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Switzerland: US FDA's Medtech Can Bridge Innovation Gap Left By MDR

Medtech industry wants more urgency from Swiss authorities to address worsening product shortfall

by Ashley Yeo

Setting the patient safety bar too high will likely have the opposite effect in the case of the EU MDR. So believes the medtech industry in Switzerland, where work has begun at government level to pave the way for Swiss patients to have access to US FDA-approved medtech.

Switzerland and the EU have begun to experience cases of medtech products no longer being available on their respective markets. The Medical Device Regulation's more stringent regulatory criteria, its cost to users and persisting lack of structural integrity have compelled some companies to abandon niche and other medtech solutions on the EU market.

In Switzerland, the situation is made worse by the failure of the Federal Council to agree terms that would allow its Institutional Agreement with the EU to be renewed. This is the bilateral agreements mechanism that among other things enabled the free flow of medtech goods under harmonized regulation across the EU-Swiss border by means of a mutual recognition agreement (MRA).

The MRA ceased to apply on 26 May 2021, when the MDR came into effect.

Since then, foreign companies without an office in Switzerland who want to enter the Swiss medtech market must appoint a Swiss-based authorized representative (CH-Rep). Their access to EU based authorized representatives ended when the MDR came into effect. Switzerland's MDR-equivalent Medical Devices Ordinance (MedDO/MepV) was implemented concurrently.

Opening The Door To US FDA Products

Not all companies are economically able to maintain full portfolios in the face of higher market access hurdles. Seeing the loss of access to existing products and potentially much slower patient access to medtech innovations under the more stringent MDR, Switzerland has opened the door to US Food and Drug Administration-approved medical devices reaching the Swiss market and patients.

The initiative began when state council member Damian Müller proposed that medtech from outside Switzerland and the EU be permitted for use in Switzerland. The motion was recently approved by both Swiss parliamentary chambers. The Federal Office of Public Health (FOPH/BAG) has been given two years in which to propose a change to the law.

Industry association Swiss Medtech says that local companies, distributors and importers overwhelmingly support the initiative. Association head of regulation and innovation Daniel Delfosse said: "They need to find more substitution products. Some products are already missing here, and others will be missing when the phase-out of Medical Devices Directive (MDD) legacy products begins in earnest."

Phasing Out Of Products

He continued: "We know that at least 15% of the portfolio will be phased out once the MDR and IVDR are the only regulatory instruments applying in the EU." Companies and device users have recently been granted more transition time to use MDD legacy products. However, Delfosse notes that many companies have already started product phase-out processes. "They won't wait until the end of 2027 or 2028 to finish streamlining their portfolios."

While the MDR has the laudable aim of ensuring only the safest products reach the EU market, setting regulatory hurdles too high and preventing valid innovations from reaching patients will have the unwanted effect of harming patient safety and wellbeing, in Swiss Medtech's view.

Switzerland has the additional problem that 15% of the medtech products (60,000) imported before the market access issues are no longer available. That is a result of over 1,000 foreign manufacturers deciding not to establish a CH-Rep. Swiss surgeons accordingly have access to fewer treatments. In some cases, they must resort to previous-generation technology, if the newest iteration is not available in Switzerland.

For surgeons, finding these equivalent products can be time consuming, and there might be a learning curve and/or training needs. They also know that some of the quality has been lost. Patients are still treated well, with safe substitution devices, Delfosse stressed. But the situation is far from ideal.

Hospitals Need To Seek Alternative Technologies

Typical experiences of Swiss companies and surgeons were described in a February 2023 issue of

Schweizerische Ärztezeitung.

Staff at the Kantonsspital Winterthur (KSW) have observed lower availability of all types of medtech, which can be problematic if special devices are affected. So far, the hospital has been able to work around certain brand non-availability. However, should the current trend continue, KSW fears the shortfall could grow to 1,200 products in 2024, representing a potentially large health care problem.

Moreover, finding the right substitute products to use is a time-consuming task for KSW, which has hired extra staff to cope with the increased workload. Endoscopy systems importer and distributor Anklin (Reinach) has had to do likewise, adding staff resources to be able to source alternative products for timely delivery to customers. The situation has led to delays, the company said.

Delfosse expects that companies serving Switzerland could cut a *further* 15% of their product portfolio – on top of the 15% of products already lost to the market. "At some stage, it risks becoming dangerous," he said, urging the authorities to react swiftly before the unfolding situation becomes irretrievable.

Earlier Access To Innovations

Allowing US FDA-approved products into Switzerland would give Swiss surgeons greater choice regarding substitution products that are not yet approved in Switzerland or the EU.

This would potentially grant Switzerland much earlier access to medtech innovations, given that EU approvals under the MDR are typically three to five years behind FDA approval; and that up to 50% of European companies are deciding to go to the US first to make their product launches, according to a MedTech Europe survey in summer 2022. (Also see "*Extensive EU Medtech Regulatory Survey Reveals Scale Of MDR Hurdles And Where Problems Lie*" - Medtech Insight, 18 Jul, 2022.)

The US is more attractive not just because of the MDR's elevated hurdles, but also because the FDA has followed industry's needs very closely in developing software and artificial intelligence laws, says Swiss Medtech. The EU in contrast has built high hurdles into its draft AI regulation, and has not solicited industry's input.

Renewed MRA Still Far Off

Switzerland's US efforts do not negate the value of the EU, which is Switzerland's biggest trade partner, an agreement with whom at some stage "is inevitable," Delfosse said. For the time being, the state secretariat for economic affairs (seco) has been involved in several rounds of sounding-out talks in Brussels. Progress on renewing the Institutional Agreement, the medtech MRA and all the other bilateral agreements is moot.

The two blocs are said to be closing some of their gaps, but even under the best of outcomes, an agreement would not arise before summer 2024. The Swiss medical technology industry has been living without an MRA since May 2021 and sees no clear sign that the situation will change any time soon.

As other Swiss industry sectors such machinery and construction materials one by one are locked out of EU equivalency, the pressure for Switzerland to reach an agreement with the EU will mount. Medtech and research were the first two elements to be affected by MRA non-renewals.

Delfosse also fears loss of attractiveness of Switzerland as a European HQ base for non-European companies. Swiss Medtech recently started a project to highlight the value of the country as a medtech location. *Medtech Standort Schweiz 2030* includes a set of 12 aims for the industry and wider sector to work on over the coming years.

Improving market access and driving product innovation are part of the project. “We cannot predict how 2030 will look, but we are preparing for all eventualities,” Delfosse said.