparagraph 2, of the Law within 30 days following the FAMHP assessment referred to in Article 14, § 1 or 2, and, where applicable, the opinion of the Pharmacopoeia Commission referred to in Article 14, § 2.

Subsection 3. Suspension or withdrawal of approval of a monograph

Article 16. § 1. The holder(s) of the monograph shall submit their written comments to the Minister or the Minister's delegate in accordance with Article 10, § 1, subparagraph 3, of the Law within 30 days from receipt of the proposed decision.

The Minister or the Minister's delegate shall either confirm or reverse the decision to suspend or withdraw approval of the monograph concerned in accordance with Article 10, § 1, subparagraph 5, of the Law, within 60 days of receipt of the comments from the holder(s) of the monograph.

§ 2. The Minister or the Minister's delegate shall withdraw approval of the monograph in accordance with Article 10, § 2, of the Law within 10 days of receiving a request from its holder(s).

Section 2. Raw material authorisation

Subsection 1. Official pharmacopoeias reflecting the current state of scientific and technical knowledge

Article 17. The official pharmacopoeias corresponding to the current state of scientific and technical knowledge, referred to in Article 11, § 1, subparagraph 1, point 2, of the Law, are as follows:

1. the British Pharmacopoeia;
2. the Deutsches Arzneibuch;
3. the Deutsches Homöopathisches Arzneibuch (HAB);
4. the French national pharmacopoeia;
5. the Swiss Pharmacopoeia;
6. the Farmacopea ufficiale della Repubblica italiana;
7. the Japanese Pharmacopoeia;
8. the Österreichisches Arzneibuch;
9. the United States Pharmacopeia.

Subsection 2. Authorisation of a raw material

Article 18. Any application for authorisation of a raw material, as referred to in Article 12, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.
In addition to the personal data referred to in Article 49, subparagraph 1, of the Law, the application for authorisation must include the following elements:

1. the name of the raw material in accordance with the analytical reference and, if the analytical reference is a monograph referred to in Article 11, § 1, point 4, of the Law and the raw material is a mixture of substances, also the names of the substances of which it is composed, in accordance with the names given in their analytical references;
2. the name of the pharmacopoeia referred to in Article 11, § 1, points 1 to 3, of the Law or of the monograph referred to in Article 11, § 1, point 4, of the Law, specified as the analytical reference;
3. the storage conditions as described in the analytical reference, unless the applicant can demonstrate, by means of stability data, that the alternative storage conditions ensure preservation equivalent to that provided by the analytical reference during the proposed validity period;

4. the labelling requirements as described in the analytical reference;

5. the validity period of the raw material;
6. the pack sizes envisaged;

7. the declaration that the labelling of the raw material will comply with the requirements of Article 79, subparagraphs 2 to 6;

8. the applicant's declaration that the applicant holds the following declarations:

    a) if the raw material is an active substance, a declaration signed by each producer stating that the analytical reference according to which the active substance will be analysed is appropriate in relation to the relevant production method(s) of the active substance and that the producer(s) hold the necessary documentation to support that declaration, namely:

    i. a certificate of compliance with the relevant monograph of the European Pharmacopoeia (CEP) issued by the EDQM; or

    ii. a declaration that the raw material is a substance referred to in Article 1, § 1, point 2, 2bis or 2ter, of the Law on medicinal products, which forms part of the composition of a medicinal product authorised in the European Union and was intended, from the time of its production, for the manufacture of medicinal products referred to in Article 1, § 1, point 1, of that Law, or a substance referred to in Article 4, points 2 to 4, of Regulation (EU) 2019/6, which forms part of the composition of a medicinal product authorised in the European Union and was intended, from the time of its production, for the manufacture of medicinal products referred to in Article 1, point 1, of that Regulation and which is supported by an active substance master file (ASMF), as referred to in Annex I, Part I, III, 3.2(8), of the Royal Decree of 14 December 2006 on medicinal products for human use or in the national provisions transposing Annex I, Part I, 3.2(8), of Directive 2001/83/EC, assessed and approved, by Module 3 of an application dossier for a marketing authorisation for a medicinal product for human use, as referred to in Annex I, Part I, of the Royal Decree of 14 December 2006 on medicinal products for human use or in the national provisions transposing Annex I, Part I, of Directive 2001/83/EC, assessed and approved, or by a second part of the application dossier for a marketing authorisation for a veterinary medicinal product, as referred to in Annex II to Regulation (EU) 2019/6, assessed and approved;

b) the declaration signed by each producer that the raw material complies with the general monograph 'Substances for pharmaceutical use' of the European Pharmacopoeia, where this general monograph applies to the raw material concerned;

9. the applicant's declaration that the applicant holds the following documents:

a) if the raw material is an active substance and the applicant does not hold a

declaration signed by the producer(s) concerned, as referred to in point 8(a), a file of its own drawn up on the basis of the information provided by the producer(s), in accordance with Module 3 of a marketing authorisation application dossier for a medicinal product for human use, as referred to in Annex I, Part I, to the Royal Decree of 14 December 2006 on medicinal products for human use or in the national provisions transposing Annex I, Part I, to Directive 2001/83/EC, or in accordance with a second part of the marketing authorisation application dossier for a veterinary medicinal product, as referred to in Annex II to Regulation (EU) 2019/6, demonstrating that the analytical reference according to which the active substance will be analysed is appropriate in relation to the relevant production method(s) of the active substance;

b) if the raw material is an active substance or a compound excipient, the stability data justifying the validity period;

10. the name(s) and address(es), if a natural person, or the business number assigned in accordance with Article III.22 of the Economic Law Code or the registration number in the register referred to in the national provisions transposing Article 16 of Directive (EU) 2017/1132 of the European Parliament and of the Council of 14 June 2017 on certain aspects of company law, if a legal person, of the producer(s) of the substance and, in the case of a mixture of substances, of the producer(s) of the substances forming part of the mixture;

11. where applicable, the name(s) and address(es), if a natural person, or the business number assigned in accordance with Article III.22 of the Economic Law Code or the registration number in the register referred to in the national provisions transposing Article 16 of Directive (EU) No 2017/1132 of the European Parliament and of the Council of 14 June 2017 on certain aspects of company law, if a legal person, of the manufacturer(s) to which manufacturing activities are subcontracted;

12. the name(s) and address(es), if a natural person, or the business number assigned in accordance with Article III.22 of the Economic Law Code or the registration number in the register referred to in the national provisions transposing Article 16 of Directive (EU) No 2017/1132 of the European Parliament and of the Council of 14 June 2017 on certain aspects of company law, if a legal person, of the primary distributor(s).

The information referred to in subparagraph 2, points 1, 3 and 4, shall be submitted in the three national languages.
If the application is submitted in accordance with Article 11, § 2, of the Law, it must also include a reasoned request for a derogation, setting out the public health grounds justifying that derogation.

Article 19. The FAMHP shall notify the applicant, within 30 days from receipt of the application, whether the application for authorisation of a raw material contains all the elements referred to in Article 18, subparagraph 2 and, where applicable, subparagraph 4.

If the application does not contain all the elements referred to in Article 18, subparagraph 2 and, where applicable, subparagraph 4, the FAMHP shall notify the applicant, specifying the missing or incorrect elements. Under penalty of inadmissibility, the applicant shall have

30 days from the date of that notification to complete and/or correct their application.
The FAMHP shall notify the applicant who has supplemented and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it contains all the elements referred to in Article 18, subparagraph 2 and, where applicable, subparagraph 4. If the application still does not contain all the elements referred to in Article 18, subparagraph 2 and, where applicable, subparagraph 4, the FAMHP shall declare it inadmissible.

Article 20. § 1. Where the application for authorisation of a raw material is submitted in accordance with Article 11, § 1, of the Law, the FAMHP shall carry out the assessment of the application for authorisation of a raw material, in accordance with Article 13, subparagraph 1, of the Law, within 60 days of notification to the applicant that the application contains all the elements referred to in Article 18, subparagraph 2, in accordance with Article 19, subparagraph 1 or 3.

§ 2. If the FAMHP deems it necessary, it shall, stating its reasons and at most once, require the applicant to supplement or amend the application for authorisation of a raw material or provide additional information.

Where the option referred to in subparagraph 1 is exercised, the time limit referred to in paragraph 1 shall be suspended from the date of the request for supplementation or amendment of the application for authorisation or for additional information until the date on which those elements are provided. This period shall not exceed 180 days, except in exceptional cases for which detailed reasons are given by the applicant and accepted by the FAMHP.

If the applicant has still not supplemented or amended the application for authorisation of a raw material in a satisfactory manner or has still not provided a satisfactory response to the questions raised within the time limit referred to in subparagraph 2, the FAMHP shall issue an unfavourable assessment.

§ 3. The FAMHP shall forward its assessment to the Minister or the Minister’s delegate within 10 days of its completion.

Article 21. § 1. Where the application for authorisation of a raw material is submitted in accordance with Article 11, § 2, of the Law, the FAMHP shall assess the elements referred to in Article 18, subparagraph 4, of the application, and the Commission for Medicinal Products for Human Use shall issue its opinion on those elements, in accordance with Article 13, subparagraph 2, of the Law, within 180 days of notification to the applicant that the application contains all the elements referred to in Article 18, subparagraphs 2 and 4, in accordance with Article 19, subparagraph 1 or 3.

§ 2. If the FAMHP and the Commission for Medicinal Products for Human Use deem it necessary, they shall, stating their reasons and at most once, require the applicant to supplement or amend the elements referred to in Article 18, subparagraph 4, of the applicant’s application or to provide additional information. To that end, the Commission for Medicinal Products for Human Use shall validate the complete list of questions to be sent to the applicant.

At the applicant's request or if the FAMHP and the Commission for Medicinal Products for Human Use consider that the applicant's arguments require detailed explanation, they shall invite the applicant to present their arguments in writing or orally.

Where the option referred to in subparagraph 1 is exercised, the time limit referred to in paragraph 1 shall be suspended, in addition to any suspension referred to in subparagraph 4, from the date of the request for supplementation or amendment of the reasoned application for a derogation or for additional information until the date on which those elements are provided. This period shall not exceed 180 days, except in exceptional cases for which detailed reasons are given by the applicant and accepted by the FAMHP.

Where the option referred to in subparagraph 2 is exercised, the time limit referred to in paragraph 1 shall be suspended, in addition to any suspension referred to in subparagraph 3, from the date of the invitation to the applicant to present their arguments until the date on which those arguments are received, for a maximum period of 90 days, except in exceptional cases for which detailed reasons are given by the applicant and accepted by the FAMHP.

If the applicant has still not supplemented or amended the elements referred to in Article 18, subparagraph 4, of the application in a satisfactory manner or has still not provided a satisfactory response to the questions raised within the time limit(s) referred to in subparagraph(s) 3 and/or 4, the FAMHP shall issue an unfavourable assessment and the Commission for Medicinal Products for Human Use shall issue an unfavourable opinion.

§ 3. If the FAMHP issues an unfavourable assessment and/or the Commission for Medicinal Products for Human Use issues an unfavourable opinion on the elements referred to in Article 18, subparagraph 4, of the application, in accordance with paragraph 1 or paragraph 2, subparagraph 5, the FAMHP shall not carry out the assessment of the elements referred to in Article 18, subparagraph 2, of the application for authorisation of the raw material.

If the FAMHP issues a favourable assessment and if the Commission for Medicinal Products for Human Use issues a favourable opinion on the elements referred to in Article 18, subparagraph 4, of the application, in accordance with paragraph 1, the FAMHP shall carry out the assessment of the elements referred to in Article 18, subparagraph 2, of the application for authorisation of the raw material, in accordance with Article 13, subparagraph 2, of the Law, within 60 days of receipt of the favourable opinion of the Commission for Medicinal Products for Human Use. Article 20, § 2, shall apply.

§ 4. The FAMHP shall forward its assessment referred to in paragraph(s) 2 and/or 3 and the opinion of the Commission for Medicinal Products for Human Use to the Minister or the Minister's delegate within 10 days of their completion.

Article 22. The Minister or the Minister's delegate shall grant the raw material authorisation or refuse to grant it, in accordance with Article 13, subparagraph 1 or 2, of the Law, within 20 days of receipt of the FAMHP's assessment and, where applicable, the opinion of the Commission for Medicinal Products for Human Use, in accordance with Article 20, § 3, or Article 21, § 4.

Subsection 4. Amendment of a raw material authorisation

Article 23. The changes affecting the quality of the raw material, referred to in Article 14, subparagraph 1, point 3, of the Law, are changes other than the following:

1. change in the name or surname and/or first name and/or address of the holder of the authorisation;

2. change in the name or surname and/or first name and/or address of the producer(s), primary distributor(s) or subcontracting manufacturer(s);

3. removal of a producer(s), a primary distributor(s) or a subcontracting manufacturer(s).

Article 24. § 1. Any application to amend a raw material authorisation, submitted pursuant to Article 14, subparagraph 1, of the Law, and any application not to modify a raw material authorisation, submitted pursuant to Article 14, subparagraph 2, of the Law, shall be submitted electronically using the form published on the FAMHP website.

§ 2. Where the application to amend a raw material authorisation is submitted pursuant to Article 14, subparagraph 1, point 1 or 2, of the Law, or to Article 14, subparagraph 2, of the Law, the application shall be submitted no later than 90 days after publication of the new analytical reference or the updated analytical reference. If no new application is submitted, the procedure referred to in Article 17 of the Law shall be initiated.

Where an application to a raw material authorisation, submitted in accordance with Article 14, subparagraph 1, point 2, of the Law, concerns a change to a reference with a higher, but not the highest, level of authority, in accordance with Article 11, § 1, subparagraph 2, of the Law, and is refused by the Minister or the Minister's delegate, a new application shall be submitted pursuant to Article 14, subparagraph 1, point 2, of the Law, to modify the authorisation to the highest analytical reference no later than 90 days after the initial refusal. If no new application is submitted, the procedure referred to in Article 17 of the Law shall be initiated.

Where an application to amend a raw material authorisation, submitted in accordance with Article 14, subparagraph 2, of the Law, is refused by the Minister or the Minister's delegate, a new application shall be submitted pursuant to Article 14, subparagraph 1, point 2, of the Law, no later than 90 days after the refusal to grant the exception from modifying the raw material authorisation. If no new application is submitted, the procedure referred to in Article 17 of the Law shall be initiated.

§ 3. The content of the application to amend a raw material authorisation, submitted pursuant to Article 14, subparagraph 1, of the Law, shall comply with Article 18, subparagraphs 2 and 3, and shall contain a complete update clearly indicating each change made.

By way of derogation from subparagraph 1, the content of the application to amend a raw material authorisation, submitted pursuant to Article 14, subparagraph 1, point 2, of the Law, which concerns a change to an analytical reference with a higher, but not the highest, level of authority, in accordance with Article 11, § 1, subparagraph 2, of the Law, shall comply with Article 18, subparagraphs 2 to 4, and shall contain a complete update clearly indicating each change made.

The content of the application not to modify a raw material authorisation, submitted pursuant to Article 14, subparagraph 2, of the Law, shall be submitted in accordance with Article 18, subparagraph 4.

Article 25. Article 19 shall apply to any application to amend a raw material authorisation, submitted pursuant to Article 14, subparagraph 1, of the Law, or to any application not to modify a raw material authorisation, submitted pursuant to Article 14, subparagraph 2, of the Law.

Article 26. Article 20 shall apply to an application to amend a raw material authorisation:

1. where the application to amend the raw material authorisation has been submitted in accordance with Article 14, subparagraph 1, point 1 or 2, of the Law;

2. where the application to modify the raw material authorisation was submitted in accordance with Article 14, subparagraph 1, point 3, of the Law, and the FAMHP considers that an opinion of the Pharmacopoeia Commission is not necessary.

By way of derogation from subparagraph 1, point 1, and Article 20, § 1, the FAMHP shall carry out the assessment of the application to amend a raw material authorisation, submitted pursuant to Article 14, subparagraph 1, point 2, of the Law, which concerns a change to an analytical reference with a higher, but not the highest, level of authority, in accordance with Article 11, § 1, subparagraph 2, of the Law, within 180 days of notification to the holder of the raw material authorisation that the application contains all the elements referred to in Article 18, subparagraphs 2 and 4, in accordance with Article 19, subparagraph 1 or 3.

Article 27. § 1. Where the application to amend the raw material authorisation is submitted in accordance with Article 14, subparagraph 1, point 3, of the Law and the FAMHP deems an opinion of the Pharmacopoeia Commission to be necessary, it shall carry out the assessment of the application to amend the raw material authorisation and the Pharmacopoeia Commission shall issue its opinion, in accordance with Article 15, § 2, of the Law, within 300 days of notification to the holder of the raw material authorisation that the application contains all the elements referred to in Article 18, subparagraph 2, in accordance with Article 19, subparagraph 1 or 3, pursuant to Article 25.

§ 2. If the FAMHP and the Pharmacopoeia Commission deem it necessary, they shall, stating their reasons and at most once, require the holder of the raw material authorisation to supplement or amend the application to amend the authorisation or provide additional information. To that end, the Pharmacopoeia Commission shall validate the complete list of questions to be sent to the holder of the raw material authorisation.

At the request of the holder of the raw material authorisation or if the FAMHP and the Pharmacopoeia Commission consider that the holder's arguments require detailed explanation, they shall invite the holder to present their arguments in writing or orally.

Where the option referred to in subparagraph 1 is exercised, the time limit referred to in paragraph 1 shall be suspended, in addition to any suspension referred to in subparagraph 4, from the date of the request for supplementation or amendment of the application to amend the raw material authorisation or for additional information until the date on which those elements are provided. This period shall not exceed 180 days, except in exceptional cases for which detailed reasons are given by the holder of the raw material authorisation and accepted by the FAMHP.

Where the option referred to in subparagraph 2 is exercised, the time limit referred to in paragraph 1 shall be suspended, in addition to any suspension referred to in subparagraph 3, from the date of the invitation to the holder of the raw material authorisation to present their arguments until the date on which those arguments are received, for a maximum period of 90 days, except in exceptional cases for which detailed reasons are given by the holder of the raw material authorisation and accepted by the FAMHP.

If the holder of the raw material authorisation has still not supplemented or amended the application to amend the raw material authorisation in a satisfactory manner or has still not provided a satisfactory response to the questions raised within the time limit(s) referred to in subparagraph(s) 3 and/or 4, the FAMHP shall issue an unfavourable assessment and the Pharmacopoeia Commission shall issue an unfavourable opinion.

§ 3. The FAMHP shall forward its assessment and the opinion of the Pharmacopoeia Commission to the Minister or the Minister's delegate within 10 days of their completion.

Article 28. Article 21, §§ 1, 2 and 4 shall apply where the holder of the raw material authorisation has submitted an application not to modify the authorisation, in accordance with Article 14, subparagraph 2, of the Law.

Article 29. § 1. The Minister or the Minister's delegate shall grant the amendment of the raw material authorisation or refuse to grant it, in accordance with Article 15, § 1, of the Law, on the basis of the FAMHP assessment, in accordance with Article 20, § 3, pursuant to Article 26, point 1.

§ 2. The Minister or the Minister's delegate shall grant the amendment of the raw material authorisation or refuse to grant it, in accordance with Article 15, § 2, of the Law, within 20 days of receipt of the FAMHP assessment, in accordance with Article 20, § 3, pursuant to Article 26, point 2.

The Minister or the Minister's delegate shall grant the amendment of the raw material authorisation or refuse to grant it, in accordance with Article 15, § 2, of the Law, within 20 days of receipt of the FAMHP assessment and the opinion of the Pharmacopoeia Commission, in accordance with Article 24, § 3.

§ 3. The Minister or the Minister's delegate shall grant the exception from modifying a raw material authorisation, or refuse to grant that exception, in accordance with Article 15, § 3, subparagraph 1, of the Law, within 20 days of receipt of the FAMHP assessment and the opinion of the Commission for Medicinal Products for Human Use, in accordance with Article 21, § 4, pursuant to Article 28.

Article 30. § 1. The notification referred to in Article 16 of the Law shall be submitted electronically using the form published on the FAMHP website.

The holder of one or more raw material authorisations shall submit a single notification of changes to several elements of the same raw material authorisation or of several raw material authorisations.

§ 2. The notification shall specify the change(s) to be made, as referred to in Article 23, and shall contain an update clearly indicating each change made.

§ 3. The FAMHP shall notify the holder of the raw material authorisation, within 30 days from receipt of the notification, whether the notification referred to in this Article is complete and correct.

If the notification is incomplete or incorrect, the FAMHP shall notify the holder of the raw material authorisation, specifying the missing or incorrect elements. Under penalty of inadmissibility, the holder of the raw material authorisation shall have 30 days from the date of that notification to complete and/or correct the notification.

The FAMHP shall notify the holder of the raw material authorisation who has supplemented and/or corrected the notification in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the notification, whether it is complete and correct. If the notification is still incomplete or incorrect, the FAMHP shall declare it inadmissible.

§ 4. The Minister or the Minister's delegate shall grant the amendment of one or more raw material authorisations, in accordance with Article 16 of the Law, within 30 days of notification to the holder of the raw material authorisation that the application is complete and correct in accordance with paragraph 3, subparagraph 1 or 3, unless the FAMHP has indicated, stating reasons, that the notification could not be accepted.

Subsection 5. Suspension or withdrawal of a raw material authorisation

Article 31, § 1. The holder of the raw material authorisation shall submit their written comments to the Minister or the Minister's delegate in accordance with Article 17, § 2, subparagraph 2, of the Law within 30 days from receipt of the proposed decision.

The Minister or the Minister's delegate shall either confirm or reverse the decision to suspend or withdraw the raw material authorisation concerned in accordance with Article 17, § 2, subparagraph 4, of the Law, within 60 days of receipt of the comments from the holder of the raw material authorisation.

§ 2. The Minister or the Minister's delegate shall withdraw the raw material authorisation in accordance with Article 17, § 4, of the Law within 10 days of the request from its holder.

Section 3. Limited-use raw material status

Subsection 1. Granting of limited-use raw material status

Article 32. Any application for the granting of limited-use raw material status, as referred to in Article 19, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Article 49, subparagraph 1, of the Law, the application must include the following elements:

1. the name and address of the hospital(s) and/or centre(s) for which the hospital pharmacist(s) work;

2. the name of the raw material;

3. the proposed therapeutic indication(s) and their justification by a doctor specialising in the disease or condition from the hospital(s) and/or centre(s) concerned, based on scientific literature or any other relevant information on any existing method of diagnosis, prevention or treatment of the disease or condition;

4. the signed certificate from the specialist doctor referred to in point 3, stating that the raw material offers a significant benefit to patients suffering from the relevant disease or condition, and the discussion of this significant benefit, drawn up in accordance with the template set out in Annex 1, pursuant to Article 18, subparagraph 1, point 7, of the Law;

5. the elements demonstrating that the raw material meets the conditions of Article 18 of the Law;

6. the analytical reference on the basis of which the certificates of analysis are issued at the time of the application, and, if this is not an analytical reference referred to in Article 11, subparagraph 2, points 1 to 3, of the Law, a copy of that analytical reference, together with a certificate of analysis;

7. where applicable, an undertaking by the copyright holder(s) of the monograph that they agree to assign their copyright in the monograph to the FAMHP, in accordance with Article 19, subparagraph 3, of the Law, and the standard copyright assignment agreement drawn up by the FAMHP, duly completed;

8. the undertaking by the hospital pharmacist(s) to submit to the FAMHP a sufficient quantity of the raw material produced in accordance with the monograph, at the request of the FAMHP, in accordance with Article 42, § 1, subparagraph 1. Article 4, § 2, subparagraphs 1 and 2 shall apply.

By way of derogation from subparagraph 2, point 4, if one or more conditions referred to in Article 18, points 2 to 4, of the Law are not met, the application shall contain the justification that the raw material(s), its derivatives and/or the medicinal product(s) concerned are in practice inaccessible to the patients concerned due to an abnormally high cost.

Article 33. The FAMHP shall notify the applicant(s), within 30 days from receipt of the application, whether the application referred to in Article 18, subparagraph 1, of the Law is complete and correct.

If the application is incomplete or incorrect, the FAMHP shall notify the applicant(s), specifying the missing or incorrect elements. Under penalty of inadmissibility, the applicant(s) shall have 30 days from the date of that notification to complete and/or correct the application.
The FAMHP shall notify the applicant(s) who have supplemented and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it is complete and correct. If the application is still incomplete or incorrect, the FAMHP shall declare it inadmissible.

Article 34. The FAMHP shall carry out the assessment of the elements referred to in Article 32, subparagraph 2, of the application, in accordance with Article 19, subparagraph 3, of the Law, and the Commission for Medicinal Products for Human Use shall issue its opinion on these elements, in accordance with Article 19, subparagraph 3, of the Law, within 120 days of notification to the applicant that the application contains all the elements referred to in Article 32, subparagraph 2, in accordance with Article 33, subparagraph 1 or 3.

By way of derogation from subparagraph 1, if one or more conditions referred to in Article 18, points 2 to 4, of the Law are not met, the FAMHP shall carry out the assessment of the elements referred to in Article 32, subparagraphs 2 and 3, of the application, in accordance with Article 19, subparagraph 3, of the Law, and the Commission for Medicinal Products for Human Use shall issue its opinion on these elements, in accordance with Article 19, subparagraph 3, of the Law, within 180 days of notification to the applicant that the application contains all the elements referred to in Article 32, subparagraphs 2 and 3, in accordance with Article 33, subparagraph 1 or 3.

Article 35. § 1. If the FAMHP and the Commission for Medicinal Products for Human Use deem it necessary, they shall, stating their reasons and at most once, require the applicant(s) to supplement or amend the elements referred to in Article 32, subparagraph 2, of their application or to provide additional information. To that end, the Commission for

Medicinal Products for Human Use shall validate the complete list of questions to be sent to the applicant(s).

Where the option referred to in subparagraph 1 is exercised, the time limit referred to in Article 34, subparagraph 1, shall be suspended from the date of the request for supplementation or amendment of the application or for additional information until the date on which those elements are provided. This period shall not exceed 30 days, except in exceptional cases for which detailed reasons are given by the applicant and accepted by the FAMHP.

If the applicant(s) have still not supplemented or amended the elements referred to in Article 32, subparagraph 2, of their application in a satisfactory manner or have still not provided a satisfactory response to the questions asked within the time limit referred to in subparagraph 2, the FAMHP shall issue an unfavourable assessment and the Commission for Medicinal Products for Human Use shall issue an unfavourable opinion.

§ 2. The FAMHP shall forward its assessment and the opinion of the Commission for Medicinal Products for Human Use, as referred to in Article 34, to the Minister or the Minister's delegate within 10 days of their completion.

Article 36. The Minister or the Minister's delegate shall communicate the decision on granting limited-use raw material status to a raw material, in accordance with Article 20 of the Law, within 20 days from receipt by the Minister or the Minister's delegate of the FAMHP assessment and the opinion of the Commission for Medicinal Products for Human Use.

Article 37. The FAMHP shall publish on its website the references of any raw material for which the application referred to in Article 18, subparagraph 1, of the Law has been the subject of a notification that it is complete and correct in accordance with Article 33, subparagraph 1 or 3, without delay following that notification.

The FAMHP shall publish on its website the granting or refusal to grant limited-use raw material status to a raw material without delay following the decision referred to in Article 20 of the Law.

The FAMHP shall publish on its website the raw materials for which limited-use raw material status has expired, without delay after the expiry of that status.

Subsection 2. Renewal of limited-use raw material status

Article 38. No later than 240 days before the expiry of the five-year period for which limited-use raw material status was granted, the original applicant(s) for the status or any other hospital pharmacist referred to in Article 19, subparagraph 1, of the Law shall submit an application for renewal of limited-use raw material status electronically using the form

published on the FAMHP website.

The application shall contain an update of the elements referred to in Article 32, subparagraph 2.

Article 39. Articles 33, 34 and 35 shall apply to the application for renewal of limited-use raw material status.

Article 40. The FAMHP shall publish on its website the renewal or refusal to renew limited-use raw material status for a raw material without delay following the decision referred to in Article 21 of the Law.

Subsection 3. Drafting and publication of a minimum analytical reference

Article 41. A minimum analytical reference, as referred to in Article 22, § 3, subparagraph 1, of the Law, describes:

1. an identification of the limited-use raw material;

2. a determination of the content of the limited-use raw material.

Article 42. § 1. The FAMHP shall draw up no more than three minimum analytical references each year or ensure that they are drafted by a laboratory, in accordance with Article 22, § 3, subparagraph 1, of the Law. The minimum analytical references shall be drawn up in the chronological order in which limited-use raw material status was granted, provided that the FAMHP has received a sufficient quantity of the raw material, in accordance with Article 32, subparagraph 2, point 8, within 7 days following notification to the hospital pharmacist(s) that it is initiating the drafting procedure and, if the copyright holder(s) of the monograph have undertaken to assign their copyright in the monograph to the FAMHP in accordance with Article 32, subparagraph 2, point 7, provided that the transfer of the monograph concerned has indeed taken place within that same period.

The FAMHP shall forward the minimum analytical reference for opinion to the Pharmacopoeia Commission within 10 days of its finalisation.

§ 2. The Pharmacopoeia Commission shall verify whether the minimum analytical reference complies with Article 41 and shall formulate its opinion within a maximum of 210 days starting on the day of transmission for opinion of the minimum analytical reference, in accordance with paragraph 1, subparagraph 2.

If the Pharmacopoeia Commission deems it necessary, it shall, stating its reasons and at most once, require the minimum analytical reference to be amended or supplemented. The time limit referred to in subparagraph 1 shall be suspended from the date of the request for supplementation or amendment until the date of receipt of the supplemented or amended minimum analytical reference.

Article 43. The FAMHP shall publish the minimum analytical reference in the Belgian Pharmacopoeia, in accordance with Article 22, § 2, subparagraph 3, of the Law, within two weeks of receiving the Pharmacopoeia Commission's opinion.

Chapter 3. Provisions relating to the manufacturer

Section 1. Authorisation to manufacture raw materials

Subsection 1. Procedure for obtaining authorisation to manufacture raw materials

Article 44. Any application for authorisation to manufacture raw materials, as referred to in Article 24, § 1, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Articles 24, § 4, subparagraph 1, and 49, subparagraph 1, of the Law, the application must include the following elements:

1. the name of the raw materials to be manufactured or imported, their different pack sizes and, where applicable, their authorisation numbers;

2. the nature of the manufacturing or import operations;

3. the description and characteristics of the premises and equipment used in the manufacturing or import activity;

4. a site master file within the meaning of the detailed guidelines published by the European Commission in 'The rules governing medicinal products in the European Union', in accordance with the principles relating to good manufacturing practices for medicinal products laid down in Annex IV to the Royal Decree of 14 December 2006 on medicinal products for human use;

5. any other information demonstrating compliance with the requirements referred to in Article 25, § 1, of the Law.

Article 45. The FAMHP shall notify the applicant, within 30 days from receipt of the application, whether the application for authorisation to manufacture raw materials contains all the elements referred to in Article 44, subparagraph 2.

If the application does not contain all the elements referred to in Article 44, subparagraph 2, the FAMHP shall notify the applicant, specifying the missing and/or incorrect elements. Under penalty of inadmissibility, the applicant shall have 30 days from the date of that notification to complete or correct their application.

The FAMHP shall notify the applicant who has supplemented and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it contains all the

elements referred to in Article 44, subparagraph 2. If the application still does not contain all the elements referred to in Article 44, subparagraph 2, the FAMHP shall declare it inadmissible.

Article 46. The inspection referred to in Article 26, subparagraph 1, of the Law shall be carried out by one or more persons referred to in Article 14, § 1, of the Law on medicinal products. The Minister or the Minister's delegate shall appoint one of these persons to lead the investigation.

The person or persons referred to in subparagraph 1 may be accompanied by experts appointed for that purpose by the Minister or by the Minister's delegate.

In the course of the inspection, the applicant may be required to provide additional information concerning the information supplied in the application for authorisation. Where the person or persons referred to in subparagraph 1 avail themselves of that option, the time limit referred to in Article 47, subparagraph 1, shall be suspended until the required additional data are provided.

A report including reasoned conclusions shall be drawn up on the basis of the inspection. The report shall be notified to the Minister or the Minister's delegate, as well as to the applicant.

Article 47. The Minister or the Minister's delegate shall notify the applicant of the draft decision, where applicable taken on the basis of the report referred to in Article 46, subparagraph 4, within 90 days from confirmation that the application contains all the elements referred to in Article 44, subparagraph 2, pursuant to Article 45, subparagraph 1. A copy of the above-mentioned report is attached to the draft decision.

If the Minister or the Minister's delegate intends to refuse the authorisation, the applicant may present its arguments within 15 days of receiving the intended decision of the Minister or the Minister's delegate. Failing that, the decision shall become final on expiry of this period.

The Minister or the Minister's delegate shall take the decision within 90 days of receipt of the applicant's request.

Subsection 2. Procedure for modifying the authorisation to manufacture raw materials

Article 48. Any application to modify the authorisation to manufacture raw materials, as referred to in Article 28, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.
In addition to the personal data referred to in Article 49, subparagraph 1, and, where applicable, in Article 28, subparagraph 3, of the Law, the application must include the following elements:

1. the number of the authorisation to manufacture raw materials;

2. the elements of the authorisation for the manufacture of raw materials to be modified;

3. any other information demonstrating compliance with the requirements referred to in Article 24 of the Law.

Article 49. Articles 45 to 47 shall apply to the application to amend a manufacturing authorisation for raw materials.

Subsection 3. Suspension or withdrawal of the authorisation to manufacture raw materials

Article 50. The manufacturer may submit written comments to the Minister or the Minister's delegate in accordance with Article 30, § 1, subparagraph 3, of the Law, within 30 days from receipt of the proposed decision referred to in Article 30, § 1, subparagraph 2, of the Law.

If the manufacturer submits comments pursuant to Article 30, § 1, subparagraph 3, of the Law, the Minister or the Minister's delegate shall either confirm or reverse the decision to suspend or withdraw the authorisation to manufacture raw materials, in whole or in part, in accordance with Article 30, § 1, subparagraph 5, of the Law, within 60 days from receipt of the comments.

Article 51. Any application for withdrawal of the manufacturing authorisation, as referred to in Article 24, § 1, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.

The FAMHP may request information regarding the cessation of manufacturing and/or distribution activities and/or require the necessary measures to be taken to bring such activities to an end.

The Minister or the Minister's delegate shall withdraw the manufacturing authorisation, in accordance with Article 30, § 2, of the Law, within 15 days of the holder's request.

The time limit referred to in subparagraph 3 shall be suspended until the information referred to in subparagraph 2 has been received or until the measures necessary to bring the activity to an end have been taken.

Section 2. Recognition of authorisations to manufacture raw materials granted in another Member State or in a third country referred to in Article 25, § 1, subparagraph 2, of the Law, in accordance with Article 25, § 2, of the Law

Article 52. The holder of an authorisation to manufacture raw materials granted in another

Member State or in a third country referred to in Article 25, § 1, subparagraph 2, of the Law, insofar as the raw materials for which the holder seeks the manufacturing authorisation are among the products covered by the mutual recognition agreement, shall submit any application for recognition of that authorisation electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Articles 24, § 4, subparagraph 1, and 49, subparagraph 1, of the Law, the application must include the following elements:

1. a legalised translation into a national language or English of the manufacturing authorisation for which recognition is requested, duly signed and/or validated by the competent authorities of the Member State or third country concerned referred to in Article 25, § 1, subparagraph 2, of the Law;

2. the names of the raw materials to be manufactured or imported, their different pack sizes and, where applicable, their authorisation numbers;

3. the nature of the manufacturing or import operations;

4. the description and characteristics of the premises and equipment used in the manufacturing or import activity;

5. where the manufacturer is established in another Member State, the certificate of good manufacturing practices for active substances, as referred to in the national provisions transposing Article 111(5) of Directive 2001/83/EC or, where the manufacturer is established in a third country referred to in Article 25, § 1, subparagraph 2, of the Law, the certificate issued by the competent authorities certifying that the manufacturer complies with requirements applicable in that country that are equivalent to the good manufacturing practices for active substances referred to in Article 32, subparagraph 1, of the Law;

6. a legalised translation into a national language or English of the legislation applicable to the manufacture of raw materials in force in the Member State or third country referred to in Article 25, § 1, subparagraph 2, of the Law, where the manufacturer is established;

7. a legalised translation into a national language or English of the inspection report used to issue the valid certificate referred to in point 5 for the manufacturer whose authorisation is sought to be recognised;

8. any other information demonstrating compliance with the requirements referred to in Article 25, § 1, subparagraph 1, of the Law.

Article 53. The FAMHP shall notify the applicant, within 30 days from receipt of the application, whether the application for recognition of the authorisation to manufacture raw materials granted in another Member State or in a third country referred to in Article 25, § 1, subparagraph 2, of the Law, contains all the information and documents referred to in Article 52, subparagraph 2.

If the application does not contain all the information and documents referred to in Article 52, subparagraph 2, the FAMHP shall notify the applicant, specifying the missing and/or incorrect elements. Under penalty of inadmissibility, the applicant shall have 30 days from the date of that notification to complete or correct their application.

The FAMHP shall notify the applicant who has completed and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it contains all the information and documents referred to in Article 52, subparagraph 2. If the application still does not contain all the information and documents referred to in Article 52, subparagraph 2, the FAMHP shall declare it inadmissible.

Article 54. An assessment of the elements of the application shall be carried out by one or more persons referred to in Article 14, § 1, of the Law on medicinal products. The Minister or the Minister's delegate shall appoint one of these persons to lead this assessment.

The person or persons referred to in subparagraph 1 may be assisted by experts appointed for that purpose by the Minister or by the Minister's delegate.

As part of the assessment, the applicant may be required to provide additional information concerning the information provided in the application for recognition. Where the person or persons referred to in subparagraph 1 avail themselves of that option, the time limit referred to in Article 55 shall be suspended until the required additional data are provided.

A report including reasoned conclusions shall be drawn up on the basis of the assessment. This report shall conclude:

1. either that the manufacturer is not subject to provisions equivalent to those contained in the Law and its implementing decrees and that the authorisation to manufacture raw materials granted in another Member State cannot be recognised;

2. or that the manufacturer is subject to provisions equivalent to those contained in the Law and its implementing decrees and that the authorisation to manufacture granted in another Member State can be recognised.

The person referred to in subparagraph 1 shall communicate the report to the applicant. The applicant may present their arguments against the report within 15 days of receiving it.

The person(s) referred to in subparagraph 1 shall assess the arguments referred to in subparagraph 5 and draw up a final report. The final report shall be notified to the Minister or the Minister's delegate, as well as to the applicant.

Article 55. The Minister or the Minister's delegate shall grant or refuse recognition of the authorisation to manufacture raw materials granted in another Member State or in a third country referred to in Article 25, § 1, subparagraph 2, of the Law, within 90 days from confirmation that the application contains all the information and documents referred to in Article 52, subparagraph 2, in accordance with Article 53, subparagraph 1 or 3.

Article 56, § 1. If the Minister or the Minister's delegate finds that a manufacturer to which recognition of its authorisation to manufacture raw materials has been granted, in accordance with Article 55, is not complying with the provisions of the Law or its implementing decrees, the Minister or the Minister's delegate may prohibit that manufacturer from carrying out manufacturing activities in Belgium.

The Minister or the Minister's delegate shall notify the manufacturer of the proposed decision, unless immediate action is required to protect public health.

The manufacturer may submit written comments to the Minister or the Minister's delegate within 30 days from receipt of the proposed decision referred to in subparagraph 2.

In the absence of the comments referred to in subparagraph 3, the proposed decision shall become final.

If the manufacturer submits comments pursuant to subparagraph 3, the Minister or the Minister's delegate shall decide whether or not to suspend or withdraw the right to carry out manufacturing activities in Belgium, within 60 days from receipt of the comments.

§ 2. The Minister or the Minister's delegate shall withdraw without delay the right to carry out manufacturing activities in Belgium in the event of withdrawal of the certificate of good manufacturing practices for active substances, as referred to in the national provisions transposing Article 111, § 5, of Directive 2001/83/EC, or of suspension or withdrawal of the authorisation of the manufacturer established in another Member State.

The Minister or the Minister's delegate shall withdraw without delay the right to carry out manufacturing activities in Belgium in the event of withdrawal of the certificate issued by the competent authorities certifying that the manufacturer established in a third country referred to in Article 25, § 1, subparagraph 2, of the Law complies with requirements applicable in that country that are equivalent to the good manufacturing practices for active substances referred to in Article 32, subparagraph 1, of the Law, or in the event of suspension or withdrawal of its manufacturing authorisation.

Section 3. Obligations of the manufacturer

Article 57, § 1. Where the raw material manufactured or imported is an active substance, the manufacturer is required to:

1. to carry out, under the responsibility of the person(s) in charge of manufacturing, a full identification of every container in the same production batch that it imports or manufactures;

2. to carry out, under the responsibility of the person(s) in charge of manufacturing, for each production batch of an imported or manufactured raw material, the complete qualitative and quantitative analysis of a statistically representative number of samples, as well as all other tests or checks necessary to ensure the quality of the raw material;

3. to identify, under the responsibility of the person(s) in charge of manufacturing, a representative number of manufactured or imported packages.

The analyses referred to in subparagraph 1 shall be carried out in accordance with the analytical reference, referred to in Article 11, § 1, subparagraph 2, of the Law, on the basis of which the raw material authorisation is granted.

The analysis referred to in subparagraph 1, point 2, shall be distinct from that carried out by the producer of the bulk raw material and may under no circumstances be subcontracted to that producer.

The manufacturer may subcontract all or part of the analyses referred to in subparagraph 1 to a laboratory. This subcontracting arrangement is governed by a written contract that clearly sets out the respective obligations and responsibilities of each party. The manufacturer remains responsible for the subcontracted activities.

§ 2. Where the raw material manufactured or imported is an excipient, the manufacturer is required to:

1. to carry out, under the responsibility of the person(s) in charge of manufacturing, a full identification of every container in the same production batch that it imports or manufactures;

2. to demonstrate, under the responsibility of the person(s) in charge of manufacturing, that the raw material has been produced in compliance with the synthesis or production requirements necessary to apply the analytical reference included in the raw material authorisation; more specifically, where the analytical reference for the raw material is the European Pharmacopoeia, that the producer holds a certificate of compliance with the relevant monograph of the European Pharmacopoeia (CEP) issued by the EDQM;

3. to demonstrate under the responsibility of the person(s) in charge of manufacturing that the production batch of the raw material has undergone a full and complete analysis at least once since its production, carried out by the producer holding the CEP and a certificate of analysis for the production batch concerned;

4. where it is not possible to demonstrate compliance with the requirements set out in point 3, or where the analytical reference specified in the raw material authorisation is not the European Pharmacopoeia, to carry out, under the responsibility of the person(s) in charge of manufacturing, for each production batch of an imported or manufactured raw material, a complete qualitative and quantitative analysis of a statistically representative number of samples, as well as all other tests or checks necessary to ensure the quality of the raw material;

5. to identify, under the responsibility of the person(s) in charge of manufacturing, a representative number of manufactured or imported packages.

The analyses referred to in subparagraph 1 shall be carried out in accordance with the analytical reference, referred to in Article 11, § 1, subparagraph 2, of the Law, on the basis of which the raw material authorisation is granted.

The manufacturer may subcontract all or part of the analyses referred to in subparagraph 1 to a laboratory. This subcontracting arrangement is governed by a written contract that clearly sets out the respective obligations and responsibilities of each party. The manufacturer remains responsible for the subcontracted activities.

Article 58, § 1. The person(s) responsible for manufacturing referred to in Article 25, § 1, subparagraph 1, point 4, of the Law shall possess the necessary qualifications to perform their duties, in accordance with the good manufacturing practices for active substances referred to in Article 32, subparagraph 1, of the Law and the detailed guidelines published by the European Commission in 'The rules governing medicinal products in the European Union'.

The manufacturer shall organise itself in such a way that the contact person referred to in Article 24, § 4, subparagraph 1, of the Law can be contacted without delay.
§ 2. The premises referred to in Article 25, § 1, subparagraph 1, point 6, of the Law shall comply with the good manufacturing practices for active substances referred to in Article 32, subparagraph 1, of the Law or with Commission Implementing Regulation (EU) 2025/2154 of 17 October 2025 laying down good manufacturing practices for active substances used as raw materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council, if the raw material is intended solely for a preparation for veterinary use.

Article 59. The person responsible for manufacturing shall certify on release that each batch of raw material:

1. has been manufactured and tested in accordance with the requirements of the Law and its implementing decrees or, if the manufacturer is established in another Member State or in a third country referred to in Article 25, § 1, subparagraph 2, of the Law, in accordance with the requirements applicable in that Member State or third country;

2. is placed on the market in accordance with the requirements of the Law and its implementing decrees.

Article 60. The manufacturer established in another Member State shall inform the FAMHP without delay of the renewal or withdrawal by the competent authority of its certificate of good manufacturing practices for active substances, as referred to in the national provisions transposing Article 111(5) of Directive 2001/83/EC and, where applicable, of the renewal, amendment or withdrawal of its manufacturing authorisation.

The manufacturer established in a third country referred to in Article 25, § 1, subparagraph 2, of the Law shall inform the FAMHP without delay of the renewal or withdrawal by the competent authority of its certificate issued by the competent authorities certifying that it complies with requirements applicable in that country that are equivalent to the good manufacturing practices for active substances referred to in Article 32, subparagraph 1, of the Law and, where applicable, of the renewal, amendment or withdrawal of its manufacturing authorisation.

Article 61. The manufacturer shall make its premises accessible at all times to the persons referred to in Article 14, § 1, of the Law on medicinal products.

Chapter 4. Provisions relating to the distributor

Section 1. Authorisations to distribute raw materials
Subsection 1. Procedure for obtaining authorisation to distribute raw materials

Article 62. Any application for authorisation to distribute raw materials, as referred to in Article 36, § 1, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.
In addition to the personal data referred to in Articles 36, § 4, subparagraph 1, and 49, subparagraph 1, of the Law, the application must include the following elements:

1. the specifications of the raw materials that the distributor wishes to distribute:

    a. the names of the raw materials, their analytical reference, their different pack sizes and, where applicable, their authorisation numbers;

    b. the number of the authorisation to manufacture raw materials of the manufacturer(s) of the raw materials;

2. the nature of the distribution operations envisaged;

3. the description and characteristics of the premises and equipment used in the applicant's activity;
4.
5. the attestation(s) and/or certificate(s) issued by the competent authorities certifying that it complies with the principles and guidelines on good distribution practices for medicinal products, as referred to in Article 12ter, § 1, subparagraph 20, of the Law on medicinal products or in the national provisions transposing Article 111(5) of Directive 2001/83/EC;

6. any other information demonstrating compliance with the requirements referred to in Article 37, § 1, of the Law.

Article 63. The FAMHP shall notify the applicant, within 30 days from receipt of the application, whether the application for authorisation to distribute raw materials contains all the information and documents referred to in Article 62, subparagraph 2.

If the application does not contain all the information and documents referred to in Article 62, subparagraph 2, the FAMHP shall notify the applicant, specifying the missing or incorrect elements. Under penalty of inadmissibility, the applicant shall have 30 days from the date of that notification to complete and/or correct their application.

The FAMHP shall notify the applicant who has supplemented and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it contains all the information and documents referred to in Article 62, subparagraph 2. If the application still does not contain all the information and documents referred to in Article 62, subparagraph 2, the FAMHP shall declare it inadmissible.

Article 64. The inspection referred to in Article 38, subparagraph 1, of the Law shall be carried out by one or more persons referred to in Article 14, § 1, of the Law on medicinal products. The Minister or the Minister's delegate shall appoint one of these persons to lead the investigation.

The person or persons referred to in subparagraph 1 may be accompanied by experts appointed for that purpose by the Minister or by the Minister's delegate.

In the course of the inspection, the applicant may be required to provide additional information concerning the information supplied in the application for authorisation. Where the person or persons referred to in subparagraph 1 avail themselves of that option, the time limit referred to in Article 65, subparagraph 1, shall be suspended until the required additional data are provided.

A report including reasoned conclusions shall be drawn up on the basis of the inspection. The report shall be notified to the Minister or the Minister's delegate and to the applicant.

Article 65. The Minister or the Minister's delegate shall communicate the draft decision to the applicant, where applicable taken on the basis of the report referred to in Article 64, subparagraph 4, within 90 days from confirmation that the application contains all the information and documents referred to in Article 61, subparagraph 2, pursuant to Article 63, subparagraph 1 or 3. A copy of the report is attached to the decision.

If the Minister or the Minister's delegate intends to refuse the authorisation, the applicant may present its arguments within 15 days of receiving the intended decision of the Minister or the Minister's delegate. Failing that, the decision shall become final on expiry of this period.

The Minister or the Minister's delegate shall take the decision on the basis of the opinion of the FAMHP within 90 days of receipt of the applicant's request.

Subsection 2. Procedure for amending the authorisation to distribute raw materials

Article 66. Any request for amendment of the authorisation for the distribution of raw materials, as referred to in Article 39, paragraph 1, of the Law, shall be submitted electronically, using the form published on the website of the FAMHP.

The application shall include the following elements:

1. the number of the authorisation to distribute raw materials;

2. the elements of the authorisation to distribute raw materials to be modified;

3. any other information demonstrating compliance with the requirements referred to in Article 37, § 1, of the Law.

Article 67. Articles 63 to 65 shall apply to an application to modify an authorisation to distribute raw materials.

Subsection 3. Suspension or withdrawal of the authorisation to distribute raw materials

Article 68. The distributor may submit written comments to the Minister or the Minister's delegate in accordance with Article 41, § 1, subparagraph 3, of the Law, within 30 days from receipt of the proposed decision referred to in Article 41, § 1, subparagraph 2, of the Law.

If the distributor submits comments pursuant to Article 41, § 1, subparagraph 3, of the Law, the Minister or the Minister's delegate shall either confirm or reverse the decision to suspend or withdraw the authorisation to distribute raw materials, in whole or in part, in accordance with Article 41, § 1, subparagraph 5, of the Law, within 60 days from receipt of the comments.

Article 69. Any application for withdrawal of the distribution authorisation, as referred to in Article 36, § 1, subparagraph 1, of the Law, must be submitted electronically using the form published on the FAMHP website.

The FAMHP may request information regarding the cessation of manufacturing and/or distribution activities and/or require the necessary measures to be taken to bring such activities to an end.

The Minister or the Minister's delegate shall withdraw the distribution authorisation, in accordance with Article 41, § 2, of the Law, within 15 days of the holder's request.

The time limit referred to in subparagraph 3 shall be suspended until the information referred to in subparagraph 2 has been received or until the measures necessary to bring the activity to an end have been taken.

Section 2. Notification of wholesale distributors as referred to in Article 1, § 1, point 17, and in Article 12*ter* of the Law on medicinal products

Article 69/1, § 1. Any wholesale distributor referred to in Article 1, § 1, point 17, and Article 12*ter* of the Law on medicinal products shall notify the FAMHP of their raw material distribution activities electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Articles 36, § 4, subparagraph 1, and 49, subparagraph 1, of the Law, the notification shall include the elements referred to in Article 62, subparagraph 2, points 1 to 5.

§ 2. The persons referred to in paragraph 1 shall submit the notification form to the

FAMHP at least 60 days before the scheduled date for commencing their activity.

§ 3. If the Minister or the Minister's delegate informs the applicant within 60 days of receipt of the notification form that, on the basis of a risk assessment, an inspection will be carried out, the activity may not be commenced until the applicant has been notified that they may commence the activity. If, within 60 days of receiving the notification form, the Minister or the Minister's delegate has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.

The Minister or the Minister's delegate shall confirm the notification to the applicant either 15 days after the expiry of the 60-day period or 15 days after the inspection has taken place.

The data relating to the notification shall be entered by the FAMHP in the Union database referred to in Article 12*bis*, § 1, subparagraph 7, of the Law on medicinal products.

§ 4. The persons referred to in paragraph 1 shall provide the FAMHP annually with a list of any changes that have occurred in relation to the information provided in the notification form. However, all changes that may affect the quality or safety of the distributed raw materials shall be notified immediately.

§ 5. If, during an investigation, it appears that the person referred to in paragraph 1 whose raw materials distribution activity has been notified does not, or no longer, comply with the obligations under the Law and this Royal Decree, the Minister or the Minister's delegate may, on the basis of a report drawn up in accordance with Article 64, suspend or cancel that person's notification.

The Minister or the Minister's delegate shall inform the person referred to in subparagraph 1 of the intention to suspend or cancel the notification. The person referred to in subparagraph 1 may present their arguments within 15 days of receiving the intended decision of the Minister or the Minister's delegate. Failing that, the decision shall become final on expiry of this period.

The Minister or the Minister's delegate shall take a decision within 90 days of receiving the arguments of the person referred to in subparagraph 1.

The data relating to the suspension and cancellation shall be entered by the FAMHP in the Union database referred to in Article 12*bis*, § 1, subparagraph 7, of the Law on medicinal products.

Section 3. Recognition of authorisations to distribute raw materials granted in another Member State, in accordance with Article 37, § 2, of the Law

Article 70. The holder of an authorisation to distribute raw materials granted in another Member State must submit any application for recognition of that authorisation electronically using the form published on the FAMHP website.

In addition to the personal data referred to in Articles 36, § 4, subparagraph 1, and 49, subparagraph 1, of the Law, the application must include the following elements:

1. a legalised translation into a national language or English of the distribution

authorisation for which recognition is sought, duly signed and/or validated by the competent authorities of the Member State concerned;

2. the specifications of the raw materials it wishes to distribute:

3. the nature of the distribution operations;

    a. the names of the raw materials, their analytical reference, their different pack sizes and, where applicable, their authorisation numbers;

    b. the number of the authorisation to manufacture raw materials of the manufacturer(s) of the raw materials;

4. the description and characteristics of the premises and equipment used in the context of the distribution activity;

5. the certificate of good distribution practices for medicinal products, as referred to in the national provisions transposing Article 111(5) of Directive 2001/83/EC;

6. a legalised translation into a national language or English of the legislation applicable to the distribution of raw materials in force in the Member State in which the distributor is established;

7. a legalised translation into a national language or English of the inspection report used to issue the valid certificate referred to in point 5 for the distributor whose authorisation is sought to be recognised;

8. any other information demonstrating compliance with the requirements referred to in Article 37, § 1, subparagraph 1, of the Law.

Article 71. The FAMHP shall notify the applicant, within 30 days from receipt of the application, whether the application for recognition of an authorisation to distribute raw materials granted in another Member State contains all the information and documents referred to in Article 70, subparagraph 2.

If the application does not contain all the information and documents referred to in Article 70, subparagraph 2, the FAMHP shall notify the applicant, specifying the missing and/or incorrect elements. Under penalty of inadmissibility, the applicant shall have 30 days from the date of that notification to complete or correct their application.

The FAMHP shall notify the applicant who has completed and/or corrected their application in accordance with subparagraph 2, within 30 days from receipt of the additional information and/or the correction to the application, whether it contains all the information and documents referred to in Article 70, subparagraph 2. If the application still does not contain all the information and documents referred to in Article 70, subparagraph 2, the FAMHP shall declare it inadmissible.

Article 72. An assessment of the elements of the application shall be carried out by one or

more persons referred to in Article 14, § 1, of the Law on medicinal products. The Minister or the Minister's delegate shall appoint one of these persons to lead this assessment.

The person or persons referred to in subparagraph 1 may be assisted by experts appointed for that purpose by the Minister or by the Minister's delegate.

As part of the assessment, the applicant may be required to provide additional information concerning the information provided in the application for recognition. Where the person or persons referred to in subparagraph 1 avail themselves of that option, the time limit referred to in Article 73 shall be suspended until the required additional data are provided.

A report including reasoned conclusions shall be drawn up on the basis of the assessment. This report shall conclude:

1. either that the distributor is not subject to provisions equivalent to those contained in the Law and its implementing decrees and that the authorisation to distribute raw materials granted in another Member State cannot be recognised;

2. or that the distributor is subject to provisions equivalent to those contained in the Law and its implementing decrees and that the authorisation to distribute granted in another Member State may be recognised;

The person referred to in subparagraph 1 shall communicate the report to the applicant. The applicant may present their arguments against the report within 15 days of receiving it.

The person(s) referred to in subparagraph 1 shall assess the arguments referred to in subparagraph 5 and draw up a final report. The final report shall be notified to the Minister or the Minister's delegate, as well as to the applicant.

Article 73. The Minister or the Minister's delegate shall grant or refuse recognition of the authorisation to distribute raw materials granted in another Member State, within 90 days from confirmation that the application contains all the information and documents referred to in Article 70, subparagraph 2, in accordance with Article 71, subparagraph 1 or 3.

Article 74, § 1. If the Minister or the Minister's delegate finds that a distributor to which recognition of its authorisation to distribute raw materials has been granted, in accordance with Article 73, does not comply with the provisions of the Law or its implementing decrees, the Minister or the Minister's delegate may prohibit that distributor from carrying out distribution activities in Belgium.

The Minister or the Minister's delegate shall notify the distributor of the proposed decision, unless immediate action is required to protect public health.

The distributor may submit written comments to the Minister or the Minister's delegate within 30 days from receipt of the proposed decision referred to in subparagraph 2.

In the absence of the comments referred to in subparagraph 3, the proposed decision shall become final.

If the distributor submits comments pursuant to subparagraph 3, the Minister or the Minister's delegate shall decide whether or not to suspend or withdraw the right to carry out distribution activities in Belgium, within 60 days from receipt of the comments.

§ 2. The Minister or the Minister's delegate shall withdraw without delay the right to carry out distribution activities in Belgium in the event of withdrawal of the certificate of good distribution practices for medicinal products, as referred to in the national provisions transposing Article 111(5) of Directive 2001/83/EC.

Section 4. Obligations of the distributor

Article 75. The person(s) responsible for distribution, as referred to in Article 37, § 1, subparagraph 1, point 4, of the Law, shall hold a statutory qualification as a pharmacist or a master's degree in pharmaceutical sciences, as a doctor or a master's degree in medicine, as a veterinary surgeon or a master's degree in veterinary medicine, as a chemist or a master's degree in chemical sciences, as a biologist or a master's degree in biological sciences, as a biomedical scientist or a master's degree in biomedical sciences, or as a bioengineer or a master's degree in bioengineering obtained in accordance with the legislation on the awarding of academic degrees and the university examination programme, or be legally exempt from this requirement.

Article 76. The premises referred to in Article 37, § 1, subparagraph 1, point 6, of the Law shall comply with the principles relating to good distribution practices laid down by or in accordance with Article 43 of the Law.

Article 77. The distributor is required to comply with the following obligations:

1. make its premises accessible at all times to the persons referred to in Article 14, § 1, of the Law on medicinal products;

2. source raw materials only from manufacturers and distributors, except for limited-use raw materials;

3. distribute the raw materials only to manufacturers, distributors and pharmacists referred to in Article 6, § 1, of the Law on the exercise of the healthcare professions coordinated on 10 May 2015, practising in a pharmacy open to the public or in a hospital pharmacy;

4. inform the Minister or the Minister's delegate without delay in the event of unforeseen replacement of the responsible person(s) referred to in Article 37, § 1, subparagraph 1, point 4, of the Law;

5. have an emergency plan that guarantees the effective implementation of any recall action ordered by the FAMHP or by the competent authorities of another Member State, or undertaken in cooperation with the holder of the raw material authorisation

concerned;

6. keep records, which may be in the form of purchase and sales invoices or in electronic form, containing, for every incoming or outgoing transaction, whether or not it involves a payment, at least the following information:

a) the date;

b) the name of the raw material;

c) the quantity received and/or supplied;

d) the name and address of the supplier or recipient, as appropriate;

e) the batch number of the raw materials;

7. produce, at the request of the FAMHP, a statement of the quantities of raw materials delivered, broken down by raw material and by recipient supplied, for a period determined by the FAMHP, provided that this period does not go back more than five years;

8. ensure that a person responsible for distribution referred to in Article 37, § 1, subparagraph 1, point 4, of the Law is present during distribution activities; if those activities are carried out on a part-time basis, their schedule shall be declared precisely; where there are several distribution points, the schedule shall be declared for each distribution point; the attendance schedule shall ensure that the responsible person(s) can perform their tasks and assume their responsibilities, taking into account the scale of the distribution activity;

9. organise itself in such a way that a person responsible for distribution referred to in Article 37, § 1, subparagraph 1, point 4, of the Law can be contacted without delay;

10. maintain a quality system establishing the responsibilities, procedures and risk management measures relating to its activities;

11. immediately inform the FAMHP and, where appropriate, the holder of the raw material authorisation of any raw materials which they receive or which are offered to them and which they identify as falsified or suspect of being falsified.

For the purposes of subparagraph 1, point 3, where the raw material is acquired from another distributor, the distributor shall verify whether the distributor who supplied the raw material holds an authorisation to distribute raw materials. Where the raw material is obtained from the manufacturer, the distributor shall verify that the manufacturer holds an

authorisation to manufacture.

Chapter 5. Placing on the market of raw materials

Section 1. Exclusions

Article 78. Section 2 shall not apply to limited-use raw materials, raw materials referred to in Article 50/3 of the Law, or raw materials that fall within the category of phages.

Section 2. Requirements for the placing on the market of raw materials

Article 79. Any raw material shall be packaged in a tamper-evident container of a quality such that it ensures preservation in conditions preventing any contamination and, as far as possible, any deterioration during its validity period.

Each container and, where applicable, each outer packaging shall bear the following information, in accordance with its raw material authorisation:

1. the name and address of the holder of the raw material authorisation;
2. the authorisation number assigned to the raw material;
3. the name of the raw material, in accordance with its raw material authorisation;
4. the quantity of raw material;
5. the manufacturing batch number;
6. the expiry date;
7. the storage conditions;
8. the analytical reference;
9. when the raw material is a mother tincture for homeopathic preparations:

a) the indication of the first safe dilution (*first safe dilution*);

b) if the dilution of the raw material is less than the first safe dilution, instructions for diluting it to the first safe dilution;

10. any other information specified in accordance with the analytical reference for the raw material.

The entries referred to in subparagraph 2, points 3, 7, 9 and 10, shall be drafted in the three national languages. This shall not prevent such data from also being drawn up in other languages, provided that the same information is given in all the languages used. The holder of the raw material authorisation is responsible for ensuring consistency between the different language versions.

The information referred to in subparagraph 2 shall be displayed in such a way as to be

easily legible, clearly understandable and indelible.

Containers and, where applicable, their outer packaging may include other information, signs or pictograms compatible with the analytical reference and useful for the pharmacist, to the exclusion of any element of a promotional nature. The accuracy of such other information, signs or pictograms shall be the responsibility of the holder of the raw material authorisation.

The Minister may impose particulars other than those referred to in subparagraph 2, where applicable for certain categories of raw materials, for reasons of public health.

Article 80, § 1. The holder of a raw material authorisation shall make the notifications referred to in Article 47, subparagraphs 1 and 2, of the Law using the form published on the FAMHP website.

§ 2. The notification of placing on the market, referred to in Article 47, subparagraph 1, of the Law, shall be made no later than 15 days before placing on the market.

Notification of temporary or permanent cessation of placing on the market, as referred to in Article 47, subparagraph 2, of the Law, shall take place, except in exceptional circumstances, no later than 60 days before the actual cessation of the placing on the market of the raw material.

Any changes to the data referred to in Article 81, subparagraph 3, points 2 and 3, shall be notified without delay.

Article 81. The notifications referred to in Article 47, subparagraphs 1 and 2, of the Law shall contain, in addition to the personal data referred to in Article 49, subparagraph 1, of the Law, the following elements:

1. the authorisation number of the raw material;

2. the pack size(s) of the raw material concerned by the notification.

The notification referred to in Article 47, subparagraph 1, of the Law shall also contain the date of the start of placing on the market.

The notification of temporary cessation of placing on the market referred to in Article 47, subparagraph 2, of the Law shall contain, in addition, the following information:

1. the date of the start of the temporary cessation of placing on the market;

2. the expected date on which placing on the market will resume;
3. the reasons for the temporary cessation of placing on the market.

The notification of permanent cessation of placing on the market referred to in Article 47, subparagraph 2, of the Law shall contain, in addition, the following information:

1. the date of the start of the permanent cessation of placing on the market;

2. the reasons for the permanent cessation of placing on the market.

Section 3. Withdrawal from the market

Article 82. If raw materials are found to be spoiled, adulterated, expired, falsified, imitated or non-compliant with the provisions of the Law or its implementing decrees, or in cases where measures are taken pursuant to Article 17 of the Law, the holder of the raw material authorisation shall withdraw from the market, at its own expense, those raw materials or the batch(es) concerned within the time limit specified in the notification of the finding, and at the latest within 30 days of that notification, and keep them at the disposal of the FAMHP. The holder may not object to their immediate removal by the persons referred to in Article 54 of the Law.

By way of derogation from subparagraph 1, the Minister or the Minister's delegate may charge the costs associated with withdrawal from the market to a liable third party if it has been established that a third party is responsible for the raw materials being spoiled, adulterated, expired, falsified, counterfeit or non-compliant with the provisions of this Law or its implementing decrees.

Chapter 6. Provisions relating to the pharmacist

Article 83. § 1. By way of derogation from Article 50, subparagraph 1, of the Law, the pharmacist may obtain limited-use raw materials and the raw materials referred to in Article 50/3 of the Law from suppliers other than manufacturers and distributors.

§ 2. Any limited-use raw material or raw material referred to in Article 50/3 of the Law obtained by a pharmacist shall be packaged in a tamper-evident container of a quality such that it ensures preservation in conditions preventing any contamination and, as far as possible, any deterioration during its validity period.

The container and, where applicable, the outer packaging of the limited-use raw material or the raw material referred to in Article 50/3 of the Law shall bear, as a minimum:

1. the name of the supplier;

2. the name of the raw material;

3. the quantity of raw material;

4. the manufacturing batch number;

5. the expiry date;

6. the storage conditions.

§ 3. A pharmacist preparing a magistral preparation based on a limited-use raw material, the analytical reference of which is a minimum analytical reference as referred to in Article 22, § 3, subparagraph 1, of the Law, based on a raw material referred to in Article 50/2 of the Law or Article 50/3 of the Law, for which the analytical reference used is not referred to in Article 11, § 1, subparagraph 2, points 1 to 3, of the Law, shall dispense it only if the patient has given informed consent in writing.
The consent referred to in subparagraph 1 shall contain at least the following elements:

1. the nature of the raw material, namely:
   a. a limited-use raw material, the analytical reference of which is a minimum analytical reference, as referred to in Article 22, § 3, of the Law; or

   b. a limited-use raw material referred to in Article 50/2 of the Law, which does not comply with the analytical reference applicable to it; or

   c. a raw material referred to in Article 50/3 of the Law, for which an application for the granting of limited-use raw material status is submitted;

2. for the raw material referred to in point 1(a), that the minimum analytical reference relates only to the identification of the raw material and its content, and for the raw material referred to in point 1(b) or (c), that the analytical reference used is not an official analytical reference referred to in Article 11, § 1, subparagraph 2, points 1 to 3, of the Law;

3. that the prescribing doctor and the dispensing pharmacist nevertheless consider that the use of this raw material is justified.
The Minister may lay down the model for such consent.

Article 84. § 1. The pharmacist shall keep a register in which they shall record, or cause to be recorded under their supervision, upon receipt, each acquired pack of raw material, to which they shall assign a serial number, for traceability and control purposes.

The register shall contain the following information:

1. a serial number;

2. the name of the raw material;

3. the date of receipt of the raw material;

4. the quantity of the raw material;

5. the manufacturing batch number of the raw material;

6. the holder of the raw material authorisation;

7. the expiry date of the raw material;

8. the analytical reference for the raw material;

9. the authorisation number of the raw material;

10. a statement confirming whether or not the raw material complies with the provisions of the Law and this Royal Decree, dated and signed by the pharmacist.

By way of derogation from subparagraph 2, with regard to limited-use raw materials and the raw materials referred to in Article 50/3 of the Law, the register shall contain the following information and documents:

1. a serial number;

2. the name of the raw material;

3. the date of receipt of the raw material;

4. the quantity of the raw material;

5. the manufacturing batch number of the raw material;

6. the supplier of the raw material;

7. the expiry date of the raw material;

8. the certificate of analysis;

9. the number assigned to it by the FAMHP, except for the raw materials referred to in Article 50/3 of the Law for which the application for the granting of limited-use raw material status has not yet been considered admissible, in accordance with Article 33, subparagraph 1 or 3;

10. a statement confirming whether or not the raw material complies with the provisions of the Law and this Royal Decree, dated and signed by the pharmacist.

By way of derogation from subparagraph 2 and without prejudice to subparagraph 3, the register shall also include, for the raw materials referred to in Article 50/3 of the Law, the pharmacist's declaration, set out in Annex 2, that the pharmacist is submitting an application to the FAMHP for the granting of limited-use raw material status in accordance with Article 19 of the Law, unless another hospital pharmacist submits the application.

§ 2. The register shall be kept either in handwritten form or electronically.

If the register is kept electronically, the information and documents contained in the electronic register may be printed on paper at any time.
§ 3. The pharmacist shall keep the register at the pharmacy open to the public or the hospital pharmacy for 10 years. The pharmacist shall make it available to the members of staff of the FAMHP referred to in Article 14, subparagraph 1, of the Law on medicinal products and to the inspectors referred to in Article 49, § 1, of the Law of 22 April 2019 on the quality of healthcare practice.

§ 4. The pharmacist shall comply with the obligation referred to in Article 50/1, subparagraph 1, of the Law by keeping the register referred to in this article.

Article 85, § 1. The pharmacist shall store each raw material in its original container, in accordance with the storage conditions stated on the container and, where applicable, on the outer packaging.

The pharmacist shall keep limited-use raw materials and the raw materials referred to in Article 50/3 of the Law in a separate place clearly identified by the words ‘Limited-use raw materials’ and reserved exclusively for that purpose.

§ 2. The pharmacist shall enter on the original container of each raw material the serial number assigned to it in the register, referred to in Article 84, § 1, subparagraph 2, point 1, or subparagraph 3, point 1.

The pharmacist shall enter ‘MPUL’ on the original container of each limited-use raw material and each raw material referred to in Article 50/3 of the Law.

Article 86. Without prejudice to Articles 112(1)(c), 113(1)(d) and 114(1)(d) of Regulation (EU) 2019/6, the pharmacist shall comply with the particulars and conditions of use of the raw material shown on its container and, where applicable, on its outer packaging.

Article 87. The declaration of the prescribing doctor referred to in Article 50/2, subparagraph 1, point 3, of the Law shall be drawn up in accordance with the model referred to in Annex 3.

Article 88. The time limits referred to in Article 50/3, point 3(a), of the Law shall be set at 90 days after the decision of the Minister or the Minister’s delegate.

The time limit referred to in Article 50/3, point 3(b), of the Law shall be set at 90 days following the publication of the minimum analytical reference in the Belgian Pharmacopoeia.

Chapter 7. Transitional provisions

Article 89. By way of derogation from Article 2, subparagraph 1, any production batch or bulk consignment, or part of a production batch or bulk consignment, reassigned in accordance with Article 2, § 2, subparagraph 3, of the Law as a raw material referred to in Article 65 of the Law shall be accompanied by a certificate of analysis.

Article 90. § 1. The holder of a monograph approved in accordance with Article 3, § 2, subparagraph 2, of the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists, whose approval or last amendment dates from five years or more than five years before the entry into force of this Law, shall submit an application to modify its monograph to the FAMHP, in accordance with Article 8, subparagraph 1, of the Law, in order to update it or shall carry out a reasoned assessment of its monograph and submit an application for approval of the report on that assessment to the

FAMHP in accordance with Article 9, subparagraph 1, of the Law, in accordance with Article 63, § 1, subparagraph 2, of the Law, by 31 December 2028 at the latest.

By way of derogation from Article 9, subparagraph 2, of the Law, where the FAMHP refuses approval of the report, the holder(s) of the monograph shall submit an application to modify the monograph in accordance with Article 8, subparagraph 1, of the Law within 180 days of the FAMHP's refusal.

§ 2. The approval of the monograph as referred to in Article 63, § 1, subparagraph 1, of the Law shall be automatically withdrawn on 1 January 2029 in the absence of an application to modify the monograph or an application for approval of the report on the reasoned assessment of the monograph in accordance with Article 63, § 1, subparagraph 2, of the Law and paragraph 1, subparagraph 1.

Approval of the monograph referred to in Article 63, § 1, subparagraph 1, of the Law shall be withdrawn automatically 180 days after the FAMHP's refusal referred to in paragraph 1, subparagraph 2, in the absence of an application to modify the monograph within the time limit imposed in accordance with paragraph 1, subparagraph 2.

Approval of the monograph as referred to in Article 63, § 1, subparagraph 1, of the Law shall be automatically withdrawn 90 days after the refusal by the Minister or the Minister's delegate, in accordance with Article 11, § 5, of the application to modify the monograph submitted in accordance with Article 63, § 1, subparagraph 2, of the Law and paragraph 1.

§ 3. Raw material authorisations whose analytical reference is a monograph whose approval is withdrawn in accordance with paragraph 2, and which are not automatically withdrawn in accordance with Article 91, § 2, shall be automatically withdrawn on the date on which the monograph's approval is withdrawn.

Article 91. § 1. The time limit referred to in Article 63, § 2, subparagraph 2, of the Law shall be set no later than 31 December 2028.

By way of derogation from subparagraph 1, where the Minister or the Minister's delegate has refused to grant the exception from modifying a raw material authorisation in accordance with Article 29, § 3, the application for which was submitted in accordance with Article 63, § 2, subparagraph 2, of the Law and subparagraph 1, the holder of the raw material authorisation shall submit an application to modify the authorisation in accordance with Article 14, subparagraph 1, point 2, of the Law within 90 days of the initial refusal by the Minister or the Minister's delegate.

§ 2. The raw material authorisation as referred to in Article 63, § 2, subparagraph 1, of the Law, which has not been granted on the basis of the analytical reference with the highest level of authority, shall be automatically withdrawn on 1 January 2029 in the absence of an application to modify the authorisation in accordance with Article 14, subparagraph 1, point 2, of the Law, or in the absence of an application not to modify the authorisation, in accordance with Article 14, subparagraph 2, of the Law, in accordance with Article 63, § 2, subparagraph 2, of the Law and paragraph 1.

The raw material authorisation as referred to in Article 63, § 2, subparagraph 1, of the Law shall be withdrawn automatically 90 days after the refusal by the Minister or the Minister's

delegate, in accordance with Article 29, § 2, subparagraph 1, to grant the amendment of the authorisation, the application for which was submitted in accordance with Article 63, § 2, subparagraph 2, of the Law and paragraph 1, or after the refusal by the Minister or the Minister's delegate, in accordance with Article 29, § 3, to grant the exception from modifying a raw material authorisation, the application for which was submitted in accordance with Article 63, § 2, subparagraph 2, of the Law and paragraph 1.

By way of derogation from subparagraph 2, the raw material authorisation as referred to in Article 63, § 2, subparagraph 1, of the Law shall not be withdrawn after the refusal by the Minister or the Minister's delegate, in accordance with Article 29, § 3, to grant the exception from modifying a raw material authorisation, the application for which was submitted in accordance with Article 63, § 2, subparagraph 2, of the Law and paragraph 1, if the holder of the raw material authorisation submits an application to modify the authorisation in accordance with Article 14, subparagraph 1, point 2, of the Law within 90 days of the initial refusal by the Minister or the Minister's delegate.

Article 91/1. The authorisations to supply raw materials to pharmacies open to the public, referred to in Article 6, § 1, of the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists, deemed to be authorisations to distribute raw materials referred to in Article 36, § 1, subparagraph 1, of the Law, in accordance with Article 63, § 1, of the Law, held by wholesale distributors referred to in Articles 1, § 1, point 17, and 12*ter* of the Law on medicinal products, shall be automatically converted into a notification within the meaning of Article 69/1 upon the entry into force of the Law.
The Minister or the Minister's delegate shall confirm the notification to the person referred to in subparagraph 1 15 days after the entry into force of the Law.

Article 92. § 1. A supplier of a raw material who does not hold a raw material authorisation as referred to in Article 13 of the Law and for which there is no monograph in the analytical references referred to in Article 11, § 1, subparagraph 2, points 1 to 3, of the Law at the time of the entry into force of the Law may place it on the market in accordance with Article 64, § 1, subparagraph 2, of the Law until 90 days after the granting or refusal of the raw material authorisation, in accordance with Article 13, subparagraph 1 or 2, of the Law, subject to the following conditions:

1. an application for approval of the monograph is submitted in accordance with Article 6 of the Law, no later than 31 December 2028; and

2. an application for authorisation of the raw material shall be submitted, in accordance with Article 12 of the Law, within 90 days of the approval of the monograph.

The raw materials referred to in subparagraph 1 may no longer be placed on the market in accordance with Article 64, § 1, subparagraph 2, of the Law after the Minister or the Minister's delegate has refused approval of the monograph, in accordance with Article 7, subparagraph 1, of the Law.

§ 2. A supplier of a raw material who does not hold a raw material authorisation as referred to in Article 13 of the Law, and for which a monograph exists in the analytical references referred to in Article 11, § 1, subparagraph 2, points 1 to 3, of the Law at the time of the

entry into force of the Law, and who has submitted an application for authorisation of the raw material in accordance with Article 12 of the Law by 31 December 2028 at the latest, may no longer place it on the market in accordance with Article 64, § 1, subparagraph 2, of the Law after the granting or refusal of the raw material authorisation, in accordance with Article 13, subparagraph 1 or 2, of the Law.

§ 3. A supplier of a raw material who does not hold a raw material authorisation as referred to in Article 13 of the Law, and who has not submitted an application for authorisation of the raw material in accordance with Article 12 of the Law by 31 December 2028 at the latest, may no longer place it on the market in accordance with Article 64, § 1, subparagraph 2, of the Law from 1 January 2029.

§ 4. A pharmacist may use raw materials that do not have a raw material authorisation as referred to in Article 13 of the Law, and which have been placed on the market in accordance with Article 64, § 1, subparagraph 2, of the Law, until 31 December 2031 or until their expiry date, whichever is earlier.

Article 93. Applications for the granting of limited-use raw material status, as referred to in Article 50/3, point 1, of the Law, in accordance with Article 65 of the Law, shall be submitted by 31 December 2029 at the latest.

Article 94. Chapter 5, section 2, shall not apply to raw materials for which no raw material authorisation, as referred to in Article 13 of the Law, has been issued, placed on the market in accordance with Article 64, § 1, subparagraph 1, of the Law.

Article 95. By way of derogation from Article 84, § 1, subparagraph 2, with regard to raw materials for which no raw material authorisation, as referred to in Article 13 of the Law, has been issued and which are placed on the market in accordance with Article 64, § 1, subparagraph 1, of the Law, the register shall contain the following information and documents:

1. a serial number;
2. the name of the raw material;
3. the date of receipt of the raw material;
4. the quantity of the raw material;
5. the manufacturing batch number of the raw material;
6. the supplier of the raw material;
7. the expiry date of the raw material;
8. the certificate of analysis of the raw material;

9. a statement confirming whether or not the raw material complies with the provisions of the Law and this Royal Decree, dated and signed by the pharmacist.

Chapter 8. Amending and repealing provisions
Section 1. Amending provisions

Article 96. In Article 83*quater*, subparagraph 1, point 6, of the Royal Decree of 14 December 2006 on medicinal products for human use, inserted by the Royal Decree of 17 July 2014, the following amendments are made:

1. the words ‘the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists’ are replaced by the words ‘the Law of 29 February 2024 on raw materials used by pharmacists’;

2. the words ‘the above-mentioned Royal Decree of 19 December 1997’ are replaced by the words ‘the above-mentioned Law of 29 February 2024’;

3. the words ‘the Royal Decree of 19 December 1997’ are replaced by the words ‘the above-mentioned Law of 29 February 2024’.

Article 97. In Article 102, § 1, point 3(b), second indent, of the same Royal Decree, replaced by the Royal Decree of 17 July 2014, the words ‘the aforementioned Royal Decree of 19 December 1997’ shall be replaced by the words ‘the Law of 29 February 2024 on raw materials used by pharmacists’.

Article 98. In Annex IV*quater* of the same Royal Decree, the words ‘the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists’ are replaced by the words ‘the Law of 29 February 2024 on raw materials used by pharmacists’.

Article 99. In Article 1 of the Royal Decree of 21 January 2009 laying down instructions for pharmacists, the following amendments are made:

a) at point 1, the words ‘in the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by pharmacists’ are replaced by the words ‘by the Law of 29 February 2024 on raw materials used by pharmacists’.

b) point 10 is replaced by the following:

“10° ‘Raw material’ means a raw material within the meaning of Article 2, point 1, of the above-mentioned Law of 29 February 2024.”

Article 100. In Article 32, third indent, of the same Royal Decree, the words ‘raw materials provided for in the above-mentioned Royal Decree of 19 December 1997’ are replaced by the words ‘referred to in Article 84 of the Royal Decree of xx/xx/xxxx implementing the Law of 29 February 2024 on raw materials used by pharmacists’.

Article 101. Article 33, § 1, of the same Royal Decree is supplemented by a subparagraph which reads as follows:

‘By way of derogation from subparagraphs 1 and 2, the pharmacist may not subcontract magistral preparations based on a limited-use raw material, within the meaning of Article 2, § 1, point 3, of the Law of 29 February 2024 on raw materials used by pharmacists, or on a raw material which does not have a raw material authorisation, as referred to in Article 50/3 of that Law, to a holder of a preparation authorisation referred to in subparagraph 1, point 2. ’.

Article 102. In Article 39, § 1, subparagraph 1, of the same Royal Decree, the words ‘, and the medical doctor’s declaration documents referred to in Article 105 of the above-mentioned Royal Decree of 14 December 2006, the prescribing doctor’s declaration referred to in Article 50/2, subparagraph 1, point 3, of the Law of 29 February 2024 on raw materials used by pharmacists as well as any document supporting that the condition referred to in Article 50/2, subparagraph 1, point 2, of the same Law is met, and the informed consent referred to in Article 83, § 3, of the same Law,’ shall be inserted between the words ‘and the pharmaceutical care follow-up records, referred to in Annex I, point 7.2, II’ and the words ‘shall be kept for at least 10 years’.

Article 103. In Annex 1, Guide to good officinal pharmaceutical practice, F. Principles and general rules, 5. Raw materials, and in the title of Annex II, as replaced by the Royal Decree of 21 March 2018, of the same Royal Decree, the words ‘the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists’ are replaced in each instance by the words ‘the Law of 29 February 2024 on raw materials used by pharmacists’.

Article 104. In Article 1, § 1, of the Royal Decree of 30 September 2020 on the preparation and supply of medicinal products and the use and distribution of medical devices in healthcare establishments, point 20 is replaced by the following:

“20. ‘raw material’ means
a raw material within the meaning of Article 2(1) of the Law of 29 February 2024 on raw materials used by pharmacists;”.

Article 105. In Article 18, point 3, of the same Royal Decree, the words ‘of the raw materials provided for in the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists’ are replaced by the words ‘referred to in Article 84 of the Royal Decree of xx.xx.xxxx implementing the Law of 29 February 2024 on raw materials used by pharmacists’.

Article 106. Article 22, § 1, of the same Royal Decree is supplemented by a subparagraph which reads as follows:

‘By way of derogation from subparagraph 1, the hospital pharmacist may not subcontract magistral preparations based on a limited-use raw material, within the meaning of Article 2,

§ 1, point 3, of the Law of 29 February 2024 on raw materials used by pharmacists, or on a raw material which does not have a raw material authorisation, as referred to in Article 50/3 of that Law, to a holder of a preparation authorisation referred to in subparagraph 1, point 2. ’.

Article 107. In Article 31, § 1, subparagraph 1, of the same Royal Decree, the words ‘, and the medical doctor’s declaration documents referred to in Article 105 of the above-mentioned Royal Decree of 14 December 2006, the prescribing doctor’s declaration referred to in Article 50/2, subparagraph 1, point 3, of the Law of 29 February 2024 on raw materials used by pharmacists as well as any document supporting that the condition referred to in Article 50/2, subparagraph 1, point 2, of the same Law is met, and the informed consent referred to in Article 83, § 3, of the same Law,’ shall be inserted between the words ‘and the annual statements referred to in Article 29,’ and the words ‘shall be kept for at least 10 years,’.

Section 2. Repeal provision

Article 108. The Royal Decree of 19 December 1997 on the control and analysis of raw materials used by dispensing pharmacists, as last amended by the Royal Decree of 17 February 2021, is repealed.

Chapter 9. Final provisions

Article 109. The Law and this Royal Decree shall enter into force on 1 January 2027.

Article 110. The Minister for Public Health shall be responsible for the implementation of this Royal Decree.

Issued at

By the King:
The Minister for Public Health,

Frank VANDENBROUCKE

Annex 1. Model attestation by the doctor referred to in Article 18, subparagraph 1, point 7, of the Law

A signed statement from the treating doctor that the raw material is of significant benefit to patients affected by the relevant disease or condition and discussion of such significant benefit

I, the undersigned:
..... name and first name of the doctor

INAMI No: .....
doctor practising at (name of institution): .....
address: .....
tel.: .....
e-mail address: .....

attests that:

the following raw material (name of the raw material): …….

is of significant benefit to patients with (name of disease or condition): ……...

More specifically, the benefit is as follows (discussion of the benefit):
……...
.....
.....
.....
.....
.....
.....

Date .....
Doctor’s signature, ...

Seen to be annexed to our Royal Decree of …… implementing the Law of 29 February 2024 on raw materials used by pharmacists

Issued at

By the King:
The Minister for Public Health,

Frank VANDENBROUCKE

Annex 2. Model declaration by the pharmacist referred to in Article 83, § 1, subparagraph 4

Declaration by a pharmacist using a raw material referred to in Article 50/3 of the Law of 29 February 2024 on raw materials used by pharmacists, concerning the submission of an application to the FAMHP for the raw material to be granted 'limited-use raw material' status in accordance with Article 19 of the same Law

I, the undersigned:
..... name and first name of the pharmacist
INAMI No: .....
pharmacist practising at (name of institution): .....
address: .....
tel.: .....
e-mail address: .....

declare that I use the following raw material …….. (name of the raw material), of which the serial number assigned in the register referred to in Article 84, § 1, subparagraph 3, point 1, of the Royal Decree of xx.xx.xxxx implementing the Law of 29 February 2024 on raw materials used by pharmacists is as follows ……., pursuant to Article 50/3 of the Law of 29 February 2024, and that:

1. I am submitting an application to the FAMHP for the granting of limited-use raw material status for this raw material, in accordance with Article 19 of the same Law;

2. another pharmacist, …….. (name and first name of the pharmacist), pharmacist at …….. (hospital, coordinated multidisciplinary centre or medico-paediatric centre for children with chronic disease) is submitting, for this raw material, an application to the FAMHP for the granting of limited-use raw material status, in accordance with Article 19 of the same Law.

Date .....
Pharmacist's signature, ...

Seen to be annexed to our Royal Decree of …… implementing the Law

of 29 February 2024 on raw materials used by pharmacists

Issued at

By the King:
The Minister for Public Health,

Frank VANDENBROUCKE

Annex 3. Model declaration by the doctor referred to in Article 50/2, subparagraph 1, point 3, of the Law

Declaration by the doctor intended for the pharmacist for the dispensing of a magistral preparation on the basis of a limited-use raw material that does not comply with the analytical reference applicable to it, absolutely necessary to treat a patient in a life-threatening situation or to avoid a significant and irreversible deterioration of their condition, in accordance with Article 50/2, subparagraph 1, point 3, of the Law of 29 February 2024 on raw materials used by pharmacists

I, the undersigned:
..... name and first name of the doctor

INAMI No: .....
doctor practising at (name of institution): .....
address: .....
tel.: .....
e-mail address: .....

declare that the treatment of my patient, (name and first name)....., with a magistral preparation based on a limited-use raw material **which does not comply with the analytical reference applicable to it is** absolutely necessary:

1. to treat the patient who is in a life-threatening situation
2. or to prevent a significant and irreversible deterioration in their condition

Name of the raw material: .....

Posology: .....

Duration of treatment (up to one year):

.....

Date .....
Doctor's signature, ...

Seen to be annexed to our Royal Decree of …… implementing the Law

of 29 February 2024 on raw materials used by pharmacists

Issued at

By the King:
The Minister for Public Health,

Frank VANDENBROUCKE