KINGDOM OF BELGIUM

FEDERAL AGENCY FOR MEDICINAL AND HEALTH PRODUCTS

Law relating to raw materials used by pharmacists

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

The Minister of Public Health is responsible for introducing to the House of Representatives on our behalf the draft Law which reads as follows:

Chapter 1. General provisions

Article 1. This Law governs a subject referred to in Article 74 of the Constitution.

Article 2. For the purposes of this Law and its implementing Decrees, the following definitions shall apply:

1° raw material: any substance or mixture of substances, which is not a medicinal product within the meaning of Article 1, §1(1), of the Law of 25 March 1964 on medicinal products for human use or Article 4(1) of Regulation (EU) 2019/6, which a pharmacist obtains for delivery or incorporation in a magistral or officinal preparation;

2° substance: any organic or inorganic substance, whatever its origin, used as an active substance or excipient in the composition of a magistral or officinal preparation, as referred to in Article 6*c*, §3, subparagraph 1(1) or (2) of the Law on Medicinal Products;

3° limited use raw material: a raw

	material which has been granted this status in accordance with Articles 18 to 20;
4°	reference material: substance or mixture of substances used as a reference in the assessment of the quality of a raw material;
5°	officinal preparation: medicinal product prepared in a pharmacy according to the indications of a pharmacopoeia or the Magistral Therapeutic Form and intended to be delivered directly to patients or end-users supplied by this pharmacy, as referred to in Article 6*c*, §3, subparagraph 1(2), of the Law of 25 March 1964 on Medicinal Products for human use or medicinal product referred to in Article 2(6)(c) of Regulation (EU) 2019/6;
6°	magistral preparation: a medicinal product prepared in a pharmacy according to a prescription intended for a patient, a group of patients or a specified animal/animal(s), as referred to in Article 6*c*, §3, subparagraph 1(1) of the Law of 25 March 1964 on Medicinal Products for human use or medicinal product referred to in Article 2(6)(b) of Regulation (EU) 2019/6;
7°	production lot or bulk: homogeneous mass of raw material from the same production operation;
8°	manufacturing batch: all packagings of a raw material from the same division operation, starting from a homogeneous mass;
9°	production: the production of raw materials by synthesis, extraction, mixing or any other appropriate production method;
10°	producer: natural or legal person

engaged in production activities;
11° manufacture: the total or partial manufacture of raw materials, including division, packaging and presentation operations, with the exception of production activities, except where such operations are carried out by the pharmacist, for retail supply;
12° manufacturer: natural or legal person who has an authorisation to manufacture raw materials;
13° distribution: any activity consisting of the procurement, possession or delivery of raw materials intended for use by pharmacists; the following definitions shall apply:
a) procure: obtaining, acquiring, ordering and purchasing raw materials from manufacturers;
b) deliver: any activity of supplying, selling or donating raw materials to wholesalers-distributors referred to in Article 1, §1(20) of the Law on Medicinal Products, to distributors and pharmacists;
14° distributor: natural or legal person who has an authorisation for the distribution of raw materials;
15° pharmacist: a pharmacist referred to in Article 6(1), subparagraph 1 of the Law on the Exercise of Health Care Professions coordinated on 10 May 2015, who work in a dispensary open to the public or in a hospital pharmacy;
16° laboratory: a laboratory with an authorisation for the manufacture of medicinal products, as referred to in Article 12*a*, §1, subparagraph 1 of the Law on Medicinal Products or issued in accordance with Article 40(1) of Directive 2001/83/EC or Article 88(1) of Regulation (EU) 2019/6, or Sciensano;

17° certificate of analysis: a document containing the results of the identity and quality checks on the batch of raw materials, carried out by a laboratory using methods corresponding to the current state of scientific knowledge, dated and signed by the qualified person referred to in Article 97 of Regulation (EU) 2019/6 of the laboratory, or, in the absence of such a person, by the director of the laboratory;
18° public service obligation: the obligation on distributors to guarantee at all times an assortment of raw materials capable of meeting the requirements of a geographically determined territory and of ensuring the delivery of orders requested in a very short time throughout that territory;
19° minister: the minister responsible for public health;
20° FAMHP: the Federal Agency for Medicinal and Health Products as established by the Law of 20 July 2006 on the establishment and operation of the Federal Agency for Medicinal and Health Products;
21° Pharmacopoeia Commission: the commission set up at the FAMHP in accordance with Article 12/3 of the Law of 20 July 2006 on the creation and functioning of the Federal Agency for Medicinal and Health Products;
22° Member State: a Member State of the European Union or a State which is a party to the Agreement on the European Economic Area;
23° third country: a country which is not a Member State;
24° law on medicinal products: the Law

of 25 March 1964 on medicinal products for human use;
25° Directive 2001/83/EC: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
26° Regulation (EC) No 726/2004: Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
27° Regulation (EU) 2019/6: Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
Article 3. For the purposes of this Law, the general administrator of the FAMHP shall be designated as the Minister's delegate.
The Minister may also designate other members of the FAMHP staff as delegates, while indicating the limit of the powers delegated to them.
Article 4. Articles 52, subparagraph 1, 53, 53*a* and 54 of the Judicial Code shall apply to the time limits referred to in this Law and its implementing decrees.
Chapter 2. Monographs, raw material authorisations and limited use raw material status

Section 1. Monographs
Subsection 1. Approval of a monograph
Article 5. The King defines the criteria that a monograph must meet for approval. The King can define different criteria according to the categories of raw materials that He defines.
Article 6. Any application for approval of a monograph shall be submitted to the FAMHP.
When submitting his/their application, the applicant(s) shall also submit to FAMHP a sufficient quantity of the raw material manufactured in accordance with the monograph and the reference material(s) necessary for its analysis, when these are not described in a Pharmacopoeia referred to in Article 11, §1(1) to (3). The FAMHP subjects them to the control of a laboratory, to ensure that the control methods described in the monograph are satisfactory and correspond to the current state of scientific knowledge. The King may specify what a sufficient quantity is and the terms and conditions for the delivery of the raw material and the reference material(s) by the applicant(s).
The King shall determine the content of the application for approval of a monograph and may determine the form of this application and the manner in which it is submitted. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions, deadlines and procedures for the assessment of the application.

Article 7. The Minister or his delegate shall approve a monograph on the basis of the opinion of the Pharmacopoeia Commission and, where applicable, the FAMHP, if the monograph meets the criteria laid down in accordance with Article 5.
The King shall set the time limit within which the Minister or his delegate must take the decision referred to in subparagraph 1. The King may determine the cases in which the FAMHP gives its opinion, in accordance with subparagraph 1.
Subsection 2. Modification of an approved monograph
Article 8. The holder(s) of an approved monograph shall ensure that it is updated according to the current state of scientific and technical knowledge. To do so, he shall, as soon as possible, submit a request to amend his monograph with the FAMHP as soon as necessary.
The Minister or his delegate shall approve the request to amend a monograph on the basis of the opinion of the Pharmacopoeia Commission and, where applicable, the FAMHP, when the monograph so amended meets the criteria set out in Article 5. The King shall set the time limit within which the Minister or his delegate shall take this decision.
The King determines the form and content of the request for modification of the monograph and the manner in which it is made. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions,

deadlines and procedures for the assessment of the application. The King may make the obligation of Article 6, subparagraph 2, applicable to the request, in cases which He determines, as well as specify the terms and conditions for the implementation of this obligation. The King may determine the cases in which the FAMHP gives its opinion, in accordance with subparagraph 2.
Subsection 3. Approval of the report on the 5-year reasoned assessment of the monograph
Article 9. No later than 5 years after the initial approval of the monograph, in accordance with Article 7, or after the last approval of an amendment to the monograph, in accordance with Article 8, or after the last approval of the report of the reasoned assessment, in accordance with this Article, whichever is the latest, the holder(s) of an approved monograph shall carry out a reasoned assessment of his monograph and submit a request for approval of the report of this assessment to the FAMHP, concluding that the monograph is always up-to-date according to the current state of scientific and technical knowledge and should not be modified, unless the holder(s) make(s) an application to modify his/their monograph in accordance with Article 8.
The FAMHP shall approve the reasoned assessment report when the analysis and conclusion are scientifically sound and correct, where appropriate, on the basis of the opinion of the Pharmacopoeia Commission. Otherwise, the FAMHP shall refuse approval of the report and the holder(s) of the monograph shall submit a request to amend the monograph in

accordance with Article 8 within 30 days of the decision of the FAMHP.
The King shall determine the content of the request for approval of the report of the reasoned assessment of the monograph and may determine the form of this request and the manner in which it is made. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions, deadlines and procedures for the assessment of the application. The King may determine the cases in which the Pharmacopoeia Commission gives its opinion, in accordance with subparagraph 2
Subsection 4. Suspension or withdrawal of approval of a monograph
Article 10, §1. The Minister or his delegate shall suspend or withdraw the approval of the monograph concerned, when the holder(s) of the monograph fail(s) to comply with the obligations referred to in Article 8, subparagraph 1 or 9, subparagraph 1 and 2.
Before proceeding with these measures, the Minister or his delegate shall notify the monograph holder(s) of his proposal for a decision.
The holder(s) of the monograph may submit his/their written comments to the Minister or his delegate.
In the absence of comments referred to in subparagraph 3, the proposed decision shall become final.
If the monograph holder(s) submit(s) comments under subparagraph 3, the Minister or his delegate confirms his decision to suspend or withdraw the

approval of the monograph in question.
§2. The Minister or his delegate withdraws the approval of the monograph concerned at the request of its holder(s).
§3. The King shall fix the time limits and may lay down the procedure and terms for the application of this Article.
Section 2. Authorisations of raw material
Subsection 1. Authorisation of a raw material
Article 11, §1. A manufacturer or distributor may place a raw material on the market only if it is authorised. The authorisation is only valid for the raw material and the different presentations for which the authorisation has been granted.
A raw material may only be authorised if it is described, in descending order of authority, in one of the following analytical references:
1° the European Pharmacopoeia;
2° the Belgian Pharmacopoeia or an official Pharmacopoeia corresponding to the current state of scientific and technical knowledge;
3° the *Deutscher Arzneimittel-Codex*, provided that the monograph concerned is capable of verifying the final quality of the raw material;
4° a monograph approved by the Minister or his delegate, in accordance with Article 7, subparagraph 1 or 8, subparagraph 2.
A raw material described in several

references referred to in subparagraph 2(1) to (4), may be authorised only on the basis of the reference with the highest level of authority.
§2. By way of exemption from paragraph 1, a raw material described in several references referred to in paragraph 1, subparagraph 2(1) to (4), may be authorised on the basis of a reference not having the highest level of authority, where justified for reasons of public health.
§3. The King shall draw up the list of official pharmacopoeias corresponding to the current state of scientific and technical knowledge referred to in paragraph 1, subparagraph 2(2).
The King may set additional conditions to those referred to in paragraphs 1 and 2, for obtaining a raw material authorisation.
Article 12. Any manufacturer or distributor shall submit any application for authorisation of raw material to the FAMHP.
The King shall determine the content of the application referred to in subparagraph 1 and may determine the form of this application and the manner in which it is made. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions, deadlines and procedures for the assessment of the application.
Article 13. Where the application for authorisation of raw material is submitted in accordance with Article 11, §1, the Minister

or his delegate shall grant the raw material authorisation on the basis of the assessment of the application by the FAMHP, if the application for authorisation meets the conditions for authorisation referred to in Article 11, §1 and, where applicable, the additional conditions laid down in accordance with Article 11(3). The King shall set the time limit within which the Minister or his delegate shall take this decision.
When the application for authorisation of raw material is submitted in accordance with Article 11(2), the Minister or his delegate shall grant the authorisation of the raw material on the basis of the assessment of the FAMHP and, where appropriate, on the opinion of the Pharmacopoeia Commission, if the application for authorisation meets the conditions for authorisation referred to in Article 11(2) and, where appropriate, the additional conditions laid down in accordance with Article 11(3). The King shall set the time limit within which the Minister or his delegate shall take this decision.
The King may determine the cases in which the Pharmacopoeia Commission gives its opinion, in accordance with subparagraph 2.
Subsection 2. Modification of a raw material authorisation
Article 14. The holder of the raw material authorisation shall submit an application for modification of his authorisation to the FAMHP when:
1° the name, storage conditions and/or labelling requirements of the raw material are amended in the

analytical reference on the basis of which the authorisation of the raw material was granted;
2° the authorised raw material is described, after its authorisation, in an analytical reference with a higher level of authority than that on which it was authorised;
3° the holder of the raw material authorisation wishes to modify any other element of his raw material authorisation that affects the quality of the raw material.
By way of exemption from subparagraph 1(2), the holder of the raw material authorisation may submit to the FAMHP an application not to modify his raw material authorisation, on the grounds of public health.
The King shall determine the content of the requests referred to in subparagraphs 1 and 2 and may determine the form of such requests, the manner in which and the time limits within which they are submitted. The King shall lay down the rules on the admissibility of these applications. The King shall lay down the conditions, time limits and procedures for the examination of these applications. The King can set different rules according to the types of changes that He determines.
The King may define the changes that affect the quality of the raw material, referred to in subparagraph 1(3).
Article 15, §1. When the request for modification has been submitted in accordance with Article 14, subparagraph 1(1) or (2), the Minister or his delegate shall

grant the authorisation of the modified raw material on the basis of the assessment by the FAMHP, if the conditions referred to in Article 11(1) or (2) and, where applicable, the additional conditions laid down in accordance with Article 11(3) are fulfilled.
§2. When the request for amendment has been submitted in accordance with Article 14, subparagraph 1(3), the Minister or his delegate shall grant the authorisation of the modified raw material on the basis of the assessment of the FAMHP and, where appropriate, the opinion of the Pharmacopoeia Commission, if the application for authorisation meets the conditions for authorisation referred to in Article 11(1) or (2) and, where appropriate, with the additional conditions laid down in Article 11(3).
§3. When the holder of the authorisation of raw material has submitted an application not to amend his authorisation, in accordance with Article 14, subparagraph 2, the Minister or his delegate shall grant this exception on the basis of the assessment of the FAMHP and, where appropriate, the opinion of the Pharmacopoeia Commission, when such exemption is justified for reasons of public health and, where appropriate, if the additional conditions laid down in accordance with Article 11(3) are still satisfied.
If the Minister or his delegate refuses to grant the exception in accordance with subparagraph 1, the holder of the raw material authorisation shall without delay submit an application to the FAMHP for modification of his authorisation in accordance with Article 14, subparagraph 1(2).

§4. The King shall set the time limit within which the Minister or his delegate takes the decisions referred to in paragraphs 1 to 3. The King may determine the cases in which the Pharmacopoeia Commission shall give its opinion in accordance with paragraphs 2 and 3, first subparagraph.
Article 16. The holder of the raw material authorisation who wishes to modify any other element of his raw material authorisation, not referred to in Article 14, shall notify the FAMHP, under the conditions laid down by the King.
Subsection 3. Suspension or withdrawal of a raw material authorisation
Article 17, §1. The Minister or his delegate suspends or withdraws the relevant raw material authorisation when:
1° the holder of a raw material authorisation does not comply with the obligations referred to in Article 14, subparagraph 1 or 2, or in the second subparagraph of Article 15(3), subparagraph 2;
2° the analytical reference on which the authorisation is based no longer exists;
3° public health reasons require that no magistral or officinal preparation containing this raw material can be delivered.
§2. Before taking such measures, the Minister or his delegate shall notify the holder of the raw material authorisation of his proposal for a decision.

The holder of a raw material authorisation may submit his written comments to the Minister or his delegate.
In the absence of comments referred to in subparagraph 2, the proposed decision shall become final.
Whether or not the holder of the raw material authorisation submits comments under subparagraph 2, the Minister or the Minister's delegate confirms its decision to suspend or withdraw the relevant raw material authorisation.
§3. By way of exemption from paragraph 2, in the event of urgent public health reasons justified on the basis of paragraph 1(3), the Minister or his delegate may directly suspend a raw material authorisation. In this case, he shall communicate his decision directly to the holder of the raw material authorisation.
§4. The Minister or his delegate shall withdraw the relevant raw material authorisation at the request of the holder.
§5. The King shall fix the time limits and may lay down the procedure and terms for the application of this Article.
Section 3. Of the limited-use raw material status
Subsection 1. Allocation of the limited-use raw material status
Article 18. A raw material may be granted the status of a limited-use raw material if the following conditions are met:
1° the raw material is made up of magistral preparations for human use

	intended for the diagnosis, prevention or treatment of a rare disease or chronic disease, a disease which seriously weakens health or a disease which poses a threat to life, at the time of submission of the application for that status;
2°	the raw material or its derivatives shall not be placed on the market in Belgium in accordance with this Law, unless its derivatives placed on the market in accordance with this Law cannot be used for the management of the disease or condition in question, in terms of safety and/or efficacy;
3°	there is no medicinal product authorised or registered in accordance with the Law on Medicinal Products or Regulation (EC) No 726/2004 on the market in Belgium containing as the single active substance the same active substance as the raw material, or, if such a medicinal product is on the market in Belgium, the pharmaceutical form of that medicinal product cannot be used for the intended magistral preparation;
4°	Article 6*c*, § 1(4) of the Law on Medicinal Products may not be applied to import a medicinal product containing the same active substance and intended for the diagnosis, prevention or treatment of the same disease or condition as the magistral preparation envisaged;
5°	there is no medicinal product containing the same active substance and intended for the diagnosis, prevention or treatment of the same disease or condition made available as part of a compassionate use programme referred to in Article 6*c*,

	§1(2), of the Law on Medicinal Products, or of an emergency medical programme as referred to in Article 6*c*, §1(3), of the same Law, in which patients who could be treated with the magistral preparation, may be admitted;
6°	there is no investigational medicinal product containing the same active substance for the diagnosis, prevention or treatment of the same disease or condition in a clinical trial within the meaning of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, in which patients who could be treated with the magistral preparation may be admitted;
7°	the raw material has a significant benefit for patients with the disease or condition referred to in (1).
Article 19. Any hospital pharmacist practising in a hospital as defined in Article 4 of the Law on Hospitals and Other Care Institutions, coordinated on 10 July 2008, in a coordinated multidisciplinary centre referred to in Article 23(1), subparagraph 1 of the Law on Compulsory Health Care and Compensation Insurance coordinated on 14 July 1994, or in a paediatric medical centre for children with chronic disease referred to in Article 34(9)(a), of the same Law, may submit an application for the award of the status of raw material for limited use to the FAMHP.	
The King shall determine the content of the application referred to in subparagraph 1 and may determine the form of this application and the manner in which it is	

made. The King shall lay down the rules on the admissibility of the application.
The application is assessed by the FAMHP. It requires the opinion of the Commission for medicinal products for human use as regards the conditions referred to in Article 18(1), (2) and (7). The King shall lay down the conditions, time limits and procedures for the assessment of the application and the delivery of the opinion of the Commission for Medicinal Products for Human Use.
Article 20. The Minister or his delegate shall assign to a raw material the status of a restricted raw material for a period of 5 years, on the basis of the assessment of the FAMHP and the opinion of the Commission for Medicinal Products for Human Use, if the conditions referred to in Article 18 are met.
By way of exemption from subparagraph 1, the Minister or his delegate may award the status of a limited-use raw material if one or more conditions referred to in Article 18(2) to (4) are not met when the raw material(s), its derivatives and/or the medicinal product(s) concerned is/are in practice inaccessible to the patients concerned due to an abnormally high cost.
Subsection 2. Renewal of the limited-use raw material status
Article 21. The Minister or his delegate may renew the status of a limited-use raw material for each time for a new period of 5 years, on the basis of an assessment of the FAMHP and the opinion of the Commission for medicinal products for human use, if the conditions referred to in Article 18 are still fulfilled. The King shall lay down the

conditions, time limits and procedures for this purpose.
Subsection 3. Consequences of the request for the award of the limited-use raw material status and of the award of that status
Article 22, §1. When a limited-use raw material is described in one or more analytical references referred to in Article 11, subparagraph 2(1) to (3), the analytical reference(s) with the highest level of authority shall be used as an analytical reference(s) of the limited-use raw material in question.
§2. When a limited-use raw material is not described in a reference referred to in paragraph 1 but is the subject of a monograph in a hospital as defined in Article 4 of the Law on Hospitals and Other Care Institutions, coordinated on 10 July 2008, in a coordinated multidisciplinary centre referred to in Article 23(1), subparagraph 1 of the Law on Compulsory Health Care and Compensation Insurance coordinated on 14 July 1994, or in a paediatric medical centre for children with chronic disease referred to in Article 34(9) (a) of the same Law, the Minister or his delegate approves this monograph in accordance with Article 7.
If the Minister or his delegate approves the monograph in accordance with subparagraph 1, the monograph so approved shall be used as an analytical reference for the limited-use raw material in question.
If the Minister or his delegate refuses approval of the monograph in accordance with subparagraph 1, the FAMHP shall draw

up a minimum analytical reference for the relevant raw material in accordance with paragraph 3.
§3. When a limited-use raw material is not described in a reference referred to in paragraph 1 or 2, the FAMHP shall draw up a minimum analytical reference for the relevant raw material. The FAMHP may delegate the drafting of the monograph to a laboratory.
The Minister or his delegate shall approve the minimum analytical reference thus drawn up, on the advice of the Pharmacopoeia Commission and, where applicable, of the FAMHP, if the minimum analytical reference meets the criteria laid down by the King, in accordance with subparagraph 4.
The FAMHP publishes in the Belgian Pharmacopoeia the minimum analytical reference of the limited-use raw material, as soon as it is approved under subparagraph 2. The minimum analytical reference is used as an analytical reference for the limited-use raw material in question.
The King defines the criteria that a minimum analytical reference meets to be approved. The King can define different criteria according to the categories of raw materials that He defines. The King shall lay down the conditions, time limits and modalities of the procedure referred to in subparagraphs 1 and 2. The King may determine the cases in which the FAMHP gives its opinion, in accordance with paragraph 2.
Article 23. The King may lay down specific provisions applicable to limited-use raw materials and raw materials for which an

application for the award of status has been made in accordance with Article 19, subparagraph 1, and, where appropriate, exempt them from the application of certain provisions of this Law or exempt manufacturers, distributors and pharmacists from certain obligations relating to raw materials imposed by this Law in respect of them.
Chapter 3. Manufacturer provisions
Section 1. Authorisation to manufacture raw materials
Subsection 1. Procedure and requirements for granting a manufacturing authorisation for raw materials
Article 24, §1. The manufacture of raw materials is subject to an authorisation for the manufacture of raw materials, granted by the Minister or his delegate.
By way of exemption from subparagraph 1, the manufacture of limited-use raw materials shall not be subject to an authorisation to manufacture raw materials.
§2. The authorisation for the manufacture of raw materials shall be valid only for the premises indicated in the authorisation, as well as for the raw materials and the different presentations for which the authorisation has been granted.
Authorisation for the manufacture of raw materials may be accompanied, in order to ensure compliance with this Law and its implementing Decrees, by certain obligations imposed either on the occasion

of its grant or subsequent to its granting.
§3. The King shall determine the content of the application referred to in paragraph 1 and may determine the form of this application and the manner in which it is made, depending on whether the applicant is established in Belgium or in another Member State. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions, time limits and procedures for the examination of applications.
§4. Without prejudice to paragraph 3 or Article 48, the request referred to in paragraph 1 shall in any case contain the following personal data:
1° the surname, first name and professional contact details of a contact person for the FAMHP;
2° the name, first name and professional contact details of the person(s) responsible for the manufacture.
The purposes of the processing are to enable the FAMHP to identify and contact without delay the persons referred to in sub paragraph 1 in the event of a defect found or suspected by the FAMHP concerning the quality, safety or efficacy of a raw material.
The FAMHP is responsible for processing.
The FAMHP shall retain the personal data concerned 15 years after the manufacturer has notified a new contact person, the person responsible for the manufacture no longer performs this role or the manufacturer has ceased its activities.
The following have access to the data

referred to in paragraph 2:
1° members of the staff of the FAMHP who deal with authorisations for the manufacture of raw materials;
2° the FAMHP inspectors referred to in Article 51.
The King may specify the detailed rules for the application of this paragraph.
Article 25. In order to obtain an authorisation for the manufacture of raw materials, the applicant shall meet the following requirements:
1° be established in a Member State;
2° have a certificate of good manufacturing practice for active substances, as referred to in Article 12*a*(1), subparagraph 8 of the Law on Medicinal Products or Article 111(5) of Directive 2001/83/EC;
3° apply 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 for the manufacture of the raw materials referred to in this Law;
4° have one or more manufacturing managers who take over the release of each production lot in accordance with Article 30;
5° be able to comply with Article 31 and obligations under Article 33.
By way of exemption from subparagraph 1(1), the manufacturer may be established in a third country included in the list referred

to in Article 111*b*(1) of Directive 2001/83/EC, insofar as the raw materials for which he requires manufacturing authorisation form part of the products covered by the Mutual Recognition Agreement. In this case, by way of exemption from subparagraph 1(2) and (3), the manufacturer meets the equivalent application requirements in his country.
By way of exemption from subparagraph 1(2) and (3), the King may require, for the categories of raw materials that he defines, the possession of a certificate of good manufacturing practice for medicinal products, as referred to in Article 12*a*, §1, subparagraph 8 of the Law on Medicinal Products or in Article 111(5) of Directive 2001/83/EC and/or compliance with the principles and guidelines on good manufacturing practices for medicinal products laid down by the King in accordance with Article 12*a*, §1, subparagraph 11, of the Law on Medicinal Products or by Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to the principles and guidelines on good manufacturing practices for medicinal products for human use. The King may lay down specific provisions concerning the manufacturer referred to in subparagraph 2.
The King may set the conditions which must be met by the person(s) responsible for the manufacture referred to in subparagraph 1(4). The King may lay down specific provisions concerning the person(s) responsible for the manufacture of the manufacturer referred to in subparagraph 2.
Article 26. The Minister or his delegate

shall grant an authorisation for the manufacture of raw materials after having ascertained, where appropriate, by an inspection, that the information provided pursuant to Article 24(3) is accurate and provided that the conditions referred to in Article 25 and its implementing decrees are fulfilled.
The King shall determine the conditions, time limits and modalities of the inspection referred to in subparagraph 1.
When the Minister or his delegate intends not to grant the authorisation, in accordance with subparagraph 1, the applicant may request a hearing. The King shall lay down the modalities and procedures relating to the exercise of this right to be heard.
Article 27. Possession of an authorisation for the manufacture of raw materials entails the right to distribute the raw materials concerned by the manufacturing authorisation.
Subsection 2. Procedure and requirements for the modification of a raw material manufacturing authorisation
Article 28. The manufacturer shall submit an application to amend his authorisation for the manufacture of raw materials if he wishes to amend one of the constituent elements.
The King shall determine the content of the application for the modification of the authorisation referred to in subparagraph 1 and may determine the form of this application and the manner in which it is

made. The King shall lay down the procedures for the admissibility of the application. The King shall lay down the conditions, time limits and procedures for the examination of applications. The King can set different rules according to the types of changes that He determines.
The request referred to in subparagraph 1 shall contain, where appropriate, the personal data referred to in Article 24(4), where the latter are subject to an amendment. In this case, Article 24(4), subparagraphs 2 to 6, shall apply.
Article 29. The Minister or his delegate shall grant the authorisation for the manufacture of modified raw materials after having ascertained, where appropriate, by an inspection, that the information provided pursuant to Article 28, subparagraph 2, is accurate and provided that the conditions referred to in Article 25 and its implementing decrees are fulfilled.
When the Minister or his delegate intends not to grant the authorisation, in accordance with subparagraph 1, the applicant may request a hearing. The King shall lay down the modalities and procedures relating to the exercise of this right to be heard.
Subsection 3. Suspension or withdrawal of the authorisation for the manufacture of raw materials
Article 30, §1. In the event of failure to comply with the requirements of this Law or its implementing decrees, the Minister or the Minister's delegate may, in whole or in part, suspend or withdraw the authorisation for the manufacture of raw materials.

The Minister or his delegate shall notify the manufacturer of his proposal for a decision, unless immediate action is required for the protection of public health.
The manufacturer may submit his written comments to the Minister or his delegate.
In the absence of comments referred to in subparagraph 3, the proposed decision shall become final.
If the manufacturer submits comments under subparagraph 3, the Minister or his delegate confirms or does not confirm its decision to suspend or withdraw the authorisation to manufacture raw materials, in whole or in part.
§2. The Minister or his delegate shall withdraw the relevant manufacturing authorisation at the request of its holder.
§3. The King shall fix the time limits and may lay down the procedure and terms for the application of this Article.
Section 2. Prohibitions and obligations of manufacturers
Article 31. Manufacturers may not import raw materials from third countries unless they are bulks on the basis of which they manufacture the raw materials.
Article 32. The release of each production lot by a manufacturing manager is required.

Article 33. The King may lay down additional prohibitions and obligations to which manufacturers are bound in the exercise of their activities. The King may impose additional obligations on the manufacturer(s).
Article 34. If the manufacturer requests application of Article 27, he shall at the same time comply with Article 41 and the prohibitions and obligations laid down in Articles 42 and 43.
Chapter 4. Distributor provisions
Section 1. Authorisation for the distribution of raw materials
Subsection 1. Procedure and requirements for granting authorisation for the distribution of raw materials
Article 35, §1. The distribution of raw materials is subject to an authorisation for the distribution of raw materials, granted by the Minister or his delegate.
By way of exemption from subparagraph 1, the distribution of limited-use raw materials shall not be subject to an authorisation for the distribution of raw materials.
The wholesaler-distributor referred to in Article 1, §1(20) of the Law on Medicinal Products shall, for the purposes of this Law and its implementing decrees, be treated as the holder of an authorisation for the distribution of raw materials, as referred to in subparagraph 1.
§2. The authorisation for the distribution of

raw materials shall be valid only for the premises indicated in the authorisation, as well as for the raw materials for which the authorisation has been granted.
Authorisation for the distribution of raw materials may be accompanied, in order to ensure compliance with this Law and its implementing Decrees, by certain obligations imposed either on the occasion of its grant or subsequent to its granting.
§3. The King shall determine the content of the application referred to in paragraph 1, subparagraph 1, and may determine the form of such application and the manner in which it is made, depending on whether the applicant is established in Belgium or in another Member State. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions, time limits and procedures for the examination of applications.
When adopting the measures referred to in subparagraph 1, the King may provide for simplified procedures for wholesalers referred to in Article 12*b* of the Law on Medicinal Products or authorised pursuant to Article 77(1) of Directive 2001/83/EC.
§4. Without prejudice to paragraph 3 or Article 48, the request referred to in paragraph 1 shall in any case contain the following personal data:
1° the surname, first name and professional contact details of a contact person for the FAMHP;
2° the surname, first name and professional contact details of the person(s) responsible for the

distribution;
3° if the application for a distribution authorisation concerns a raw material whose manufacturer is established in another Member State and does not have an authorisation to manufacture raw materials in accordance with Article 24(1):
a. the data referred to in Article 48, subparagraph 1;
b. the name, first name and professional contact details of the person(s) responsible for the manufacture.
The purposes of the processing of personal data referred to in subparagraph 1(1) and (2), are to enable the FAMHP to identify and contact the data subjects without delay in the event of a defect found or suspected by the FAMHP concerning the quality, safety or effectiveness of a material. The purpose of the processing of personal data referred to in subparagraph 1 (3) is to verify that the manufacturer of the raw material concerned complies with the requirements of 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.
The FAMHP is responsible for processing.
The FAMHP retains the personal data referred to in subparagraph 1(1) and (2), 15 years after the distributor has notified a new contact person, that the person responsible

for the distribution no longer performs this role or that the distributor has ceased its activities. The FAMHP retains the personal data referred to in subparagraph 1(3), 15 years after the distributor has obtained the withdrawal of his authorisation to distribute the raw material of which the manufacturer is established in another Member State and does not have an authorisation to manufacture raw materials in accordance with Article 24(1), of the Raw Materials Law or the distributor has ceased its activities.
Have access to the data referred to in subparagraph 1:
1° FAMHP staff members dealing with authorisations for the distribution of raw materials;
2° the FAMHP inspectors referred to in Article 51.
The King may specify the detailed rules for the application of this paragraph.
Article 36, §1. In order to obtain an authorisation for the distribution of raw materials, the applicant shall meet the following requirements:
1° be established in a Member State;
2° have a certificate of good practice in the distribution of medicinal products, as referred to in Article 12*b*, §1, subparagraph 20 of the Law on Medicinal Products in Article 111(5) of Directive 2001/83/EC;
3° apply, for the distribution of raw materials, the principles and guidelines on good practice in the distribution of medicinal products, as referred to in Article 12*b*, §1, subparagraph 16, of the Law on

Medicinal Products or Article 46(f) of Directive 2001/83/EC;
4° have one or more distribution managers;
5° be able to comply with Article 41 and the obligations laid down in Articles 42 and 43.
The King may set the conditions that must be met by the person(s) responsible for the distribution referred to in subparagraph 1(4).
§2. In order to obtain an authorisation for the distribution of raw materials whose manufacturer is established in another Member State and does not have an authorisation to manufacture raw materials in accordance with Article 24(1), the applicant shall also demonstrate that the manufacturer of these raw materials complies with the requirements referred to in Articles 25, 31 and 32, as well as the requirements laid down pursuant to Article 33.
Article 37. The Minister or his delegate shall grant the authorisation for the distribution of raw materials after having ascertained, where appropriate, by an inspection, that the information provided pursuant to Article 35(3) is accurate and provided that the conditions referred to in Article 36 and its implementing decrees are fulfilled.
The King shall determine the conditions, time limits and modalities of the inspection referred to in subparagraph 1.
When the Minister or his delegate intends not to grant the authorisation, in accordance with subparagraph 1, the applicant may request a hearing. The King shall lay down

the modalities and procedures relating to the exercise of this right to be heard.
Subsection 2. Procedure and requirements for the modification of a raw material distribution authorisation
Article 38. The distributor shall submit an application to amend his authorisation for the distribution of raw materials if he wishes to amend one of the constituent elements.
The King shall determine the content of the application for the modification of the authorisation referred to in subparagraph 1 and may determine the form of this application and the manner in which it is made. The King shall lay down the rules on the admissibility of the application. The King shall lay down the conditions, time limits and procedures for the examination of applications. The King can set different rules according to the types of changes that He determines.
The request referred to in subparagraph 1 shall contain, where appropriate, the personal data referred to in Article 35(4), where the latter are subject to an amendment. In this case, Article 35(4), subparagraphs 2 to 6, shall apply.
Article 39. The Minister or his delegate shall grant the authorisation for the distribution of modified raw materials after having ascertained, where appropriate, by an inspection, that the information provided pursuant to Article 38 is accurate and provided that the conditions referred to in Article 36 and its implementing decrees are fulfilled.
When the Minister or his delegate intends

not to grant the authorisation, in accordance with subparagraph 1, the applicant may request a hearing. The King shall lay down the modalities and procedures relating to the exercise of this right to be heard.
Subsection 3. Suspension or withdrawal of the authorisation for the distribution of raw materials
Article 40, §1. In the event of failure to comply with the requirements of this Law or its implementing decrees, the Minister or the Minister's delegate may, in whole or in part, suspend or withdraw the authorisation for the distribution of raw materials.
The Minister or his delegate shall notify the distributor of his proposal for a decision, unless immediate action is required for the protection of public health.
The distributor may submit his written comments to the Minister or his delegate.
In the absence of comments referred to in subparagraph 3, the proposed decision shall become final.
If the distributor submits comments under subparagraph 3, the Minister or his delegate confirms or does not confirm its decision to suspend or withdraw the authorisation for the distribution of raw materials, in whole or in part.
§2. The Minister or his delegate shall withdraw the distribution authorisation concerned at the request of the holder.
§3. The King shall fix the time limits and may lay down the procedure and terms for the application of this Article.

Section 2. Prohibitions and obligations of distributors
Article 41. Distributors may not import raw materials from third countries.
Article 42. The King may lay down additional prohibitions and obligations to which distributors are bound in the exercise of their authorised activities. The King may impose obligations on the person(s) responsible for the distribution.
Article 43. The King may set public service obligations and may lay down the terms and conditions under which certain public service obligations may be imposed on distributors.
Chapter 5. Placing on the market of raw materials
Article 44. The raw material authorisation holder shall be responsible for placing raw materials on the market. The King may lay down obligations, terms and conditions relating to the placing on the market of raw materials.
Article 45. The raw material authorisation holder informs the FAMHP of the date of the effective placing on the market of the raw material, taking into account the different presentations allowed.
In the event of temporary or permanent cessation of the placing on the market of the raw material, the holder of the raw material authorisation shall notify the FAMHP, as

well as the reason for this cessation. Any notification indicating a manifestly inaccurate cause or duration or incomplete notification shall be treated as non-execution of the notification referred to in this subparagraph.
The raw material authorisation holder who has notified a temporary cessation of the placing on the market of a raw material shall notify the FAMHP of the return to the market of the raw material.
The King may lay down more detailed procedures for the application of the provisions of this Article. He may in particular define what is the temporary cessation of the placing on the market, how to notify the temporary or definitive cessation of the placing on the market, as well as the return to the market of the raw material, the time limit for doing so and the information to be notified. The King may empower the FAMHP to make recommendations, in the event of temporary or permanent cessation of the placing on the market of a raw material, and may lay down the modalities and procedure for the cessation of such recommendations.
Article 46. The King may lay down the procedure and conditions under which it may be decided to temporarily restrict or even prohibit, following a notified cessation or established in accordance with Article 43, subparagraph 2, the distribution of a raw material to other Member States.
Article 47. The holder of a raw material authorisation shall notify the FAMHP without delay of any action he has taken to suspend the placing on the market of a raw material or withdraw the raw material from

the market, indicating the reasons for such action. The King may lay down more detailed procedures for the application of this Article.
Chapter 6. Processing of personal data in connection with requests, submissions and notifications established by this Law
Article 48. The requests, submissions and notifications referred to in Articles 6, 8, 12, 14, 16, 19, 24, 28, 35 and 38 shall contain the following personal data:
1° the name of the applicant, in the case of a legal person;
2° the name and first name of the applicant, in the case of a natural person;
3° the company number assigned in accordance with Article III.22 of the Code of Economic Law or its registration number in the register referred to in 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;
4° the applicant's professional contact data.
The purposes of the processing are the processing of requests, submissions and notifications by the FAMHP, the granting of the authorisations concerned by the Minister or his delegate and, where appropriate, the control of the activities authorised by the FAMHP.
The FAMHP is responsible for processing.

The FAMHP retains the personal data concerned 15 years after the end of the authorisations related to the requests, submissions and notifications referred to in subparagraph 1. The FAMHP deletes the data referred to in subparagraph 1 one year after the initial application for authorisation has been rejected.
Have access to the personal data referred to in subparagraph 1:
1° FAMHP staff members dealing with requests, submissions and notifications referred to in subparagraph 1 and related authorisations;
2° the FAMHP inspectors referred to in Article 51.
The King may specify the detailed rules for the application of this paragraph.
Chapter 7. Provisions relating to the pharmacist
Article 49. The pharmacist obtains the raw materials only from manufacturers and distributors.
By way of exemption from subparagraph 1, the King may provide for the cases in which the pharmacist may obtain raw materials from suppliers other than those referred to in subparagraph 1 and the conditions related thereto.
Article 50. The King may lay down the conditions and procedures for the supply, receipt and preservation of raw materials by pharmacists.

The King may also lay down the procedures for the administrative tasks to be performed by pharmacists and determine the administrative data relating to the raw materials, which they must keep.
Chapter 8. Publication of elements relating to raw materials on the FAMHP website
Article 51, §1. The FAMHP shall publish at least the following on its website:
1° the Belgian Pharmacopoeia and the list drawn up by the King of Official Pharmacopoeia corresponding to the current state of scientific knowledge respectively, referred to in Article 11(1), subparagraph 2(2);
2° raw materials authorised in accordance with Article 13 and their analytical reference, as well as information on whether or not they are placed on the market, in accordance with the notifications received pursuant to subparagraphs 1 to 3 of Article 45;
3° limited-use raw materials;
4° manufacturers;
5° distributors.
The King may require the publication of other elements on the FAMHP website.
§2. The categories of personal data published in accordance with paragraph 1(4) and (5) are:
1° the name, in the case of a legal person;

2° the surname and first name, in the case of a natural person;
3° the company number assigned in accordance with Article III.22 of the Code of Economic Law or its registration number in the register referred to in 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;
4° professional contact data.
The purpose of the processing is the advertising of manufacturers and distributors authorised by the FAMHP to carry out their activities in order to allow pharmacists to acquaint themselves with authorised manufacturers and distributors, to verify the origin of raw materials delivered and to be able to contact them about the raw materials in case of question or problem.
The FAMHP is responsible for processing.
The data referred to in subparagraph 1 shall be deleted from the FAMHP website within one month of the FAMHP becoming aware that the manufacturer or distributor concerned has ceased its activities.
The King may specify the detailed rules for the application of this paragraph.
Chapter 9. Inspection, control and sanctions
Article 52. Without prejudice to the powers of judicial police officers, statutory members of the staff or, failing that, members of staff engaged in the links of a

permanent employment contract, of the FAMHP, designated for this purpose by the King, shall monitor the application of this Law and its implementing decrees, by carrying out inspections, if necessary unannounced.
The staff members referred to in subparagraph 1 shall take an oath, prior to the performance of their duties, within the hands of the Minister or his delegate.
Article 53. Inspections carried out pursuant to this Law shall be carried out in accordance with the procedures laid down in Articles 14, §§ 2 to 4, 14*a* and 15(4), of the Law on Medicinal Products.
The members of staff referred to in Article 52 shall have, in the exercise of their tasks referred to in Article 52 and subparagraph 1, the powers of inspection referred to in Articles 14, §§ 1 to 4, 14*a* and 15(4), of the Law on Medicinal Products.
Opposition to the exercise of the inspection referred to in subparagraph 1 or the powers referred to in subparagraph 2 shall constitute grounds for withdrawal or suspension of the authorisations referred to in Article 24(1), subparagraph 1, and Article 35(1), subparagraph 1.
Article 54. If the raw materials are found damaged, altered, expired, falsified, imitated or not in conformity with the provisions of this Law or its implementing decrees, the person who placed them on the market shall be obliged to withdraw from the market, at his own expense, these raw materials or the lot concerned within the period specified in the notification of the finding, and at the latest within one month of such notification,

and to keep them at the disposal of the FAMHP. He may not object to their immediate removal by the persons referred to in Article 52, subparagraph 1.
The King may lay down the procedures for the application of this Article.
Article 55. Without prejudice to the application of penalties provided for in other laws and, where appropriate, to the application of disciplinary sanctions, shall be punishable by imprisonment of one month to two years and a fine of EUR 25 to EUR 250,000, or by one of those penalties only:
1° a person who contravenes Articles 11(1), subparagraph 1(24), §1, subparagraph 1(24), §2, subparagraph 2, 31, 32, 33, 34, 35, §1, subparagraph 1, 35(2), subparagraph 2, 41, 42, 43, 44, 45, subparagraphs 1, 2 and 3, 46, 47, 49, , 50 or their implementing decrees;
2° a person who buys, owns, sells, offers for sale, delivers, delivers, distributes, supplies, imports or exports raw materials damaged, altered, expired, falsified or imitated and raw materials which do not comply with the provisions of this Law or its implementing decrees;
3° a person who has falsified, imitated, falsified or imitated raw materials that are intended to be sold, offered for sale, delivered, provided, distributed, supplied, imported or exported.
Article 56. All provisions of Book 1 of the Penal Code, with the exception of Chapter

V, but including Chapter VII and Article 85, shall apply to offences provided for in this Law and its implementing decrees.
Article 57. An attempt to commit an offence provided for in this Law or its implementing decrees shall be punishable by the same penalty as that applicable to the offence itself.
Article 58. The penalties for the offences provided for in Article 55 shall be doubled if these offences:
1° have caused the death or harm to the patient's physical or mental health;
2° have been committed by a person abusing his trust as a health professional, manufacturer or distributor;
3° in respect of infringements of distribution or issue, or offer of distribution or delivery, have been committed by means of large-scale dissemination processes, such as computerised systems, including the Internet;
4° were committed as part of a criminal organisation;
Article 59. In the event of a repeat offence within 3 years of a conviction on the ground of an infringement of the provisions referred to in Article 55, the penalty may be doubled.
Without prejudice to Articles 57*a* and 99*a* of the Criminal Code, previous final convictions for crimes, offences or contraventions by the criminal courts of

another State party to the Council of Europe Convention on the counterfeiting of medical products and similar offences threatening public health, made in Moscow on 28 October 2011, shall be taken into account under the same conditions as convictions handed down by Belgian criminal courts for the offences referred to in Article 55, and shall produce the same legal effects as such convictions.
Article 60. Notwithstanding Articles 42 to 43*c* of the Penal Code, the judge may order the special confiscation of falsified, counterfeit, corrupt, altered or non-compliant raw materials.
Article 61. Article 17, §§1 to 5 and 8 of the Law on Medicinal Products applies to the offences referred to in Article 55.
Chapter 10. Transitional provisions
Article 62, §1. Monographs 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 retail pharmacists shall be treated as monographs approved in accordance with Article 7.
The King shall set the time limit within which 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 retail pharmacists, the approval or last amendment of which is 5 or more years ago before the entry into force of this Law, shall update it in

accordance with Article 8 or carry out a reasoned assessment of his monograph and submit a request for approval of the report of that assessment to the FAMHP in accordance with Article 9.
§2. Authorisations for raw materials granted in accordance with subparagraph 3 of Article 3(2) of the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by retail pharmacists shall be treated as raw material authorisations granted in accordance with Article 13.
The King shall set the time limit within which the holder of the authorisation of raw materials granted in accordance with Article 3(2), subparagraph 3 of the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by retail pharmacists and which is not authorised according to the analytical reference with the highest level of authority in accordance with Article 11(1), subparagraph 2, makes an application to amend its authorisation in accordance with Article 14, subparagraph 1(2) or an application not to modify its authorisation, in accordance with Article 14, subparagraph 2.
§3. Authorisations to manufacture and import raw materials to retail pharmacists, as referred to in Article 6(1) and (2), of the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by retail pharmacists, shall be treated as authorisations for the manufacture of raw materials referred to in Article 24(1), subparagraph 1.
§4. Authorisations to supply raw materials to retail pharmacists, as referred to in Article 6(1), of the Royal Decree of 19 December

1997 on the control and analysis of raw materials used by retail pharmacists, shall be treated as authorisations for the distribution of raw materials referred to in Article 35(1), subparagraph 1.
Article 63, §1. By way of exemption from Article 11(1), subparagraph 1, raw materials not having a raw material authorisation as referred to in Article 13 may be placed on the market for a period fixed by the King after the entry into force of this Law. The King may set different periods according to the categories of raw material, analytical references and suppliers of the raw materials that He defines.
The manufacturer shall ensure that its certificate of analysis accompanies each container containing the raw material referred to in subparagraph 1, and the distributor shall ensure that it is present. This certificate of analysis shall be issued by a laboratory demonstrating its impartiality vis-à-vis the manufacturer of the raw material concerned.
The pharmacist may use a raw material as referred to in subparagraph 1 only to make a magistral preparation.
§2. Raw materials placed on the market in accordance with subparagraph 1 shall not be taken into account for the purposes of Article 18, subparagraph 1(2).
Article 45 shall not apply to the raw materials referred to in subparagraph 1.
Article 64. By way of exemption from Article 11(1), subparagraph 1, Article 49, subparagraph 1 and Article 63, the pharmacist may use a raw material which

does not have a raw material authorisation as referred to in Article 13 and which is not accompanied by a certificate of analysis, whether supplied by a manufacturer, distributor or other supplier, subject to the following conditions:
1° the pharmacist shall submit an application for the award of the status of a limited-use raw material to the FAMHP in accordance with Article 19, within the time limit to be fixed by the King, unless another pharmacist has made such an application;
2° the pharmacist delegates the analysis of the raw material to a laboratory which provides him with the certificate of analysis;
3° the pharmacist uses the raw material concerned only for the making of magistral preparations;
4° the pharmacist shall use the raw material concerned only:
a. until the decision of the Minister or his delegate in accordance with Article 20 if the raw material concerned is described in one or more analytical references referred to in Article 11, subparagraph 2(1) to (3), in accordance with Article 22(1), or if the Minister or his delegate refuses to award status as a limited-use raw material;
b. until approval of the monograph in accordance with Article 7, if the raw material concerned was the subject of a monograph in accordance with Article 22(2),

subparagraph 1;
c. until the publication of the minimum analytical reference in the Belgian Pharmacopoeia, in accordance with Article 22(3), subparagraph 3, when the raw material concerned was not described in a reference referred to in Article 22(1) or (2).
Article 65. The website on raw materials referred to in Article 51(1), contains for 5 years after the longest period fixed by the King referred to in Article 63(1), subparagraph 1, the list of laboratories.
The categories of personal data published in accordance with subparagraph 1 are:
1° the name, in the case of a legal person;
2° the surname and first name, in the case of a natural person;
3° the company number assigned in accordance with Article III.22 of the Code of Economic Law or its registration number in the register referred to in 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;
4° professional contact data.
The purpose of the processing is the advertising of laboratories in order to enable pharmacists to ensure that the certificate of analysis of raw materials which does not

have an authorisation as referred to in Article 13 indeed originates from a laboratory within the meaning of this Law.
The FAMHP is responsible for processing.
The data referred to in subparagraph 1 shall be deleted from the web portal within one month of the FAMHP becoming aware that the laboratory concerned has ceased its activities.
The King may specify the detailed rules for the application of this paragraph.
Article 66. The King may lay down the conditions, procedures and measures necessary for the execution of Articles 62 to 65.
Chapter 11. Amending provisions
Article 67. Article 4(1), subparagraph 3(6) (a), of the Law of 20 July 2006 on the creation and operation of the Federal Agency for Medicines and Health Products, as last amended by the Law of 8 February 2022, is supplemented by an indent, worded as follows:
"- The law of xx.xx.xxxx relative to raw materials used by pharmacists."
Article 68. In Article 12/3 subparagraph 1(3), of the same Law, inserted by the Law of xx.xx.xxxx, the words "the Royal Decree of 19 December 1997 on the control and analysis of raw materials used by retail pharmacists" are replaced by the words "the Law of xx.xx.xxxx on raw materials used by pharmacists".

Article 69. In Annex III to that Law, inserted by the Law of 11 March 2018, the following amendments are made:
(1) in III.4, the words “holder of general authorisation for the distribution of raw materials” are replaced by the words “distributor of raw materials, as referred to in Article 2(14), of the Law of xx.xx.xxxx relating to raw materials used by pharmacists”;
(2) in III.5, the words “holder of general authorisation for the manufacture of raw materials” are replaced by the words “manufacturer of raw materials, as referred to in Article 2(12), of the Law of xx.xx.xxxx relating to raw materials used by pharmacists”.
Article 70. In Annex VII to the same Law, inserted by the Law of 11 March 2018 and replaced by the Law of 7 April 2019, the following amendments are made:
1° Title 1, Chapter 12 is repealed;
2° a Title 14 is inserted, entitled: “ Fees for the application of the Law of ... on raw materials used by pharmacists (hereinafter: “ Law on Raw Materials”)”;
3° in Title 14, inserted by (2), a table is inserted, which is annexed to this Law.
Chapter 12. Entry into force
Article 71. This Law shall enter into force on a date to be fixed by the King and no later than 18 months after its publication in the Moniteur belge.
Issued

By the King:
The Minister for Public Health,
Frank VANDENBROUCKE

Annex to the Law of ... on raw materials used by pharmacists

Generating event	**Liable**	**Amount**
VII.1.12.1		
Validation of a request to review a new monograph, in accordance with Article 6, subparagraph 3, of the Law on Raw Materials, or a revised monograph, in accordance with Article 8(3) of the Law on Raw Materials, for a raw material that is not described in a pharmacopoeia.	The applicant	EUR 198
VII.1.12.2		
Evaluation of a request to review a new monograph, in accordance with Article 6, subparagraph 2, of the Law on Raw Materials, or an amended monograph, in accordance with Article 8, subparagraph 1, of the Law on Raw Materials, for a raw material that is not described in a pharmacopoeia, requiring laboratory analysis.	The applicant	EUR 5,422.10 EUR 2,711.05 in the year of application and EUR 2,711.05 in the following year
VII.1.12.3		
Evaluation of a request for examination of a modified monograph, in accordance with Article 8, subparagraph 1, of the Law on Raw Materials, for a raw material which is not described in a pharmacopoeia, which does not require laboratory analysis.	The applicant	If the request is made in the first half of the current year: EUR 2,600.49 EUR 1,950.37 in the year of application and EUR 650.12 in the following year If the request is made in the second half of the current year: EUR 2,600.49 EUR 650.12 in the year of application and EUR 1,950.37 in

		the following year
VII.1.12.4		
Submission of the report of the reasoned assessment of the approved monograph, pursuant to Article 9 of the Law on Raw Materials.	The holder(s) of the monograph	EUR 198
VII.1.12.5		
Application for authorisation or modification of an authorisation of a raw material manufactured in Belgium or in another Member State, in accordance with Articles 12 and 14 of the Law on Raw Materials.	The applicant	EUR 93
VII.1.12.6		
Application for a manufacturing authorisation, in accordance with Article 24(1), of the Law on Raw Materials.	The applicant	EUR 6,572
VII.1.12.7		
Application for an authorisation for the distribution of raw materials not manufactured by the applicant, manufactured in Belgium and/or in another Member State, in accordance with Article 35(1) of the Law on Raw Materials.	The applicant	EUR 5,822

Seen to be annexed to the law- of ...

BY THE KING:

The Minister for Public Health,

Frank VANDENBROUCKE