Novelties regarding Clinical Trials – Law of 30 October 2018 containing Miscellaneous Provisions regarding Health

The Law of 7 May 2017 on clinical trials involving medicinal products for human use[1] (the ***Law of 7 May 2017***) supplements the new EU Clinical Trial Regulation (*i.e.*, Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC – the ***CTR***). The entry into force of the Law of 7 May 2017 will coincide with that of the CTR, which is currently expected to happen in 2020. As you probably know, the CTR will only become applicable once it has been verified that the EU Portal and Database are fully functional.

Today, the Belgian Official Journal publishes a Law of 30 October 2018 containing miscellaneous provisions regarding health[2] (the ***Law***). The Law deals with a wide variety of health-related topics, including amendments to the Law of 7 May 2017.

Here is what you should know about the new rules governing clinical trials:

1. The Law inserts in Article 3 of the Law of 7 May 2017 a reference to Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council (the ***Implementing Regulation***).

2. The Law inserts a new Article 6/1 which requires ethics committees to retain for at least 25 years after the end of clinical trials for which they issued a positive opinion details on (i) the members that composed the ethics committee; and (ii) the experts that were consulted by the ethics committee (including their name, capacity, *curriculum vitae* and declaration of interest). To ensure compliance with the GDPR, the new Article 6/1 sets out detailed rules on the processing of these personal data. The 25 year retention period corresponds to the minimum period during which the sponsor and investigator should retain the clinical trial master file pursuant to Article 58 of the CTR.

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1 *Wet van 7 mei 2017 betreffende klinische proeven met geneesmiddelen voor menselijk gebruik/Loi du 7 mai 2017 relative aux essais cliniques de médicaments à usage humain*.

2 *Wet van 30 oktober 2018 houdende diverse bepalingen inzake gezondheid/Loi du 30 octobre 2018 portant des dispositions diverses en matière de santé*.

3. The general rule under Article 7 of the Law of 7 May 2017 is that the ethics committee of the clinical trial location(s) cannot be designated as the competent ethics committee. The Law amends Article 7 so as to allow for an exception to this rule in situations where there are no accredited ethics committees other than these of the clinical trial locations.

4. Implementing Article 29(2), c) of the CTR, the Law clarifies that the member of the investigating team responsible for performing the prior interview with a view to obtaining the patient's informed consent should be a physician (or a dentist, in case of dental trials). This physician/dentist is entitled to entrust activities that qualify as nursing activities (*See*, Article 46 of the Coordinated Law of 10 May 2015 on the exercise of health care professions[3]) to a nurse, but only "*under his/her own responsibility and supervision*".

5. The Law allows investigators and sponsors to have recourse to the simplified procedure for obtaining informed consent in cluster trials as described in Article 30 of the CTR. The Law of 7 May 2017 initially precluded this possibility.

6. The Law amends Article 37 of the Law of 7 May 2017 so as to require phase I centres to register both themselves and their activities with the Federal Agency for Medicines and Health Products[4] (***FAMHP***). This notification duty should make it easier for the FAMHP to perform a risk assessment and organise its inspection activities. The date of entry into force of this notification duty is to be determined by Royal Decree. Phase II, III and IV trials are not subject to this notification duty. According to the legislative preparatory works, this difference in treatment is justified in view of the characteristics of a phase I trial (first in human trial – healthy volunteers).

7. Implementing Article 10(8) of the Implementing Regulation, the Law grants inspectors from other EU Member States access to (i) clinical trial sites; (ii) any premise of any entity related to the clinical trial; and (iii) data related to the clinical trial, provided these inspectors are accompanied by at least one Belgian inspector.

8. The Law makes it possible for a Royal Decree to determine whether or not a fee is due by sponsors for the various applications foreseen by the Law of 7 May 2017. Alternative financing mechanisms may be considered with a view to promoting clinical research in Belgium.

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[3] *Gecoördineerde Wet van 10 mei 2015 betreffende de uitoefening van de gezondheidszorgberoepen/Loi coordonnée du 10 mai 2015 relative à l'exercice des professions des soins de santé*.

[4] *Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten/Agence fédérale des medicaments et des produits de santé*.

9. The Law inserts a new Article 47/1 which, in line with Article 92 of the CTR, provides that the costs for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol shall be borne by the sponsor. However, by derogation from this rule, the Law enables the health insurance to bear these costs provided that:

(i) the clinical trial is a low-intervention clinical trial; and

(ii) the sponsor can demonstrate at any time that the medicine concerned would have been prescribed in any case by the treating physician and that the medical devices would have been used for their administration should the patient not have been included in the trial.

We attach for your perusal a copy of the Law.

We trust the above is useful. Please do not hesitate to contact us should you have any further questions in relation to the above.