SIDLEY

Products With Non-Medical Purpose — MDR Annex XVI Is Looming

Andreas Balsiger Betts

In the circles of medical devices manufacturers, the European Regulation for Medical Devices 2017/745 (MDR), which entered into force on May 25, 2017, and will become applicable on May 26, 2020, has cast its shadow well ahead. Everyone is doing their best to comply with the new regulation so as to be able to continue to supply the market without disruptions.

The challenges Swiss medical devices manufacturers are facing are even bigger than those of their European competitors, as it seems that the EU will not be willing to adapt the Mutual Recognition Agreement (MRA) with Switzerland to the MDR in time. Currently, it seems that Swiss manufacturers will be regarded as "third country" manufacturers and therefore will not be allowed to supply the EU market equally as EU manufacturers. Every Swiss manufacturer will need an authorized representative (based in one of the EU member states) to be able to continue exporting its products to the EU. This authorized representative has a number of important obligations laid down in the MDR and therefore assumes the same responsibilities and risks as the manufacturer. As a result, they have to be insured, which results in significant additional costs for Swiss manufacturers.

In all probability, Swiss medical devices manufacturers will be aware that not only are their products traditionally sold as medical devices but also other, similar products can fall under the MDR in the future. But what about all the manufacturers that never produced medical devices but only products without a medical indication that will now be regulated as medical devices?

Currently, the following groups of products, listed in the MDR's Annex XVI, will be subject to the MDR as of May 26, 2020:

- Non-prescription colored contact lenses and other products to be introduced on or into the eye
- Horn implants and other products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy
- Dermal fillers and other substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling
- Equipment intended to be used to reduce, remove or destroy adipose tissue
- Intense pulsed light machines for body hair removal and other high-intensity electromagnetic radiation (e.g., infrared, visible light and ultraviolet) emitting equipment intended for use on the human body

- Equipment intended for brain stimulation that apply (non-surgically invasive) electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain

The EU Commission (Commission) has the competence to amend this list, thereby submitting more product groups to MDR's scope. It is also to be expected that the Commission will issue some guidance regarding the application of the MDR to such products; however, nobody knows when this will be, with the only message being "Commission factsheet coming soon." Awaiting the Commission's guidance, concerned manufacturers can turn to the Guidance for products without an intended medical purpose (Annex XVI) under the new Medical Device Regulation (EU 2017/745) that the UK Medicines & Healthcare products Regulatory Agency (MHRA) recently published.

The MHRA's guidance helps manufacturers, importers and distributors of such products to understand how they will be affected by Annex XVI and how to best comply with the new rules (which are to be read alongside Articles 10, 13 and 14 of the MDR) on the UK market. Importantly, manufacturers of these products will need to demonstrate compliance with common specifications that have not yet been adopted (but are expected to be adopted by May 26, 2020).

It is high time for all market actors dealing with products falling under the MDR's Annex XVI to get acquainted with the new regulation and to take all the necessary steps to avoid a sudden disruption of their business by May 26, 2020. Last but not least, if their products should fall under a risk class that requires a conformity assessment by a notified body, they will have to start looking for such a rare animal that is willing to take on a manufacturer of products it has never seen before.