The EU Medical Device Regulation and the U.S. Medical Device Industry

Brian Daigle, Office of Industries (Brian.Daigle@usitc.gov, 202-205-3458)
Mihir Torsekar, Office of Industries (Mihir.Torsekar@usitc.gov, 202-205-3350)

By May 26, 2020, all components of the European Union's Medical Device Regulation (MDR) will be enforced across the EU member states. This regulation restructures the EU's medical device approval process (activities which include product registration, submission of clinical trial data, and labelling requirements) and may produce new delays in medical device approvals for sale in the EU market. The EU's medical device market is the world's second largest (behind the United States) and the United States is its top supplier. As such, significant time delays in the approval of medical devices for sale in the EU would likely affect U.S. medical device firms, through added compliance costs and short-term regulatory uncertainty.

The EU Medical Device Regulation: An Introduction

Following the mass recall in 2012 of faulty breast implants in the EU as well as recognition by industry and regulators of the need to update EU medical device standards,[1] on April 5, 2017, the European Parliament and Council released stricter regulatory requirements as identified in its updated Medical Device Regulation (MDR). The two bodies also released a new regulatory structure for in-vitro diagnostics (which are tests on blood and tissue samples), the In-Vitro Diagnostic Device Regulation (IVDR). These regulations provide at least three years for firms and government agencies to transition to the new system, with the MDR coming into force in May 2020.

What does the MDR change?

The MDR introduces several regulatory changes which will impact both EU and U.S. medical device manufacturers:

- **Pre-market regulatory requirements:** As noted above, nearly every step in the regulatory process of bringing a medical device to the EU market will undergo a change, often with an added layer of regulatory approval or additional reporting required. At the clinical trial stage, the MDR sets standards for conducting risk management and clinical evaluations, and the MDR establishes a higher bar for clinical justifications for device equivalence. Clinical evidence standards will now be elevated, particularly for higher risk devices.

- **Expanded definition of a medical device:** many devices and items that are not typically viewed as medical devices (typically for cosmetic purposes) are now included under the umbrella of "medical devices" for MDR enforcement. These include contact lenses for non-corrective vision purposes, liposuction equipment, skin resurfacing lasers, and substances for cosmetic injection (like botox). Additionally, following the bankruptcy of the French firm that sold the faulty implants, the MDR includes a mechanism to ensure financial compensation to victims of defective or malfunctioning medical devices, even in the event of a firm bankruptcy.

- **Post-market regulatory requirements:** Once a device has received regulatory approval from a Notified Body[2] to operate in the EU market, each medical device will be required to have a Unique Device Identification (UDI) as well as an "implant card" (for medical devices which are implanted) for the patient containing information about the device, ensuring its traceability. This data must also be entered into the European database of medical devices (EUDAMED), which will be available to the public.

[1] European Commission. "Restoring confidence in medical devices. Action Plan after the PIP scandal tightened control in Europe." Press release. June 20, 2014 (accessed August 17, 2018).

[2] A "Notified Body" in the EU is an organization designated by an EU member state that assesses whether a certain product, in this case a medical device, conforms with EU standards before it can be placed on the market. Examples include the National Standards Authority of Ireland, Lloyd's Register Quality Assurance, and the Laboratoire national de metrologie et d'essais.

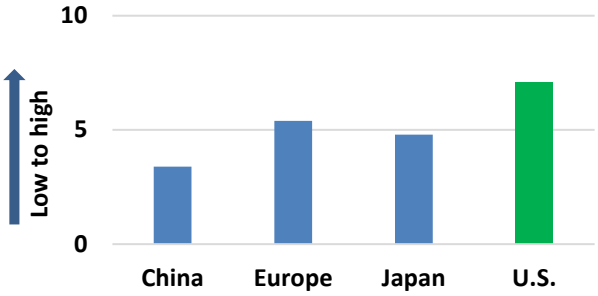
After a device has entered the market, further follow up analysis will be required, including the collection of data on the ongoing status of all medical devices in EU patients. EU member states will be required to work with manufacturers to ensure that data reaches all relevant member state regulatory bodies as well as EU agencies. In addition, manufacturers will be required to report within 48 hours of becoming aware of the malfunction of a device with a serious public health impact.

Implications for U.S. firms operating in the EU medical device market

U.S. medical device manufacturers are the biggest suppliers of the EU's medical device market, accounting for close to two-thirds of their imports in recent years and 41 percent of medical device patent filings with the European Patent Office. The new regulatory structure created by the MDR will likely create a number of challenges for U.S. medical device manufacturers, including additional compliance costs, regulatory uncertainty, and the classification of new products as medical devices. Of particular note is the possible delays to market approval, which may arise due to the time needed to comply with revisions to the EU's conformity assessment procedures (e.g. new clinical trial procedures, and labelling and registration requirements). At the same time, delays would likely result from the shortage of Notified Bodies available to approve medical devices for the EU market. As it currently stands, it is unlikely that all previous notified bodies will have sufficient capacity to meet new MDR requirements. According to one estimate[3], the number of qualified Notified Bodies that could issue approvals for EU medical devices could fall to as low as 40 (from 80-90 that exist under the current system). Such a significant reduction in approval bodies could create a substantial bottleneck in approvals for the introduction of U.S. medical devices to the EU market.

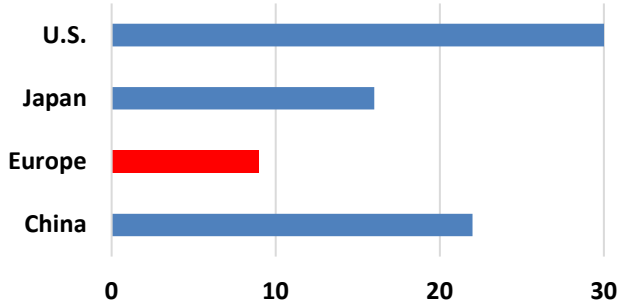
As the world's largest and most innovative medical device industry (figure 1), U.S. firms would likely be affected by delayed approval times in the EU. In particular, the relatively short product lifecycles (18-24 months) for the most innovative devices, which the United States is most competitive in producing, means that market delays could result in months of foregone sales for these firms while the device is awaiting approval. The EU has long boasted the world's lowest approval times among leading markets for high-risk devices (figure 2). As such, it has been the principal destination for U.S. exports; U.S. firms have commonly garnered 30 percent of their revenues in the EU. Extensive delays in the EU could require U.S. firms to pursue other market opportunities or incur additional operational costs, even as EU patients may benefit from more stringent requirements.

Figure 1 Medical Device Innovation Rankings (1-10) for China, Europe, Japan, and the United States



Source: PwC, Innovation Scorecard, January 2010.

Figure 2 Maximum time to approval for high-risk medical devices (months) in the U.S., Japan, Europe, and China



Source: Emergo Group, "Compare the Time, Cost, and Complexity of Getting Regulatory Approval," December 2017.

Sources: MedTech Europe. "The European Medical Technology Industry in Figures," 2015; European Commission Internal Market, Industry, Entrepreneurship and SMEs. "Regulatory Framework: The new Regulations on medical devices." July 23, 2018; Vendy, Ruthanna. "EU MDR and Clinical Evidence: What You Need to Know," Med Device Online, November 27, 2017; European Commission. Regulation (EU) 2017/745, Section 2, Article 87.4; Arbeitsgruppe MPG der Industriefachverbande. "One year of new EU MDR: many problems remained unresolved." May 28, 2018.

[3] Maxwell, "EU Regulatory Reads," January 5, 2018.