KINGDOM OF BELGIUM
FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS
DRAFT BILL AMENDING THE LAW OF 7 MAY 2017 ON CLINICAL TRIALS OF MEDICINAL PRODUCTS FOR HUMAN USE
PHILIPPE, KING OF BELGIUM,
To all present and those to come,
GREETINGS.
On the proposal of the Minister for Public Health,
WE HAVE DECREED AND HEREBY DECREE:
The Minister responsible for Public Health shall be responsible for presenting, on our behalf, to the legislative chambers and for tabling in the House of Representatives, the following draft bill:
Article 1. A Chapter 9/2 is added to the Law of 7 May 2017 on clinical trials of medicinal products for human use, entitled 'Chapter 9/2. Dispensing of investigational medicinal products and auxiliary medicinal products'.
Article 2. An Article 40.2 is added to the Chapter 9.2 added by Article 1, worded as follows:
'Article 40.2. (1). Investigational medicinal products and auxiliary medicinal products may be dispensed in person, at the participant's address where appropriate, where the medicinal products will be stored and administered by:
1° an investigator of the clinical trial concerned;
2° a hospital pharmacist practising in a hospital pharmacy approved in accordance with Article 66 of the Coordinated Law of 10 July 2008 on hospitals and other

healthcare establishments, at one of the clinical trial sites, or at a hospital operated by the Ministry of Defence, if it is one of the clinical trial sites; or
3° a pharmacist practising in a pharmacy open to the public, who holds an operating licence in accordance with Article 18 of the Coordinated Law of 10 May 2015 on the practice of healthcare professions.
Investigational medicinal products and auxiliary medicinal products may be dispensed remotely, via a delivery service, at the participant's address, where the medicinal products will be stored and administered, by:
1° an investigator of the clinical trial concerned; or
2° a hospital pharmacist practising in a hospital pharmacy approved in accordance with Article 66 of the Coordinated Law of 10 July 2008 on hospitals and other healthcare establishments, at one of the clinical trial sites, or at a hospital operated by the Ministry of Defence, if it is one of the clinical trial sites.
By way of derogation from subparagraph 1, an investigator operating in a health institution shall not supply an authorised auxiliary medicinal product with a unique identifier within the meaning of Article 3(2)(a) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, unless additional information is included on the outer packaging and the immediate packaging in accordance with Article 67(2) of the Regulation.
(2). The investigator may delegate in-person dispensing, where appropriate to the participant's address, where the medicinal products will be stored and administered, to the following persons:
1° another investigator;

2°	a nurse holding the approval referred to in Article 10 of the Law of 22 April 2019 on the quality of healthcare practice; or
3°	a coordinator of the study, namely an associate of the principal investigator to whom the latter has delegated (part of) the practical organisation of the clinical trial and the tasks related to the clinical trial, who is neither investigator nor nurse.
The investigator may delegate remote dispensing, via a delivery service, to the address of the participant, where the medicinal products will be stored and administered, to the following persons:	
1°	the holder of the manufacturing or import authorisation for an authorised investigational medicinal product or authorised auxiliary medicinal product, as referred to in Article 12*a* of the Law of 25 March 1964 on medicinal products for human use, in the case of such a medicinal product;
2°	the holder of the manufacturing or import authorisation for an unauthorised investigational medicinal product, an unauthorised auxiliary medicinal product or an authorised auxiliary medicinal product subject to a change that is not covered by a marketing authorisation, referred to in Article 38 of the Law, in the case of such a medicinal product;
3°	a wholesale distributor referred to in Article 12*b* of the Law of 25 March 1964 on medicinal products for human use, when distributing an authorised investigational medicinal product or authorised auxiliary medicinal product;
4°	the holder of a distribution authorisation meeting the conditions laid down by the King, referred to in Article 40/1, in the case of an unauthorised investigational medicinal product, an unauthorised auxiliary medicinal product or an authorised auxiliary medicinal product subject to a change that is not covered by a

marketing authorisation.
(3). In-person dispensing or remote dispensing, via a delivery service, to the participant's address, where the medicinal products will be stored and administered, may take place at the address of a participant in Belgium, where that participant participates in a clinical trial authorised in one or more other Member States, even if it is not authorised in Belgium.
Where in-person dispensing or remote dispensing, via a delivery service, to the participant's address, where the medicinal products will be stored and administered, takes place in another Member State, the person referred to in paragraph 1, subparagraph 1, 1° to 3°, or subparagraph 2, 1° or 2°, or their delegate, referred to in paragraph 2, shall comply with the legal and administrative provisions in force in the Member State concerned.
(4). The King may impose conditions and procedures relating to the dispensing of investigational medicinal products and auxiliary medicinal products'.
Issued in , on .
By the King:
The Minister for Public Health,
Franck Vanden Broucke