KING & SPALDING

# Client Alert

FDA & Life Sciences Practice Group

May 31, 2016

## EU Law Making Bodies Entered into an Agreement on the New EU Medical Devices Regulations on May 25, 2016

On May 25, 2016, the European Parliament, European Council and the European Commission agreed on new rules regarding the approval and surveillance of medical devices and in vitro diagnostics for the European market.

The agreement on the new rules is still subject to approval by the Council's Permanent Representatives Committee and the Parliament's ENVI committee; however, the agreement will most likely become the basis of the text of new European regulations governing the marketing of medical devices and in vitro diagnostics.

***Goals:***

While official information is limited at this time, it appears that the agreement calls for the promulgation of two regulations to achieve the dual political goals of better ensuring that medical devices and in vitro diagnostics marketed in Europe are safe, while still allowing patients to benefit from advances in innovative health care solutions in a timely manner.

Medical devices and in vitro diagnostics cover a wide range of products, from wound dressings to implantable joints, and from pregnancy tests to HIV tests.

The agreement seeks to ensure the safety of medical devices by two means:

- strengthening the rules on placing devices on the market;

and

- tightening surveillance once the devices are available.

Obviously, this would mean increased European regulation and oversight.

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***Obligations of Notified Bodies:***

To achieve the stated goals pursuant to the new agreement, forthcoming regulation would further tighten the rules for the independent Notified Bodies that are responsible for assessing medical devices before they can be placed on the market. The new rules would strengthen the surveillance of the Notified Bodies by national authorities. They would also give these bodies the right and duty to carry out unannounced factory inspections. Notified Bodies would have to ensure that they have available qualified personnel to conduct such surveillance activities.

***Obligations of the Manufacturers:***

The draft regulations would establish express provisions on manufacturers' responsibilities for ongoing assurances related to:

- quality;
- product performance; and
- safety of devices placed on the market.

The goal is to require manufacturers to act swiftly when concerns arise and help them to improve their devices continuously on the basis of actual surveillance data. Manufacturers and other economic operators would have clearly delineated responsibilities, including with respect to liability, but also with regard to registering complaints on devices. The draft regulations would also improve the availability of clinical data on devices. The protection of patients participating in clinical investigations would also be strengthened.

Certain medical devices would be placed in different – higher – classes for pre-market review. Specifically, high risk devices, such as implants, would undergo an additional review by experts before they are placed on the market. Expert panels and laboratories would play a key role in supporting the legislative system, to provide expertise and guidance on clinical aspects to Notified Bodies, competent authorities and to manufacturers.

The new EU rules would also expressly cover certain devices without a specific treatment purpose (e.g., devices with primarily cosmetic purposes), but with similar characteristics as currently regulated medical devices. For example, fillers and colored contact lenses would become subject to regulation.

***Traceability and Database:***

Under the agreement, a central database would be set up to create an improved system for all relevant information. It would cover economic operators, Notified Bodies, market surveillance, vigilance, clinical investigations and certificates. In addition, it would provide patients, healthcare professionals and the public with comprehensive information on products available in the EU. This is intended to allow for better informed care decisions. Patients who are implanted with a device would be given key information on the product, including any precautions which might need to be taken.

Devices would have a unique identification number to provide for traceability throughout the supply chain to the end-user or patient.

***Next Legislative Steps:***

The Council's Permanent Representatives Committee will be invited to endorse the agreement around mid-June 2016. Once the Parliament's ENVI committee has also confirmed that it can accept the compromise that has been reached, the Council will be invited to confirm the agreement. Following the revision of the proposed regulatory texts by the lawyer-linguists, the two regulations would have to be formally adopted by the Council and the Parliament. If approved, which approval seems likely, the new rules would become effective three years after publication with regard to medical devices, and five years after publication with regard to in vitro diagnostics.

***Next Steps of the Manufacturers:***

Even though any final regulations would not become effective until three years after being adopted, manufacturers will need the intervening time, perhaps starting immediately, to get prepared in terms of taking steps to:

- improve the documentation for their existing devices;
- improve procedures for complaint management and reporting;
- be prepared for unexpected audits; and
- be ready to provide information for the outcomes database.

The degree to which manufacturers are able to be prepared for the forthcoming regulations may affect their ability to be most successful in the European market once the new regulatory regime is in place. Accordingly, manufacturers should now consider how to best identify areas for enhancement and implementation of those measures.

***Our European Life Sciences Practice:***

- Ranked by JUVE among the leading law firms in the areas of “Pharmaceuticals and Medical Products” and “Food Law” in its 2015/16 guide
- Ranked by Legal 500 Deutschland in the area of “Regulatory - Pharmaceuticals” in its 2016 guide
- Lawyers on our European team have been listed as
    - “Life Sciences Star” for Germany under the categories of “Regulatory” and “Non-IP Litigation” by the legal directory LMG Life Sciences in its 2013 and 2015 Europe editions
    - “leader in the field”, Germany, in the area of “Regulatory” by Who’s Who Legal: Life Sciences 2016 and in the area of “Life Sciences” by Who’s Who Legal: Germany 2016