Innovation vs. Safety: The New Proposed Rules for Medical Devices in the European Union

By François-Régis Babinet and Peter Bogaert

"Being able to use innovative products at the earliest possible time – and in Europe we deliver innovation about three years before our American counterparts with their own system – is a benefit to patients that we cannot put aside." This is how former European Union (EU) Commissioner for Health John Dalli expressed his views on the upcoming medical device regulation in a speech held in June 2012 before the European Parliament (EP).[1]

These strong words in favor of innovation were necessary to balance the emotion caused in the EU by the recent breast implants and metal-on-metal hip joint replacements scandals and the subsequent EP resolution calling for safer medical devices and the introduction of a marketing authorization system for high-risk devices.[2]

This article will analyze the main changes to the current regulatory framework for medical devices in the EU recently proposed by the EU Commission. These changes are currently being reviewed by the EP and the Council, the institution representing the 27 Member States of the EU. For U.S. companies that have -- or hope to have -- products on the EU market, it will be critical to monitor this process as the EP and Council consider the Commission's proposal. Given that this

François-Régis Babinet is an Associate in the Brussels office of Covington & Burling LLP.

Peter Bogaert is the Managing Partner and the head of the life sciences group in the Brussels office of Covington & Burling LLP.

process will unfold over at least one year, there will be numerous opportunities for companies to make their voices heard on aspects of the new regulatory system.

Basics of the Current System are Preserved

According to the Commission proposal (the Proposal),[3] medical devices would continue to be subject to a conformity assessment procedure. Manufacturers use this procedure to demonstrate that their devices meet essential safety and performance requirements. The Proposal also retains the division of medical devices into four classes, each class associated with a level of risk and a corresponding conformity assessment procedure. The conformity assessment procedure of medium and high risk devices involves an independent third party known as a "notified body" (as explained below, notified bodies would, however, be under stricter control than today). Compliant devices are then CE-marked and can be marketed in the entire European Economic Area.[4]

"Regulation" vs. "Directive"

Two Regulations, one on medical devices and one on *in vitro* diagnostic medical devices (IVDs), would replace the three current Directives (*i.e.*, Directive 90/385/EEC[5] on active implantable medical devices, Directive 93/42/EEC[6] on medical devices and Directive 98/79/EC on IVDs[7]). Importantly, Regulations are directly applicable in all EU Member States, unlike Directives that must be implemented into national laws. Thus, requirements applicable to medical devices will apply throughout the EU. This choice of a Regulation is perceived as positive for innovative companies because it achieves more legal certainty and may ultimately decrease red tape costs. However, mistakes or inconsistencies contained in Regulations cannot be corrected, unlike Directives via the implementation into national laws. This makes it all the more important that companies be involved in the process leading up to the publication of final Regulations.

Extended Scope

The Proposal subjects new products to the requirements applicable to medical devices. This is for example the case of products manufactured utilizing non-viable human tissues or cells. For the purpose of patients' safety, some aesthetic products, such as dermal fillers, non-corrective lenses or equipment for liposuction would also be included in the scope of the Regulation, whose requirements are stricter than requirements applicable to consumer or cosmetic products.[8] This extension is justified by the fact that although they do not have a medical purpose, their characteristics and risk profiles are similar to those of medical devices. On the other hand, the Proposal explicitly excludes from its scope products containing or consisting of viable biological substances (e.g. living microorganisms).

Putting in place an innovation-friendly environment also required the Commission to ensure legal certainty to manufacturers. With this objective in mind, the Proposal also empowers the Commission to clarify the demarcation between applicable regulatory regimes. Today, for example, products against head-lice are regulated as medical devices, medicinal products or cosmetics depending on the Member State. Under the new proposed rules, the Commission would thus be able to decide on an EU-wide classification for medical devices, cosmetic products and (since recently) biocides.[9] However, such possibility is not introduced for medicines, whose classification decision would still lie within each individual Member State.

Traceability and Transparency

Under the proposed rule, several measures would be introduced to ensure the traceability and transparency of the devices. First, manufacturers would have to fit their devices with a Unique Device Identification (UDI) (identifying specific product type and batch)[10] and all operators must be able to identify the actors of the supply chain.[11] Second, the European databank on medical devices (Eudamed) would also be extended and contain comprehensive information on all economic operators and products available on the EU market.[12] A significant amount of the information in Eudamed will become publicly available. Finally, manufacturers of high-risk devices would also be obliged to publish a summary of key clinical data[13] and an EU portal will be created where all serious adverse events must be reported.

Scrutiny

While the Commission has not endorsed the EP's motion for a pre-marketing authorization system, it had to take into account the strong call from the civil society for safer and more strictly controlled medical devices. Therefore, any new applications for conformity assessment of high-risk devices would now be under the potential "scrutiny" of an expert committee, the Medical Devices Coordination Group (MDCG).[14] Under that procedure, the notified bodies should inform the MDCG of any new applications for high-risk medical devices. Before a certificate can be issued, the MDCG can request the notified bodies to submit a preliminary conformity assessment on which it can issue comments within a deadline of 60 days.

This scrutiny mechanism may lead to delays in marketing new devices. It is the main source of concern of medical device companies active in the EU.

Clinical trials

The Proposal covers only clinical trials (called investigations) for regulatory purposes (i.e., not market research).[15] It introduces the concept of a "sponsor" for medical device trial; this might be the manufacturer, his authorized representative or a third-party, such as a contract research organization. Interestingly for innovative manufacturers, a possibility would be opened for sponsors to submit a single application for a multi-state trial. While health and safety aspects would be assessed under the coordination of a leading Member State, the assessment of purely local and ethical aspects would continue to be carried out by each Member State. This mirrors the new clinical trial procedures proposed in summer 2012 for clinical trials with drugs.

Reprocessing of Single-Use Devices

The Proposal introduces strict rules on the reprocessing of single-use devices.[16] As is the case in the United States, under the Proposal, reprocessing of single-use devices would be considered the manufacture of new devices so that reprocessing entities must satisfy the obligations incumbent on manufacturers. More flexible rules apply for reprocessing by hospitals for internal uses. The reprocessing of single-use devices for critical use (e.g., devices or surgically invasive procedures) is prohibited.

Today, only a few EU Member States (e.g., Germany) allow the reprocessing of single-use devices (SUD) and have developed guidelines. Other Member States prohibit (e.g., France) or discourage (e.g., United Kingdom) SUD reprocessing while most EU Member States do not have specific regulations on this issue.

Parallel Imports

Because of different price levels between various EU Member States, there can be an economic incentive for parallel importation. The rules and practices on parallel imports, however, vary considerably from one Member State to another and some *de facto* impose a prohibition. The Proposal clarifies the conditions for companies involved in parallel import of medical devices. In particular, parallel importers must put in place a quality management system that includes procedures ensuring that relabeling and repackaging of devices are properly performed, but do not have to re-apply the CE-mark under their own responsibility.[17]

IVDs

Parallel to the Proposal on medical devices, a Proposal on IVDs is being examined by the EP and the Council.[18] The Proposal refines the rules with regard to genetic tests, companion diagnostics and medical software. For example, the Proposal contains a new essential requirement section for software, both incorporated and standalone (as also does the Proposal on general medical devices). In line with the international classification proposed by the Global Harmonization Task Force, a four class system is proposed, whereby IVDs will be divided into four levels of risk: A (lowest risk), B, C and D (highest risk).

Importantly, for companion diagnostics intended to evaluate the patient's eligibility for treatment with a given drug, the notified bodies shall consult either the national drug authorities or the European Medicines Agency before issuing a design-examination certificate.

Way Forward

The proposal is now being debated within the EP and the Council and there will most likely be many amendments. This provides opportunities to influence the final legislation. The new rules may be adopted during the course of 2014: it will thus only be possible to assess at that time whether the right balance between safety and innovation has been struck. Importantly, however, the Proposal also empowers the Commission to adopt acts implementing the Regulation after its entry into force in many areas, such as the content of the technical documentation to be submitted by companies, rules on corrective measures, the exact scope of the devices subject to scrutiny, or rules on on-site inspections. The new regime may in general start applying from late 2017 but some new provisions are expected to apply earlier.

1. Debates - Wednesday, 13 June 2012 - Strasbourg - Defective silicone gel breast implants made by French company PIP (debate)
2. European Parliament resolution on defective silicone gel breast implants made by French company PIP (2012/2621(RSP))
3. Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 - 2012/0266 (COD)
4. The European Economic Area comprises the countries of the EU, plus Iceland, Liechtenstein and Norway
5. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
6. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
7. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
8. Article 1 of the Proposal
9. Article 3 and Article 93 of the Proposal
10. Article 24 of the Proposal
11. Article 23 of the Proposal
12. Article 27 of the Proposal
13. Article 26 of the Proposal
14. Article 44 of the Proposal
15. Chapter VI of the Proposal
16. Article 15 of the Proposal
17. Article 14 of the Proposal
18. Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices - 2012/0267 (COD)