Published on *The National Law Review* https://natlawreview.com

Update on the European Proposal for a Medical Devices Regulation

Article By:

Health Care Practice at Covington & Burling

After almost two years of discussions and negotiations, the adoption of new **EU medical device rules** remains a challenging process that is not likely to be completed in 2014. The recent European Parliament elections mean that new Members will need to familiarize themselves with the proposal and the issues. Here we provide an update on the European proposal for a medical device regulation.

On April 2, 2014 the European Parliament adopted a legislative resolution on the European Commission's proposal for a regulation on medical devices (along with a resolution on the Commission's proposal for a regulation on in vitro diagnostic medical devices).

The Parliament's resolution endorsed its first reading position of 22 October 2013, which introduced additional measures and intensified the ones proposed by the European Commission, despite concerns and criticism expressed by the industry on several key reform points.

Among the proposed measures, particularly important is the involvement of the European Medicines Agency (EMA) in medical device regulation, namely in the qualification and monitoring of notified bodies (NBs), as well as the enhanced roles of other bodies, *i.e.* the new Medical Devices Coordination Group (MDCG), formed by representatives of Member State competent authorities, and the Assessment Committee for Medical Devices (ACMD), a scientific expert group to assist the work of the MDCG. The Parliament's resolution imposes enhanced competence requirements for NBs as well as "special notified bodies" (SNBs) for specific categories of devices. The Parliament also calls for devices for aesthetic purposes to be included within the scope of the proposed regulation.

On the occasion of the adoption by the Parliament of its resolution, we review some aspects of the proposal that have raised particular concerns within the medical devices industry.

Medical Devices Assessment Procedure

The Parliament's position provides for a stricter conformity assessment procedure for certain high risk medical devices, such as class III and implantable devices or devices incorporating medicinal products. This procedure would be the task of SNBs, designated by the EMA on the basis of stricter requirements regarding qualifications and training of their staff. SNBs would have to notify the

Commission of applications and the Commission would submit those to the MDCG for an opinion on the product's clinical evaluation and post-marketing clinical follow-up plan. The MDCG would have the option to request assistance in its decision-making process from the experts of the ACMD, which would review the clinical data and produce a clinical assessment of the device. The SNB's decision regarding certification of the product would be based on whether the MDCG opinion, which must take into account the ACMD assessment, is favorable or not.

Clinical Investigations

In cases where clinical investigations are mandatory, these should include randomized control trials in the appropriate target population and well-controlled investigations. Randomized control trials would be considered as the standard appropriate model for all medical devices and sponsors will have to justify any other model chosen.

Manufacturers of high risk devices would have the obligation to draw up a report on the safety and performance of their devices and on the outcome of the clinical investigation, accompanied by a lay summary. Both the report and the summary would be made publicly available via the EU database for medical devices (Eudamed).

Single Use Devices

The Parliament endorsed the view that medical devices should belong to two categories: reusable or single use. Devices would be considered as reusable by default, unless they were expressly identified as single use by being included in the Commission's list of single use devices (negative list). Reprocessing of devices identified as single use would not be permissible, as to ensure the highest safety standards for patients. Stricter conditions would apply to reprocessing of medical devices, such as high quality and safety standards defined by the Commission, traceability of reprocessed devices and consideration of the reprocessor as the manufacturer of the reprocessed device, liable for the reprocessing activities.

Unique Device Identification and Implant Card

The Parliament adopted the Commission's proposal to trace medical devices *via* a Unique Device Identifier (UDI), a system that should enable effective postmarketing monitoring and protection against counterfeit devices as well as improve handling at various levels of the distribution chain. Producers of implantable devices should accompany their products with an implant card that would be made available to healthcare professionals implanting the device; these healthcare professionals would be responsible for submitting the card to the patient and registering all information contained in the implant card in the patient's medical records. The implant card would contain important information on the implanted device, such as principal characteristics, warnings, and potential adverse effects, but also the UDI.

Restriction of Hazardous Substances

The Parliament introduced a stricter regime for hazardous substances contained in medical devices or parts thereof that (i) are invasive, (ii) come into contact with the body, (iii) (re)administer medicines, body fluids, or other substances to or from the body, or (iv) transport or store such medicines, body fluids, or substances to be (re)administered to the body. Such devices or parts thereof may not exceed a maximum limit of 0,1% by weight in homogeneous materials of substances which are

carcinogenic, mutagenic, or toxic to reproduction (CMR) or have endocrine disrupting (ED) properties.

Industry concerns and criticism

The industry welcomes the general spirit of the Parliament's position, which was officially adopted just one day after the European association of medical device manufacturers, Eucomed, published its position on four key issues of the revision of the EU Medical Devices Directives. It also welcomes the effort to promote safety and innovation to the benefit of European patients.

Specific points, however, have raised concerns and they are likely to delay further the adoption of the new rules, as the debate will go on in the European Council (the other co-legislating institution of the EU). The industry argues that the added scrutiny procedure for the assessment of NBs would, in reality, duplicate the product assessment procedure and add unnecessary layers of bureaucracy, thus delaying patient access to innovative technologies. The industry also points to the risk of a "one-size-fits-all" approach in relation to clinical evaluation and proposes a case-by-case approach that would address the particularities of different kinds of products. Device manufacturers criticize the Parliament's "one-size-fits-all" approach in relation to the restriction of CMR and ED substances as well; this position could deprive patients of much needed products, where exposure risks are considered to be less than the risks associated with refraining from their use. Finally, the industry raises concerns about an unrealistic, ambiguous and categorical view on the issue of single use devices, as not all devices should be considered as in principle reusable and, in some cases, patient safety could be compromised. This approach would also create additional bureaucratic burden and costs, especially when taking into account that such a rule does not exist in other jurisdictions and that the vast majority of medical device manufacturers are small and medium enterprises.

Way forward

Achieving a consensus within the European Council appears to be a challenge, and new legislation is not expected to be adopted before 2015. Following the recent elections for a new European Parliament, several new Members of the Parliament will have to familiarize themselves with the proposed legislation, a development that is likely to delay the process even further. Industry might use this opportunity to advocate on continuing issues of importance and concern in connection with the current proposal.

National Law Review, Volume IV, Number 155