# Mutual Recognition Agreement (MRA) between the EU and Switzerland still pending

## Article by Miriam Schuh

Mutual Recognition Agreements are agreements for the mutual recognition of conformity assessments and serve in particular to eliminate trade barriers in state-regulated sectors. The EU and Switzerland have such an MRA which, in product segments where applicable Swiss law is considered to be equivalent to EU law, allows conformity assessments for the EU internal market to be conducted by a recognized Swiss conformity assessment body in accordance with Swiss technical regulations, so that those products can be placed on the market in the EU without further testing. This includes medical devices which are tested in Switzerland, since the EU Medical Devices Directives have been implemented in Swiss law.

When the EU Medical Device Regulation (MDR) takes effect, the Directives which had previously been in effect, the Medical Device Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD), will cease to apply. While Annex 1 Chapter 4 of the MRA between the EU and Switzerland does refer to the MDR, this reference is only partial. Final implementation of the medical devices regulations which have been set in motion in Switzerland requires further revisions to the MRA. The EU-Switzerland MRA was last updated on 22 December 2017.

The outdated status of the EU-Switzerland MRA is a source of legal uncertainty for medical devices in EU member states and in Switzerland as well. If the MRA is not updated, there is a risk that Swiss manufacturers of medical devices will be subject to regulation as third-country manufacturers, so that medical devices imported from Switzerland would be subject to the rules governing imports from third countries. As a result, distributors of Swiss medical devices in the member states may be classified as "importers" in terms of the MDR, which would involve the (unwanted) imposition of additional requirements and corresponding liability risks. The export of devices manufactured in the EU member states into Switzerland would also be subject to new legal requirements.

Accordingly, it appears to be of urgent importance for the MRA to be updated and revised. However, negotiations to update the MRA have become bogged down recently, so that it is unclear whether the current legal situation with respect to recognition of the MDR's requirements will continue. Nevertheless, Switzerland

is currently in the process of revising its medical device laws based closely on the new European regulations (e.g. changes to the Therapeutic Products Act (TPA), the Human Research Act (HRA) and the Medical Devices Ordinance). A new Ordinance for in-vitro diagnostics will follow in 2022. Distributors of Swiss medical devices in particular should watch developments closely in order to avoid unwillingly assuming the role of importer. reuschlaw will continue to follow the MRA negotiations and will provide regular coverage in this newsletter.

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