

Swiss Medical Devices Manufacturers to Be Blocked by Missing Framework Agreement?

[Nicolas J.S. Lockhart](#), [Andreas Balsiger Betts](#), Yannick Trudel

In the medical devices sector, Switzerland and the European Union (EU) have entered into a mutual recognition agreement (MRA). Under this treaty, each party accepts products produced by manufacturers based in the other party that meet the technical regulations of the other party. This allows manufacturers from both parties to market their products in a joint market. Following changes to EU regulations in this area, Switzerland is revising its own regulations. As a result of these changes, Switzerland and the EU must enter into a revised MRA to avoid technical barriers on their trade in medical devices.

At the same time, negotiations between the EU and Switzerland regarding an institutional framework agreement (IFA) are stalling. There are signs that the EU may link the successful conclusion of the IFA negotiations with its willingness to enter into a revised MRA. This raises a question whether any such linkage would be compatible with the disciplines under the World Trade Organization (WTO) on mutual recognition.

Companies manufacturing medical devices (MD) and in vitro medical devices (IVD) have to comply with a myriad of safety-related technical regulations to enjoy the right to put their products on the market. For each export market, a company must ensure compliance with all the technical requirements imposed in that jurisdiction. Such requirements may include the designation of a representative in the importing state, the duplication of clinical trials and the adaptation of product labels. MRAs between countries aim to reduce the burden of such processes between states having similar regulations.

Since June 1, 2002, Swiss and EU manufacturers have enjoyed the benefits of mutual recognition through the Agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessment (EU-Switzerland MRA). The EU-Switzerland MRA significantly helps to reduce technical barriers to trade for Swiss and EU exporters, effectively ensuring the harmonisation and equivalence of the regulations of both jurisdictions and eliminating the need for companies to conduct conformity assessments twice.

Despite the effectiveness of the EU-Switzerland MRA in facilitating market access between Switzerland and the EU, a veil of uncertainty has fallen on Swiss MD/IVD manufacturers as there are signs that the EU may make the renewal of the EU-Switzerland MRA dependent on Switzerland's adoption of an EU-Swiss IFA, which is being negotiated. The objective of the IFA

is to streamline the harmonisation of Swiss law with EU law, monitor the implementation of bilateral market access agreements and resolve interpretation issues through dispute settlement.

Interestingly, the IFA's objectives do not include the health protection objectives of MD/IVD regulation, but the EU seems nonetheless to tie its recognition of Swiss medical device regulation to the outcome of the IFA negotiation. This raises several questions with respect to the EU's obligations under the laws of the WTO. Specifically, the Agreement on Technical Barriers to Trade imposes obligations on the EU to consider positively the regulations and conformity assessment procedures of another WTO Member presenting a request for recognition. This obligation aims to eliminate unnecessary technical barriers in cases where an importing Member can be satisfied that its regulatory objectives — for example, the protection of health and safety of medical devices — are fulfilled by the regulations and procedures of another Member.

Although WTO Members enjoy a degree of discretion in recognizing the regulations and procedures of other Members, that discretion does not extend to permitting an importing WTO Member to link its recognition of an exporting WTO Member's regulations and procedures to the conclusion of another unrelated treaty, like the IFA, between the two Members.

Moreover, under the WTO most-favoured-nation principle, the EU is obligated to accord unconditionally to every other WTO Member the best treatment that the EU accords to the goods of any of its trading partners. If the EU were to decline to recognize Switzerland's medical device regulations and procedures, it would be constrained to accord the same — negative — treatment to other WTO Members that have equal or lower standards than Switzerland. Equally, should the EU accord recognition to the regulations and procedures of another WTO Member, it would have to do likewise to Swiss regulations and procedures that meet the same standards.

It is important for the EU to give careful consideration to the potential consequences of its decision regarding the EU-Switzerland MRA, as it may entail a violation of WTO law and also constrain its ability to negotiate MRAs in the medical devices sector with other WTO Members, such as Turkey and the United Kingdom (after Brexit).