**KINGDOM OF BELGIUM**
**----------**

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

**Royal Decree amending the Royal Decree, of 9 October 2017, implementing the Law, of 7 May 2017, on clinical trials of medicines for human use**

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

Having regard to the Law, of 7 May 2017, on clinical trials of medicines for human use, Articles 39 and 40/1, inserted by the Law, of 11 July 2023;

Having regard to the Royal Decree, of 9 October 2017, implementing the Law, of 7 May 2017, on clinical trials of medicines for human use;

Having regard to the communication to the European Commission on 12 March 2026, pursuant to Article 5, Paragraph 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 18 November 2025;

Having regard to Opinion No xx.xxxx/x of the Council of State, given on xx/xx/xxxx, pursuant to Article 84, Section 1, Paragraph 1, Point 2, of the Laws on the Council of State, consolidated on 12 January 1973;

On the proposal of the Minister for Public Health,

WE HAVE DECREED AND HEREBY DECREE:

**Article 1.** Article 43 of the Royal Decree, of 9 October 2017, implementing the Law, of 7 May 2017, on clinical trials on medicines for human use, as amended by the Decrees, of 3 November 2019, and 23 November 2023, is repealed.

**Article 2.** In Article 44, Paragraph 2, of the same decree, the words ‘Points 1 and 3’ are replaced by the words ‘Points 1 and 2’.

**Article 3.** In the same decree, a Chapter 5/1, comprising Articles 44/1 to 44/11, is inserted, worded as follows:

**‘Chapter 5/1. Distribution of investigational medicinal products, unauthorised auxiliary medicinal products and authorised auxiliary medicinal products that are undergoing a modification not covered by a marketing authorisation**

**Art. 44/1.** This chapter applies only to actors who wish to carry out or who carry out distribution activities of investigational medicinal products, unauthorised auxiliary medicinal products and authorised auxiliary medicinal products that are undergoing a modification not covered by a marketing authorisation, established in Belgium.

By way of derogation from Paragraph 1, Articles 44/2, Section 2, Paragraph 1, 44/6, 44/7, Section 1, Paragraph 1, Points 1 to 5 and 7 to 11, and Section 2, Paragraph 1, Points 1 and 2, and 4 to 7, 44/8, 44/10, Section 3, and 44/11, also apply to actors established solely in one (or more) other Member State(s) who wish to carry out or who carry out distribution activities, as referred to in this chapter, in Belgium, without a Belgian establishment of the actor being involved. When the Belgian establishment carries out distribution activities as above, this establishment is considered an actor as referred to in Paragraph 1.

**Article 44/2. Section 1.** Possession of a manufacturing or import authorisation referred to in Article 38 of the law entails the right to distribute the types and pharmaceutical forms of medicinal products concerned by this authorisation. The fact that the holder carries out both activities is also indicated on the authorisation referred to in Article 38 of the law, with regard to actors established in Belgium.

The data relating to the manufacturing or import authorisation are entered by the FAMHP (Federal Agency for Medicines and Health Products) into the European Union database referred to in Article 12a, Section 1, Paragraph 7, of the Law, of 25 March 1964, on medicines for human use. At the request of the European Commission or another Member State, all relevant data relating to the manufacturing or import authorisation are transmitted.

**Section 2.** The distribution of investigational medicinal products, unauthorised auxiliary medicinal products and authorised auxiliary medicinal products that are undergoing a modification not covered by a marketing authorisation by a distributor other than the holder of the manufacturing or import authorisation referred to in Article 38 of the law shall be limited to the storage of those medicinal products, on the order of the sponsor, settled by contract.

The distribution referred to in Paragraph 1 shall be subject to authorisation. This authorisation shall be valid only for the premises located in the Belgian territory indicated therein.

**Article 44/3.** In order to obtain the authorisation referred to in Article 44/2, Section 2, Paragraph 2, or in the event of an application by the authorisation holder to amend one of the elements referred to in Point 1, the applicant must meet at least the following requirements:

1° have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;

2° have qualified staff and a person with the qualification referred to in Article 95, Section 2, of the Royal Decree, of 14 December 2006, concerning medicines for human use, who assume the responsibility to;

| |
|---|
| 3° comply with the obligations incumbent upon them under Article 44/6. |
| The application must be submitted to the Minister or their delegate using the forms established by the FAMHP and must include supporting information concerning the requirements referred to in Paragraph 1. The application also specifies the types and pharmaceutical forms of medicinal products that the applicant wishes to distribute. |
| |
| **Article 44/4.** In the event of an application for the authorisation referred to in Article 44/2, Section 2, Paragraph 2, the Minister or their delegate shall communicate their decision to grant the authorisation or their intention to refuse it to the applicant within ninety days of the submission of a valid application. |
| In the event of an application by the authorisation holder to modify one of the elements referred to in Article 44/3, Paragraph 1, Point 1, the Minister or their delegate shall communicate their decision to grant the modification of the authorisation or their intention to refuse it to the applicant within ninety days of the submission of a valid application. |
| The person referred to in Article 44/8, Paragraph 2, shall inform the applicant of the date on which the time limit referred to in Paragraph 1 or 2 begins, as soon as it is established that the application contains all the information required under Article 44/3, Paragraph 2. |
| |
| **Article 44/5.** The Minister or their delegate may require the applicant to provide additional information concerning the information provided pursuant to Article 44/3, Paragraph 2, as well as concerning the responsible person referred to in Article 44/3, Paragraph 1, Point 2. When the Minister or their delegate exercises this power, the time limits referred to in Article 44/4, Paragraph 1 or 2, shall be suspended until the required additional information is provided. |
| |
| **Article 44/6.** The holder of a manufacturing or import authorisation in accordance with Article 61 of the Regulation or the distributor, established in another Member State, who holds an authorisation for the distribution of investigational medicinal products, unauthorised auxiliary medicinal products and authorised auxiliary medicinal products that are undergoing a modification not covered by a marketing authorisation, equivalent to the distribution authorisation referred to in Article 44/2, Section 2, Paragraph 2, or who has the right to carry out its distribution activity in the Member State in which it is established, who wishes to carry out distribution activities of the medicinal products concerned in Belgium within the meaning of this decree, shall notify the FAMHP before commencing its activities. |
| The notification referred to in Paragraph 1 is submitted electronically, using the form available on the AFMPS website. The notification shall contain the following elements: |
| 1° either a copy of the distribution authorisation declared compliant by the competent authority of the Member State in which the actor concerned is established, or a declaration from the competent authority of the Member State attesting that the actor concerned has the right to carry out this distribution activity in its territory; |
| 2° a telephone number and an email address where the person concerned can be |

| |
|---|
| reached at all times, in case of emergency; |
| 3° the declaration by the actor concerned that it will comply with the requirements applicable to it in accordance with Article 44/7, Section 1, Paragraph 2 and 44/12, Section 1, Paragraph 2, if it holds an authorisation to manufacture or import in accordance with Article 61 of the Regulation, or Articles 44/7, Section 2, Paragraph 2 and 44/12, Section 2, Paragraph 2, if it is a distributor. |
| If the data is incomplete or incorrect, the actor concerned cannot carry out distribution activities in Belgium. If the actor concerned nevertheless carries out such activities, Article 44/10, Section 3, shall be applied. |
| |
| **Article 44/7. Section 1.** The holder of the manufacturing or import authorisation referred to in Article 38 of the law, shall comply with the following obligations in the context of its distribution activities: |
| 1° have suitable and sufficient premises, facilities, and equipment to ensure the proper storage and distribution of medicinal products; |
| 2° have qualified staff and a qualified person, as referred to in Article 61, Paragraph 2, Letter b), of the regulation, who assume the responsibility to; |
| 3° make the premises, facilities and equipment referred to in Point 1 accessible at all times to the persons referred to in Article 42, Section 1, Paragraph 1, of the law; |
| 4° obtain medicinal products only from other holders of authorisation to manufacture or import, referred to in Article 38 of the law or in accordance with Article 61 of the regulation, of these medicinal products, of which it verifies that it holds an authorisation, or from holders of authorisation for distribution, referred to in Article 44/1, Section 2, Paragraph 2, or from distributors established in other Member States, of which it verifies that they hold an authorisation or the right to carry out their distribution activity under the regulations of that Member State; |
| 5° deliver medicinal products only to the persons referred to in Article 44/11, Paragraph 1; |
| 6° by way of derogation from Point 5, where the medicinal products are intended for another Member State, deliver the medicinal products only to holders of an authorisation granted by the competent authority of that Member State or to persons authorised for this purpose under the regulations of that Member State; |
| 7° ensure that the qualified person, as referred to in Article 61, Paragraph 2, Letter b) of the regulation, is present during distribution activities; if these activities are carried out on a part-time basis, their working hours must be declared precisely; where there are several distribution points, the working hours must be declared for each distribution point; the attendance schedule must ensure that the qualified person can fulfil their tasks and responsibilities, taking into account the importance of the distribution activity; |

| |
|---|
| |
| 8° maintain and make available to the FAMHP, for a period of twenty-five years, documentation for every incoming and outgoing transaction, whether or not it involves a payment. The documentation shall include at least the following records: |
| a) the date; |
| b) the name of the medicinal product; |
| 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 medicinal products or the code identifying the contents and the packaging operation and the information identifying the medicinal product; |
| f) for unauthorised investigational medicinal products, unauthorised auxiliary medicinal products, authorised investigational medicinal products and authorised auxiliary medicinal products that are labelled in accordance with Article 66, Paragraph 1, of the regulation, the participant identification number and/or treatment number and, where applicable, the visit number, and, for authorised investigational medicinal products and authorised auxiliary medicinal products that are labelled in accordance with Article 67, Paragraph 1, Letter b), and Paragraph 2, of the regulation, the clinical trial reference code enabling identification of the clinical trial site, the investigator, the sponsor and the participant, if it is included on the labelling; |
| 9° produce, at the request of the FAMHP (Federal Agency for Medicines and Health Products), a statement of the quantities of medicinal products delivered, broken down by product and by recipient, for a period determined by the FAMHP, provided that this period does not exceed five years; |
| 10° comply with the Introduction, Chapters 1 to 4, Point 5.1, Paragraphs 1 and 4, and 5.4, Paragraphs 1 and 2, and 5.5 to 5.8, as well as Chapters 6 to 9 of the principles and guidelines concerning good distribution practices provided for in Annex V of the Royal Decree, of 14 December 2006, relating to medicines for human use; |
| 10° provide the FAMHP, in case of emergency, with a telephone number and an email address at which the authorisation holder can be contacted at all times; |
| 12° maintain a quality system establishing the responsibilities, procedures, and risk management measures related to its activities. |
| |
| Section 2. A distributor other than the holder of the manufacturing or import authorisation referred to in Article 38 of the law must comply with the following obligations in the context of its distribution activities: |

1° comply with the obligations referred to in Paragraph 1, Points 3 and 8 to 12;

2° deliver medicinal products only to the persons referred to in Article 44/11, Section 2, Paragraph 1, on the order of the sponsor, settled by contract;

3° by way of derogation from Point 2, where the medicinal products are intended for another Member State, deliver the medicinal products, on the order of the sponsor, as stipulated in a contract, only to persons holding an authorisation granted by the competent authority of that Member State or to persons authorised for this purpose under the regulations of that Member State.

4° procure medicinal products only from the holder of the manufacturing or import authorisation, referred to in Article 38 of the law or in accordance with Article 61 of the regulation, for those medicinal products, whose authorisation they verify, on the order of the sponsor, settled by contract;

5° ensure that the responsible person referred to in Article 44/3, Paragraph 1, Point 2, is present during distribution activities; if these duties are performed on a part-time basis, their schedule must be precisely declared; if there are several distribution points, the schedule must be declared for each distribution point; the attendance schedule must ensure that the responsible persons can fulfil their tasks and responsibilities, taking into account the volume of the distribution activity;

6° 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 manufacturer or the marketing authorisation holder of the medicinal product concerned;

7° inform the Minister or their delegate at least fifteen days before any change they wish to make to any of the information provided pursuant to Article 44/3, Paragraph 1; however, the Minister or their delegate must be informed without delay in the event of an unforeseen replacement of the responsible person referred to in Article 44/3, Paragraph 1, Point 2.

**Article 44/8.** The inspection of the accuracy of the data provided, as referred to in Article 44/3, Paragraph 2, and of compliance with the principles and guidelines of good distribution practices referred to in Article 44/6, Section 1, Point 9, is carried out by the persons referred to in Article 42, Section 1, Paragraph 1, of the law. These persons may be accompanied by experts designated for this purpose by the Minister or their delegate.

The Minister or their delegate shall appoint one of the persons referred to in Article 42, Section 1, Paragraph 1, of the law, of the direction of the investigation.

A report including reasoned conclusions is drawn up based on this inspection. The person referred to in Paragraph 2 shall communicate the report to the Minister or their delegate.

**Article 44/9.** The Minister or their delegate shall attach a copy of the report referred to in Article 44/8, Paragraph 3, to the decision or intention to decide referred to in Article 44/4, Paragraphs 1 and 2, respectively.

| |
|---|
| If the Minister or their delegate intends to refuse the authorisation or the modification of the authorisation, the applicant may present its arguments within fifteen days of receiving the intention to decide from the Minister or their delegate. Failing that, the decision shall become final on expiry of this period. The Minister or their delegate makes a decision within ninety days of receiving the applicant's arguments. |
| Information relating to the authorisation referred to in Article 44/2, Section 2, Paragraph 2, shall be entered into the European Union database referred to in Article 12*a*, Section 1, Paragraph 7, of the Law, of 25 March 1964, on medicines for human use. At the request of the European Commission or another Member State, all relevant data relating to the individual authorisation referred to in Article 44/2, Section 2, Paragraph 2, shall be transmitted. |
| |
| **Article 44/10. Section 1.** If it appears that the holder of the authorisation referred to in Article 44/2, Section 2, Paragraph 2, no longer meets the obligations of this chapter, the Minister or their delegate may suspend or withdraw the authorisation, in whole or in part. They shall inform the holder of the authorisation of their intention to suspend or cancel. The holder of the authorisation may present its arguments within fifteen days of receiving the draft decision from the Minister or their delegate. Failing that, the decision shall become final on expiry of this period. The Minister or their delegate makes a decision within ninety days of receiving the applicant's arguments. |
| The data relating to the suspension and withdrawal are entered by the FAMHP into the European Union database referred to in Article 12*a*, Section 1, Paragraph 7, of the Law, of 25 March 1964, on medicines for human use. At the request of the European Commission or another Member State, all relevant data relating to the authorisation referred to in Paragraph 1 are transmitted. |
| **Section 2.** If it appears that the holder of the manufacturing or import authorisation referred to in Article 38 of the law no longer meets the obligations of this chapter, the Minister or their delegate may suspend the holder's right to distribute the medicinal products that are covered under this authorisation, in whole or in part. The FAMHP informs the authorisation holder of its intention to suspend the authorisation. The holder may submit its arguments within fifteen days of receiving the intention to decide from the Minister or their delegate. Otherwise, the decision becomes final upon expiry of this period. The Minister or their delegate makes a decision within ninety days of receiving the applicant's arguments. |
| The data relating to the suspension and withdrawal are entered by the FAMHP into the European Union database referred to in Article 12a, Section 1, Paragraph 7, of the Law, of 25 March 1964, on medicines for human use. At the request of the European Commission or another Member State, all relevant data relating to the authorisation referred to in Paragraph 1 are transmitted. |
| **Section 3.** By way of derogation from Article 44/1, if it appears that the holder of a manufacturing or import authorisation or the distributor referred to in Article 44/6, Paragraph 1, who having made a notification in accordance with this article and carrying out distribution activities in Belgium, does not meet the obligations of this chapter, the |

| |
|---|
| Minister or their delegate may suspend the right of the holder of the manufacturing or import authorisation or the distributor to distribute the medicinal products concerned, in whole or in part. They inform the holder of the manufacturing or import authorisation or the distributor of their intention to suspend. The holder of the manufacturing or import authorisation or the distributor may present their arguments within fifteen days of receiving the intention to decide from the Minister or their delegate. Failing that, the decision shall become final on expiry of this period. The Minister or their delegate makes a decision within ninety days of receiving the applicant's arguments. |
| |
| **Article 44/11.** The holder of the manufacturing or import authorisation referred to in Article 38 of the law shall distribute investigational medicinal products, unauthorised auxiliary medicinal products and authorised auxiliary medicinal products that are undergoing a modification not covered by a marketing authorisation only to: |
| 1° other holders of a manufacturing or import authorisation referred to in Article 38 of the law or in accordance with Article 61 of the regulation; |
| 2° holders of the authorisation for distribution, referred to in Article 44/2, Section 2, Paragraph 2, or distributors established in other Member States, acting on the order of the sponsor, settled by contract; |
| 3° hospital pharmacies that are involved in the clinical trial in which the medicinal product is used; |
| 4° pharmacies open to the public that are involved in the clinical trial in which the medicinal product is used; |
| 5° investigators who are involved in the clinical trial in which the medicinal product is used. |
| |
| The holder of the authorisation for distribution, referred to in Article 44/2, Section 2, Paragraph 2, shall only deliver investigational medicinal products, unauthorised auxiliary medicinal products and authorised auxiliary medicinal products that are undergoing a modification not covered within the scope of a marketing authorisation, on the order of the sponsor, settled by contract, to the persons referred to in Paragraph 1, Points 1 and 3 to 5. |
| |
| |
| **Article 4.** The Minister for Public Health shall be responsible for the implementation of this decree. |
| |
| Signed in …, on … |
| By the King: |

| |
|---|
| |
| The Minister for Public Health, |
| |
| Frank VANDENBROUCKE |