KINGDOM OF BELGIUM

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Royal Decree amending Royal Decree of 14 December 2006 on medicinal products for human use and Royal Decree of 9 October 2017 implementing the Law of 7 May 2017 on clinical trials of medicinal products for human use

PHILIPPE, King of the Belgians,

To all those present and to those to come, greetings.

Having regard to the Law of 25 March 1964 on medicinal products for human use (Article 6-*septies*, § 2, subparagraph 6);

Having regard to the Law of 7 May 2017 on clinical trials of medicinal products for human use, Article 40/2 § 4, inserted by the Law of xx/xx/ xxxx;

Having regard to Royal Decree of 14 December 2006 on medicinal products for human use;

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

Having regard to the communication to the European Commission on xx/xx/xxxx, in accordance with Article 5(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the opinion of the Finance Inspectorate, issued on xx/xx/2025;

Having regard to Opinion No xx.xxxx/x of the Council of State, given on xx/xx/xxxx, pursuant to Article 84, § 1, subparagraph 1(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. In the Decree of 9 October 2017 implementing the Law of 7 May 2017 on clinical trials of medicinal products for human use, as amended by the Decrees of 3 November 2019 and 23 November 2023, Chapter 5/2 is inserted, comprising Articles 44/11 and 44/12, worded as follows:

‘Chapter **5/2. Dispensing of investigational medicinal products and auxiliary medicinal products**

Article 44/11. Investigational medicinal products and auxiliary medicinal products, in

accordance with Article 40/2, § 1, subparagraph 1(3) of the Law, may only be dispensed after the pharmacist who is the licence holder/owner has received the appropriate training from the sponsor.

Dispensing carried out by a deputy or replacement pharmacist, in accordance with Article 40/2, § 1(3) of the Law, shall take place under the responsibility of the pharmacist who is the licence holder/owner, after having received training from that pharmacist.

Article 44/12. Investigational and auxiliary medicinal products, in accordance with Article 40/2, § 1, subparagraph 2 of the Law, may be dispensed only if this is justified and described in detail in the initial application dossier or application for a substantial modification of the clinical trial, namely the cover letter, the protocol, the investigational medicinal product dossier and/or auxiliary medicinal product dossier, and the implications described in the appropriate sections of the dossier.

The dispensing of investigational and auxiliary medicinal products, in accordance with Article 40/2, § 1, subparagraph 2 of the Law shall be organised in such a way that neither the sponsor nor the persons referred to in Article 40/2, § 2, subparagraph 2(1) to (4) of the Law have access to the personal data of those taking part in the trial'.

Article 2. Annex VII to Royal Decree of 14 December 2006 on medicinal products for human use, inserted by Royal Decree of 3 February 2019, is supplemented with a point 4., worded as follows:

'4. Investigators who do not operate in a health institution, who supply authorised auxiliary medicinal products to those taking part in a clinical trial, without additional information being entered on the outer packaging and immediate packaging in accordance with Article 67(2) of Regulation 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 accordance with Article 40/2, § 1, subparagraph 1 or 2((1) of the Law of 7 May 2017 on clinical trials of medicinal products for human use'.

Article 3. The Minister for Public Health shall be responsible for the implementation of this Decree.

Done at …, on …

By the King:
The Minister for Public Health,