Why Industry Anticipates a 'Cliff-Edge' Scenario With EU MDR/IVDR

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The EU's medical device and *in vitro* diagnostic regulations (MDR/IVDR) may cause a "cliff-edge scenario," meaning a disruption in the supply of certain medical devices and IVDs, industry groups and the European Commission (EC) recently cautioned.

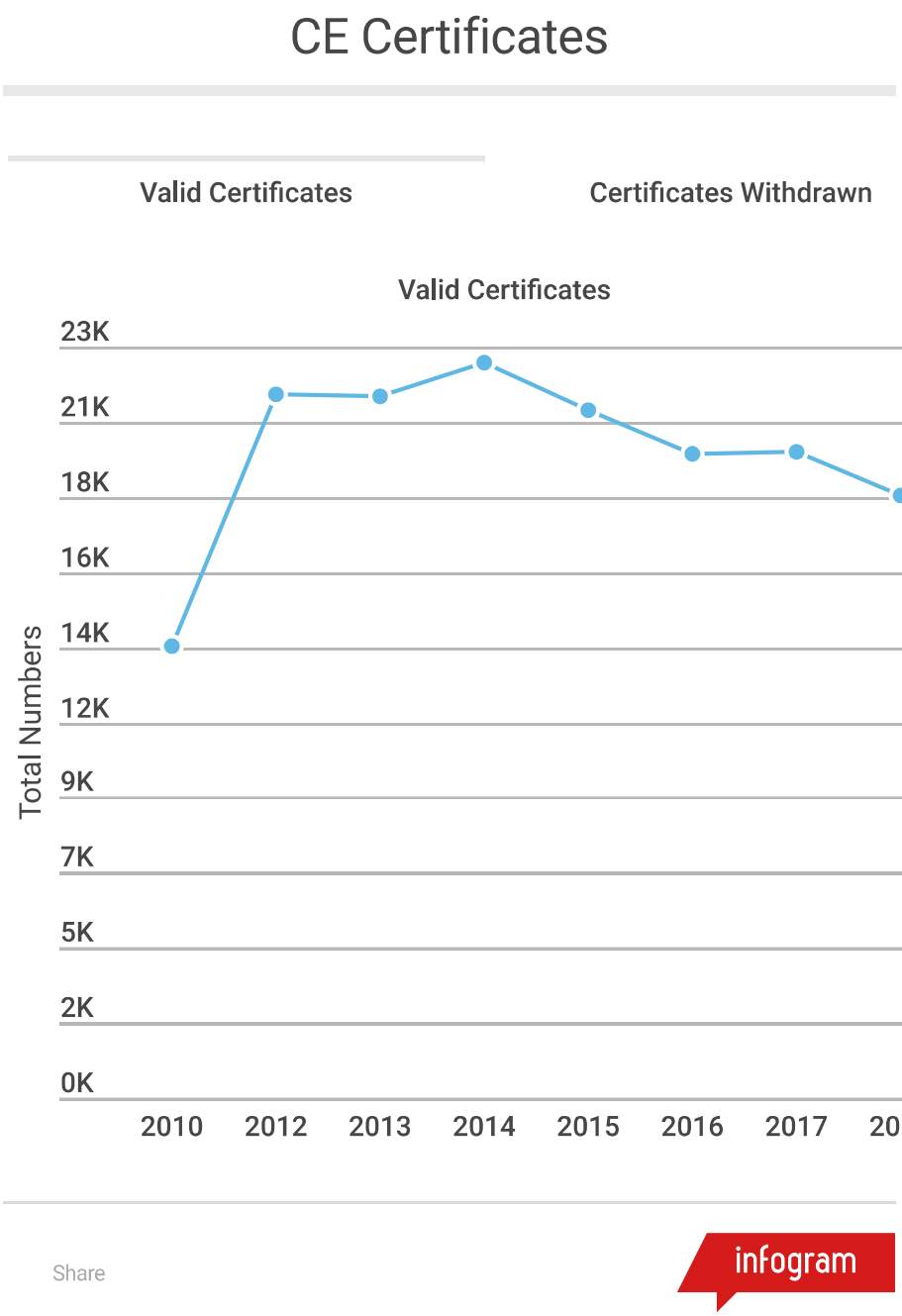
Experts see the potential for such disruptions because of roadblocks in transitioning to the new regulatory framework, including notified body (NB) designation delays. And although these issues have come under the spotlight, amid what the industry calls a "clearly untenable" transition, early work on MDR/IVDR may make submissions in other countries more appealing for manufacturers.

"Once a company is early in getting MDR, their standing in some countries where registration relies on CE marking might go up," executive director and partner at Qserve consultancy and RAPS board member Gert Bos told *Focus.* At least some of the countries that permit CE-marked devices to be used on their market in lieu of regulatory reviews or conformity assessments include India and Jordan.

Bos added that "if competitors are slow in getting to MDR, an advantage

in gaining market share is a possibility worth thinking about." The other side of the story is that once a few competitors show MDR compliance, others that do not "might start losing market share."

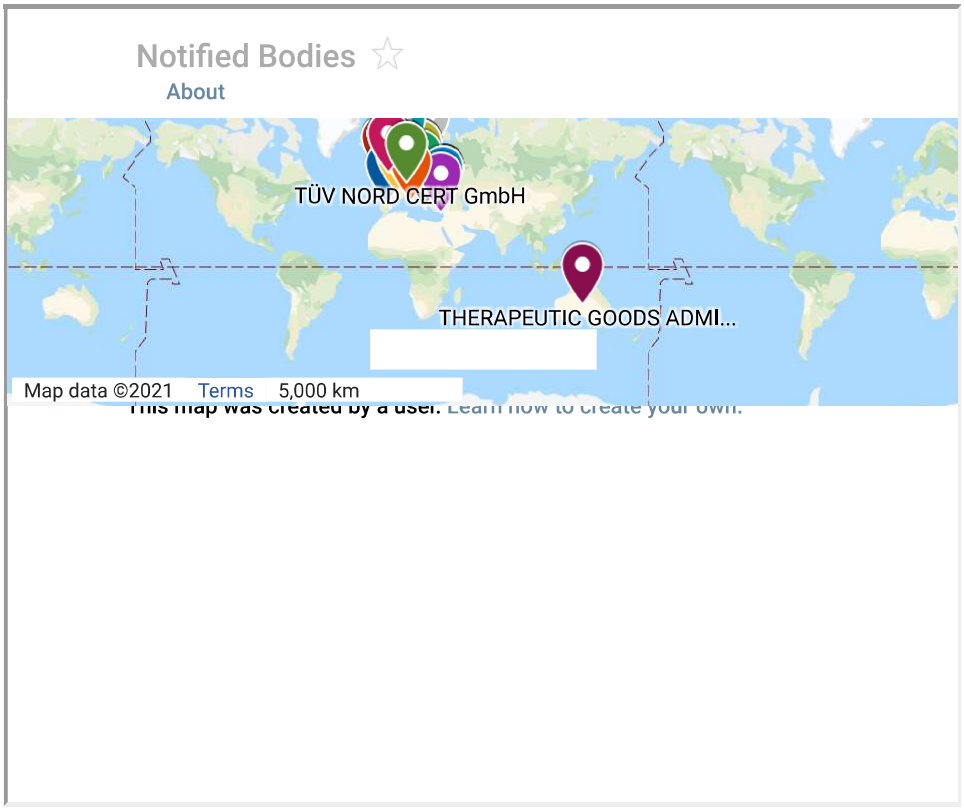
As seen from the EC's recent factsheet to health care providers and health institutions and the European Association of Notified Bodies' (Team-NB) member survey results, manufacturers and NBs alike face difficult decisions with the new regulations.



The EC cited decisions like ceasing the production of a product or being unable to get a product certified in instructing health care providers and health institutions to stock up on their most needed devices, warning that some devices may "become temporarily unavailable."

CEO and founder of UK-based MedBoard Ivan Perez told *Focus* that "stakeholders, including hospitals, are increasingly asking in some countries to create a plan or, at a national level, to evaluate hospitals and health care providers portfolios." This is because they are looking to "identify any potential gaps due to potential products discontinuations and temporarily unavailability of products" so that they can "be prepared in the case this situation happens."

Data from Team-NB's recent member survey show a dip in the total number of valid CE certificates and a slight increase in the number of withdrawn certificates, as the graphic to the right depicts. Some of the reasons manufacturers cited for withdrawing certificates include limited resources and change of NB, among others.



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The geographic data illustrate in the map to the right the smaller NB pool that manufacturers currently have to choose from when seeking (re)certification and are likely to continue having to post-MDR/IVDR, despite the larger body of products subject to NB oversight. On the IVD side, 80% of IVDs will be subject to oversight under IVDR, up from just 20% of IVDs under the EU's IVD directive.

MDR is set for 26 May 2020, followed by IVDR on 26 May 2022. BSI UK and TÜV SÜD are the only two NBs that have been designated against

MDR so far and none have been designated against IVDR. TÜV SÜD Product Service GmbH VP Bassil Akra told *Focus* that "not having medical devices reviewed and approved on time will impact the health care system critically." More devices will require NB involvement than in the past, when many were self-declaration devices, and their manufacturers will have to show MDR compliance prior to May 2020 to continue placing devices on the market after 26 May 2020.

Difficulties with the requirements of the new system—whilst some grapple with Brexit's uncertainties—have forced some NBs out. Akra further argued that the "limited capacities at two" NBs versus 58 NBs available under the EU's medical device directive "will not enable the [MDR] system to run smoothly."

Small- to mid-sized enterprises (SMEs) are of concern. Perez said that he met with a number smaller companies and noted that the situation is "very concerning" as many appear to be in a "wait-and-see-mode."

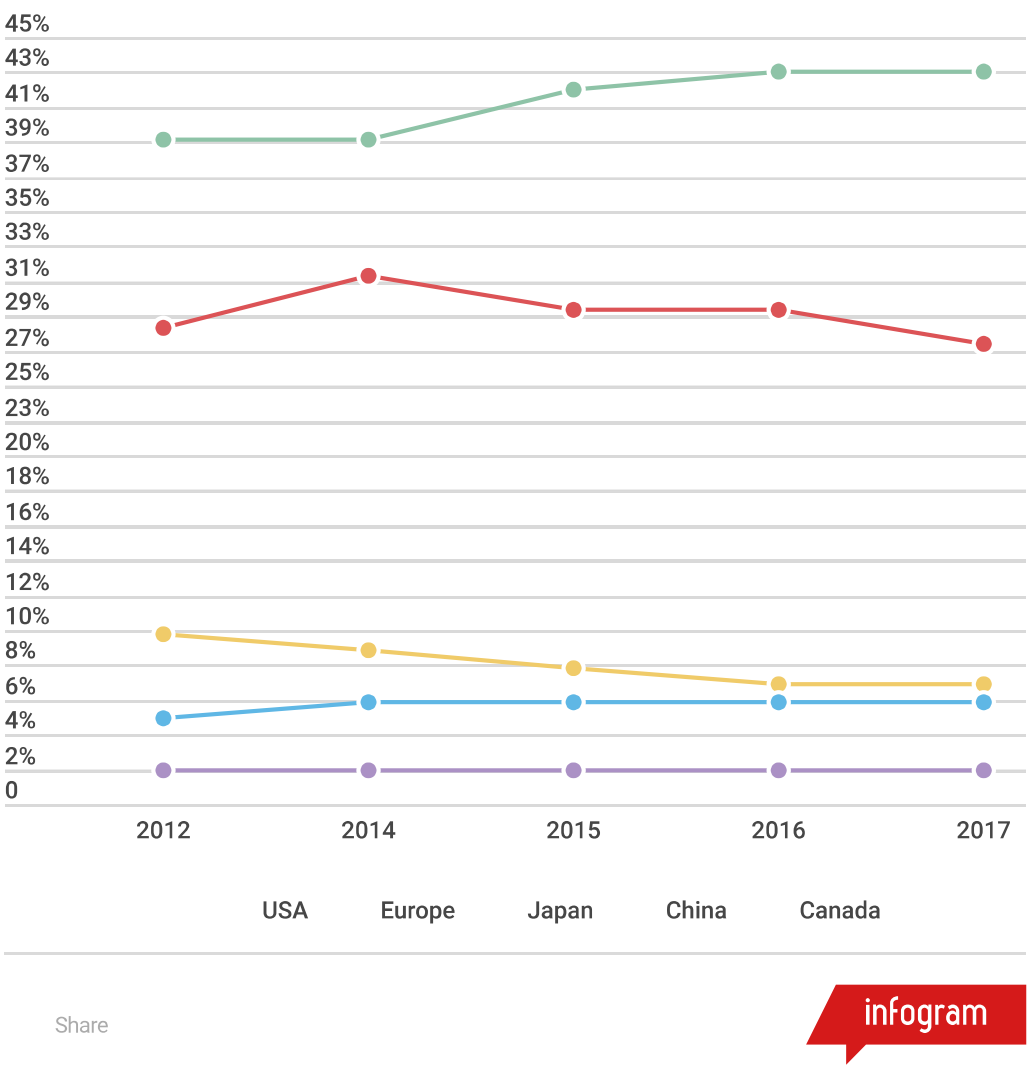
"The level of action and readiness is very low, everybody seems to 'waiting' or 'holding' for more information and certainty," he said.

MedTech Europe communications lead Jerick Parrone told *Focus:* "A severe consequence of this is that European start-ups and SMEs, which represent 95% of the medical device industry, are already turning to the US, China and other regions to develop and roll-out their innovations and bring their related economic activity outside of Europe.

"If not resolved urgently and decisively, this set of circumstances can profoundly disrupt the medical technology market in Europe, and create a significant 'cliff-edge' that puts patient safety, health care services and the EU health care environment in major disarray," Parrone said.

MedTech Europe reports on the European medical technology industry shows the US' market growing while the EU's shrinks between 2012 through 2017. Others remain relatively stable, as the graphic to the right shows.
"Regarding global markets, it still remains a case by case analysis," Perez said. The appealing factor for manufacturers to look to other countries depends on the "product demand, market access requirements and predicates, market opportunities and business strategy," he added.

Akra pointed to a closed conformity assessment process, which does not require a design documentation assessment, as a potential solution to the supply bottleneck that is expected. He added that not having such a process on time will lead to access delays in non-EU markets that rely on the EU certification system. "This means that product market access



continuity will be impacted in both the EU and non-EU countries, leading to reduction in sales globally and most importantly a negative impact on the international health care system," Akra said.

But the intentions remain for the EU's new system to foster market innovation and promote patient safety.

Perez noted that it "still is early to define where is the real 'bar' of the requirements and costs for each product type, as not all information is available yet. Many implementing acts, guidance, common specifications, interpretation of rules, etc, need to come out in order to define the 'how' and implementation of the regulations." But recertification issues and cost concerns, especially for small players, NB dropouts and transfers, to upgrade to MDR "create a very uncertain situation, that if we add Brexit in the case of the UK, forms the perfect storm of uncertainty."

Editor's Note: Updated on 7/15/19 with comment from Akra.