Agreement reached on new EU rules re: medical devices

On 25 May 2016, the Netherlands presidency of the Council of the EU ("Council") and representatives of the European Parliament ("Parliament") reached a political agreement concerning the text of the proposed regulations on medical devices and in vitro diagnostic ("IVD") medical devices. Medical devices and IVD medical devices cover a wide range of products for treatment and diagnosis, from sticking plasters to hip replacements, and from pregnancy tests to HIV tests, including dental devices.

The proposed legislation aims (i) to ensure that medical devices and IVD products are safe, and (ii) to give patients fast access to new innovative health care solutions. The rules seek to achieve these aims by (i) strengthening the rules on placing new medical devices on the market, and by (ii) tightening surveillance once they are available.

The draft regulations will clarify and strengthen the rules for notified bodies, *i.e.* independent entities responsible for assessing medical devices before they can be marketed. Under the new rules, notified bodies will be required to have ready qualified staff, but are also given the right and duty to carry out unannounced inspections of device manufacturing facilities.

In addition to this, the proposed regulations include explicit requirements for manufacturers to follow up on quality, product performance and safety of devices after they are placed on the market.

In order to improve transparency and surveillance, a new central database will be created to track economic operators, notified bodies, market surveillance, vigilance, clinical investigations and certificates. The database will offer patients, healthcare professionals and the public with comprehensive information on products available in the EU. Medical devices will have a Unique Device Identification ("UDI") number for tracking purposes throughout the supply chain all the way to the end-user or patient. The same regime is not necessarily applicable to custom-made devices.

The next step in the legislative procedure is to obtain approval by the Council's Permanent Representatives Committee and the Parliament's Committee on Environment, Public Health and Food Safety ("ENVI"). The two regulations must then be formally adopted by the Council of Ministers and the Parliament. If approved, the new rules will apply three years after publication with regard to medical devices and five years after publication with regard to IVD medical devices.

The official press release of the Council can be found here.

We hope this information is useful. We will keep you informed as soon as there are further developments.

Best regards,

Sarah / Evi

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