Medical Devices: EU Sawing Off the Branch It Sits On

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We are at the end of a countdown of three years. Since the Medical Device Regulation (MDR) came into force on May 25, 2017, the medical devices industry knew that it would have to adapt before May 26, 2020, when the MDR would become applicable. A countdown makes sense if you know what you have to do by the time the “ignition” command sounds. On the other hand, if the changes you have to make to your processes are unclear, a countdown is just agony. Currently, this is what a majority of market actors in the medtech sector experience, especially the small and medium-size enterprises (SMEs) that make up more than 90 percent of this sector.

Swiss manufacturers suffer the same fate as their European counterparts and are therefore competing on the same playing field under the same rules as the European manufacturers. This will change for the worse however, as the EU is refusing to adapt the mutual recognition agreement (MRA) that would be necessary for the Swiss manufacturers to still be allowed access to the EU market without further technical hurdles. It is to be expected that the EU will not change its current stance as long as the Swiss side is not willing to sign the Institutional Framework Agreement (IFA) also being negotiated. Notwithstanding the questionable package deal the EU is sticking to here (see our analysis here), the Swiss will politically not be able to sign the IFA in the near future. This means that Swiss manufacturers of medical devices will no longer have a level playing field with their EU competitors, but will have to compete uphill. As of May 26, 2020, Switzerland will be perceived as being a “third country” when it comes to medical devices.

This means, inter alia:

- Swiss notified bodies (NB) will not be able to be notified under MDR.
- CE certificates for medical devices issued by Swiss NBs will no longer be valid (and the transitional rules in the MDR will therefore not apply to these devices).
- Swiss manufacturers exporting medical devices to the EU will need an authorized representative in the EU, taking full responsibility for the Swiss products.
- Swiss manufacturers will need an official importer located in the EU, also taking on a significant role.
- Swiss products will have to be relabeled according to the new status of Switzerland as a third country.
These technical hurdles cost time and money. As the EU medical devices market accounting for half of the Swiss exports of medical devices, many a SME might have to stop exporting medical devices, or stop producing altogether, both for the EU and for the global market.

So far, so bad for the Swiss medtech industry. But it is not only about money and the future of the Swiss economy, it is also about the availability and security of medical devices for patients — on the Swiss and the EU market. Regarding the latter: The Swiss agency competent for the market surveillance for medical devices (Swissmedic) will no longer be part of the network of EU national competent agencies (NCA). Therefore, it will have no more access to crucial information about problems arising with individual products, nor will Swissmedic be allowed to participate in EU working groups, as it did for years and with a significant input. These working groups are more important than ever as more detail on MDR requirements will be laid down in guidance documents issued by these working groups.

This lack of access might affect the security of medical devices on the EU market. More importantly, cutting off the Swiss manufacturers from the EU market will negatively affect the availability of medical devices for hospitals, homes and individual patients in the EU. Switzerland is one of the biggest producers of medical devices in Europe, manufacturing products for more than €15 billion and putting medical devices for more than €5 billion onto the European market, and no less than €2 billion worth of products are exported to Germany alone (Sector Study 2018 by Swiss Medtech).

We expect that the MDR will have a hugely negative effect on the availability of medical devices in the EU as SMEs struggle with the time and costs of the additional regulatory burden. With the refusal to adapt the MRA with Switzerland to cover the MDR, the EU takes a stance that might be seen as consequent. However, it is contrary to the core objectives of the new regulation, namely to give patients access to medical devices of high quality and undisputed safety. The only thing worse than a substandard medical device is the absence of any medical device on the market. This, last but not least, opens the door to the black sheep putting unregulated devices on the market, a serious phenomenon the NCAs could not prevent in the past and will struggle to in the future. One hopes that the EU is also reflecting on these negative consequences of not adapting the EU/Swiss MRA to the new EU medical devices framework.