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NEW MEDICAL DEVICES REGULATIONS IN THE EU
SIGNIFICANT CHANGES BUT NO BIG BANG

Today the European Commission published its long awaited proposals for the revision of the EU regulatory framework for medical devices. Three Directives, *i.e.*, Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices and Directive 98/79/EC on *in vitro* diagnostic medical devices (IVD) will be replaced by two Regulations: one Regulation on medical devices and one Regulation on IVDs. Importantly, unlike Directives that must be implemented into national laws, the Regulations will be directly applicable in all EU Member States.

The proposals are published against a very emotional background in the EU due to the recent breast implants and metal-on-metal hip joint replacements scandals. They will now be reviewed by the European Parliament (EP) and the Council, the institution grouping the Member States. Adoption is foreseen in the course of 2014 and the new rules may gradually take effect six months to three years later.

NO BIG BANG

The new Regulations do not set out a radically new system. While clearly stricter controls of medical devices are envisaged, the Commission has not endorsed the EP call to include a pharma-like pre-marketing authorization system. Medical devices will continue to be subject to a conformity assessment which, for medium and high risk devices, involves a third party, known as "notified body". The proposed Regulation on medical devices also maintains the division of medical devices into four classes, each class being associated with a level of risk.

EXTENSION OF THE SCOPE

The scope of the proposed Regulation on medical devices is extended to products manufactured utilizing non-viable human tissues or cells (such as syringes prefilled with human collagen) unless they are covered by Regulation (EC) No 1394/2007 on advanced therapy medicinal products. It is also extended to some aesthetic products without a medical purpose but whose characteristics and risk profiles are similar to those of medical devices (such as non-corrective contact lenses). The Commission is also given the power to decide on borderline products.

NOTIFIED BODIES UNDER STRICTER CONTROL BUT WITH MORE POWER

The proposal contains stricter and more detailed criteria for the designation and monitoring of notified bodies by national competent authorities. These relate, among other aspects, to their legal status, financial and human resources capacities. Moreover, for new applications for conformity assessment of high-risk devices, notified bodies will be under "scrutiny" of an expert committee, the Medical Devices Coordination Group (MDCG). Under that procedure, they will have to notify the MDCG of any new applications for medical devices. Before the notified bodies can issue a certificate, the MDCG will be empowered to request them to submit a preliminary conformity assessment on which it can issue comments within a deadline of 60 days. This scrutiny mechanism may ultimately lead to delays for the marketing of new devices. This greater

control over notified bodies is accompanied by the reinforcement of their rights and duties *vis-à-vis* manufacturers. This will include, for example, carrying out unannounced factory inspections and conducting physical or laboratory tests on devices.

NEW TOOLS FOR MORE TRANSPARENCY AND VIGILANCE

The European databank on medical devices (Eudamed) will be extended and contain comprehensive information on all economic operators and products available on the EU market. Importantly, a significant part of the information in Eudamed will become publicly available. Manufacturers of high-risk devices would also be obliged to publish a summary of key safety and performance clinical data. In addition, the proposals introduce an obligation for manufacturers to have for each device a Unique Device Identification (UDI), which aims at ensuring full traceability of the devices (per specific product type and batch). With respect to materiovigilance, an EU portal will be created where all serious adverse events will need to be reported.

CLARIFICATION OF THE RULES FOR CLINICAL INVESTIGATIONS

The process for conducting clinical investigations is clarified. It only covers clinical investigations for regulatory purposes. The proposal also introduces the concept of "sponsor" of medical devices' investigation, who can be the manufacturer, his authorized representative or third-party, such as contract research organizations. Each clinical investigation will need to be published in Eudamed and sponsors will have the possibility to submit a single application for a multi-state investigation through Eudamed. While health and safety aspects will be assessed by the relevant Member States under the supervision of a coordinating Member State, the assessment of purely local and ethical aspects will continue to be carried out by each Member State. Clinical trials will (as is already the case) need to comply with the current Declaration of Helsinki. This includes the principle against placebo controlled trials and the obligation for ongoing availability of the best therapy after the trial. The medicines rules, in contrast, expressly refer to an older version without these principles.

REPROCESSING

The proposal clarifies the requirements applicable to the reprocessing of single-use medical devices.

FOCUS ON IVDS

The rules are refined with regard to genetic tests, companion diagnostics and medical software. A new classification system is introduced, whereby IVDs will be divided into four classes of risk: A (lowest risk), B, C and D (highest risk). Importantly, for companion diagnostics intended to be used to evaluate the patient eligibility for treatment with a given medicine, the notified bodies shall, before issuing a design-examination certificate, consult either the national competent authorities for medicines or the European Medicines Agency.

A SHIFT TOWARDS A MORE CENTRALIZED SYSTEM?

Importantly, the Commission will be directly or indirectly involved in all stages of the marketing of new devices. First, while the designation of notified bodies will still lie within the competence of the national authorities, these will have to "duly take into consideration" the recommendation made by joint assessment teams nominated by the Commission and the MDCG and composed of at least one expert from the Commission. Moreover, as explained above, the conformity assessment of new high-risk devices will be scrutinized by the MDCG, which is chaired by the European Commission. Third, the proposal also provides for the legal basis that EU reference laboratories may be designated by the Commission for specific technologies or hazards. Finally,

the Commission will be in charge of maintaining the Eudamed, which will be a key element of the implementation of these new rules. More generally, the proposal empowers the Commission to adopt implementing acts to ensure uniform application of the Regulation or delegated acts to adapt the regulatory framework for medical devices over time. The centralization developments will be reinforced by the build-up of scientific and technical expertise within the Commission, which is expressly envisaged in the proposal.

NEXT STEPS

The proposal will now be debated within the European Parliament and the Council and there will most likely be significant amendments. Interested companies can be engaged in this process.

Thanks to its integrated approach that combines superior legal analysis with a unique experience in government affairs, Covington & Burling LLP can help you navigate the complex EU decision-making process and develop a refined outreach strategy and provide tailor-made advocacy.

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