



Commission publishes information notice on the status of the EU-Switzerland Mutual Recognition Agreement for Medical Devices

Brussels, 26 May 2021

Today, the Commission has [published a notice](#) to stakeholders informing them that the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland ceased to apply on 26 May. This is linked to the new Medical Devices Regulation entering into force in the EU on the same date.

The Mutual Recognition Agreement (MRA) is one of the key agreements between the EU and Switzerland facilitating bilateral trade in a number of key sectors. It is essentially a “single market access” and “dynamic alignment” with EU rules agreement, two principles which are at the core of the Institutional Framework Agreement in negotiation with Switzerland since 2014. This is the reason why the MRA falls under the scope of the EU-Switzerland Institutional Framework Agreement. This is fundamentally a level playing field issue.

Against this background, the EU has always made clear that in the absence of a deal on the Institutional Framework Agreement, an update of the MRA, including the medical devices chapter, cannot be considered.

However, and although we do not expect potential disruptions in the health sector during the COVID-19 pandemic, on 30 March 2021 the EU proposed to Switzerland as a precautionary measure a limited modification of the medical devices chapter of the MRA providing for a transitional validity period for existing devices with Swiss certificates until 26 May 2024 (at the latest) and the same transitional validity for certificates issued in the EU. Despite consistent efforts and EU readiness to conclude such a transitional arrangement, the proposed modification was not agreed ahead of 26 May 2021.

As a result, until a potential agreement on the proposed modification to the MRA is reached, the trade facilitating effects of the MRA for medical devices, including the mutual recognition of conformity assessment results, the absence of the need for an authorised representative and the alignment of technical regulations, cease to apply as from today Wednesday 26 May 2021.

For more information

[Notice to Stakeholders](#)

[EU-Switzerland relations](#)

[Factsheet: What if there is no Institutional Framework Agreement \(IFA\)?](#)

IP/21/2684

Press contacts:

[Stefan DE KEERSMAECKER](#) (+32 2 298 46 80)

[Miriam GARCIA FERRER](#) (+32 2 299 90 75)

General public inquiries: [Europe Direct](#) by phone [00 800 67 89 10 11](#) or by [email](#)