Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
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The Federal Council

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Mutual Recognition Agreement (MRA)

Overview

In order to sell a product in a specific country, a company must prove that the product complies with that country's regulations. Obtaining this proof can be time-consuming and costly, as these regulations vary from country to country.

To reduce this burden, Switzerland and the EU have concluded a Mutual Recognition Agreement (MRA) on conformity assessments. This means that a product on the Swiss market can also be sold in the EU without additional administrative procedures, and vice versa. The agreement strengthens and simplifies cross-border production and distribution chains, thereby helping to keep prices in Switzerland low.

The MRA covers 20 product sectors, including machinery, medical devices, electrical equipment, construction products, lifts and pharmaceutical products. These sectors account for 73% of all Swiss industrial products exported to the EU. It establishes uniform product requirements and specifies that conformity assessment (proof of compliance with the requirements) need only be conducted once, either in Switzerland or the EU. This means that a hip prosthesis or machine manufactured in Switzerland, for example, can be sold both in Switzerland and the EU without any additional time or cost involved.

Because product regulations are constantly evolving, the MRA must be updated regularly. However, the EU has refused to update the agreement since May 2021 due to unresolved institutional issues. This decision is currently affecting medical devices.

Key elements

The inclusion of the new institutional elements in the MRA ensures that the agreement will be regularly adapted to the relevant developments in EU law in future. The MRA's status as an equivalence agreement remains unchanged.

In addition, Switzerland will be able to participate in EU market surveillance, consisting of measures to ensure product safety and quality. The exemption provided for in the MRA for prepackaged products, for which the product requirements in Switzerland differ from those in the EU, will remain in place.

Switzerland and the EU have set out the arrangements for their cooperation from the end of 2024 until the package comes into force. They will work closely together within this framework to ensure the proper functioning of the existing internal market agreements. In particular, they will discuss how to implement the MRA, bearing in mind the needs of economic stakeholders.

Implementation in Switzerland

Neither the Institutional Protocol nor the Amendment Protocol to the MRA requires any changes to Swiss law or accompanying measures.

In the product sectors covered by the MRA, Switzerland will continue to align its regulations with those

of the EU through a process of equivalence.

Importance for Switzerland

The MRA simplifies the export of products, thereby strengthening the export industry and helping to reduce prices in Switzerland while securing local jobs. It is important for Switzerland that products covered by the MRA can circulate freely within the EU. This reduces costs for businesses, which in turn reduces prices for consumers. It also establishes a stable legal framework between Switzerland and the EU, making Switzerland a more attractive place to do business.

Thanks to the expansion of its consultation rights in the adoption of legislation, Switzerland can contribute its expertise at EU level and actively participate in shaping EU legislative developments. This ensures that the concerns of Swiss stakeholders are taken into account at an early stage of EU legislative processes.

Specifically

- **Simplifying product certification for the EU market:** Take the example of a medium-sized Swiss industrial company specialising in manufacturing machine tools for the optical industry, generating only around 20 per cent of its sales in Switzerland. Most of its machines are exported, primarily to Italy and Germany. Thanks to the MRA, the machines only need to undergo the conformity assessment procedure once, in Switzerland. This is because the procedure is also recognised in the EU. The company also benefits from other administrative advantages. For example, unlike its US competitor, it does not have to appoint an economic operator (importer or authorised representative) in the EU, nor does it have to label its products with the contact details of such an operator.

  If the MRA for machinery ceased to apply, for example because the EU stopped updating it, this would lead to considerable additional costs. Industrial companies would then need to obtain a conformity assessment from the EU, employ an economic operator (importer or authorised representative) based in the EU, and relabel their products for the EU market. For Swiss companies that despite their specialisation are competing with larger companies in the EU, this would entail additional costs and, in some cases, severely impact their business.

- **Product safety:** There are around half a million different types of medical devices, ranging from simple tweezers to pacemakers. Each one must meet the applicable legal requirements, particularly the safety requirements, before it can be used. As safety is paramount, especially for complex devices such as pacemakers, the medical device market must be continuously monitored and unsafe products swiftly and effectively withdrawn if necessary.

  However, without resolving the institutional issues, Switzerland remains excluded from market surveillance with EU member states for medical devices. This makes it more difficult for Swiss authorities to access the information they need to respond quickly to unsafe products. Therefore, a functioning MRA also serves to protect patients in Switzerland.