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Client Alert

Unveiling the Complexity of the Belgian MedTech Legal Landscape

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The Belgian regulatory framework for medical devices is highly complex, and the already dense legal landscape was recently added to by the adoption of two new Belgian royal decrees: the Royal Decree of 25 September 2022 relating to performance studies involving in vitro diagnostic medical devices and the Royal Decree of 13 September 2022 amending and repealing various provisions regarding in vitro diagnostic medical devices.

What impact will these new Royal Decrees have? This alert will first provide you with a structured overview of the existing regulatory framework and then look more specifically at the consequences of these recent updates in the context of in vitro diagnostic medical devices.

The existing regulatory framework for medical devices

At a European level, medical devices are regulated by Regulation (EU) 2017/745 (the Medical Device Regulation), which replaced Directive 93/42/EEC (the Medical Device Directive). Belgian national measures to implement the Medical Device Regulation came into effect on 26 May 2021, and consist of the law of 22 December 2020 on medical devices, accompanied by three royal decrees:

- The Royal Decree of 12 May 2021, which implements the provisions in the Belgian law of 22 December 2020;
- The Royal Decree of 18 May 2021, which sets out the provisions regarding clinical trials involving medical devices; and
- The Royal Decree of 28 April 2021, which aligns previous national rules with the Medical Device Regulation.

The new royal decrees for in vitro diagnostic medical devices

On 26 May 2022, Regulation (EU) 2017/746 (the In Vitro Diagnostic Medical Device Regulation) came into force, replacing Directive 98/79/EC (the In Vitro Diagnostic Medical Device Directive) and introducing major updates to the European regulatory framework for in vitro diagnostic medical devices, including changes to the scope of performance studies or clinical studies involving these devices.

The Belgian legislator transposed the In Vitro Medical Device Regulation by means of a law of 15 June 2022 that came into effect on 1 July 2022. The two newly adopted royal decrees mentioned above relate to this law, and they are important additions to the Belgian legislative landscape:

- The Royal Decree of 25 September 2022 came into effect on 26 October 2022 and sets out the provisions regarding performance studies with in vitro diagnostic medical devices; and
- The Royal Decree of 13 September 2022 came into effect on 4 November 2022 and aligns previous national rules with the In Vitro Diagnostic Medical Device Regulation.

The consequences of the recent legal changes

The Royal Decree of 25 September 2022 relating to the performance studies on in vitro diagnostic medical devices

This Royal Decree governs the conduct of performance studies involving in vitro diagnostic medical devices, and includes coordinated assessment procedures for performance studies where Belgium is acting as a coordinating Member State.

Certain studies now need to obtain prior authorization from the Federal Agency for Medicines and Health Products (the FAMHP) and are subject to an ethics committee review. These studies include i) performance studies in which surgically invasive sample-taking is done, ii) interventional studies, (iii) performance studies involving additional invasive procedures or other risks for subjects, and (iv) performance studies involving companion diagnostics, and (v) performance studies that assess in vitro diagnostic medical devices even though this is outside the scope of their intended purpose.

Certain other studies, must be notified to the FAMHP, but do not require prior authorization from the FAMHP and are not subject to ethics committee review. These studies include i) PMPF studies conducted to further assess in vitro diagnostic medical devices that already bear the CE marking and that involve submitting subjects to invasive and burdensome procedures additional to those performed under the normal conditions of the use of such device, and ii) performance studies involving companion diagnostics using only left-over samples.

Unlike the In Vitro Diagnostic Medical Device Regulation, the Belgian Royal Decree establishes a separate regime for performance studies involving in vitro diagnostic medical devices which are manufactured and used exclusively in healthcare facilities.

The Royal Decree also requires that substantial modifications to any regulated studies be notified to the FAMHP for approval and are subject to ethics committee review. Additionally, the FAHMP in collaboration with the Minister for Social Affairs and Public Health or its representative is granted the discretion to revoke or suspend the study, or to require the sponsor of the performance study to modify any aspect, if any imposed requirements are not being met.

The Royal Decree of 13 September 2022 amending and repealing various provisions regarding in vitro diagnostic medical devices

This Royal Decree aims to repeal and amend various royal decrees relevant in the context of in vitro diagnostic medical devices in order to align the Belgian framework with the European level. Notably, this Royal Decree

does not only apply to in vitro diagnostic medical devices but also amends various royal decrees applicable to other types of devices, such as medical devices or implantables.

By way of example, the Royal Decree amends and specifies the tasks of materiovigilance contact points, which currently consist of i) immediately notifying the FAMHP and distributors and/or manufacturers or their agents of any serious incidents, ii) participating in investigations carried out by the FAMHP and in work related to the safety of use of devices, or iii) recording and evaluating any serious incident or risk of serious incident due to a device, according to the procedure published on the FAMHP website (see Article 3 of the Royal Decree of 15 November 2017 on the materiovigilance contact point in hospitals and the registrations of medical device distributors).

The Royal Decree further specifies that economic operators should periodically confirm the accuracy of their device's data, and the FAMHP will notify any economic operator that fails to do so that its activities could be suspended until this obligation is complied with. Furthermore, the Royal Decree clarifies which information should be submitted to the FAMHP when applying for a derogation from the conformity assessment procedures. If the request is justified, the FAMHP may approve such derogation in the interest of public health or patient safety (see Article 8/1 and Article 9 of the Royal Decree of 12 May 2021 implementing the Law of 22 December 2020 regarding medical devices).

The Belgian legislator will undoubtedly continue to make changes to this already dense and complicated regulatory framework in order to get it aligned with European Union legislation. We will continue to follow these developments and our Crowell & Moring MedTech team is here to answer any questions you may have and to provide you with ongoing updates.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Kristof Roox
Partner – Brussels
Phone: +32.2.282.1843
Email: kroox@crowell.com

Jurgen Figys
Senior Counsel – Brussels
Phone: +32.2.214.2894
Email: jfigys@crowell.com

Wietse Vanpoucke
Associate – Brussels
Phone: +32.2.897.0873
Email: wvanpoucke@crowell.com