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Health systems, medical products and innovation
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NOTICE TO STAKEHOLDERS: STATUS OF THE EU-SWITZERLAND MUTUAL RECOGNITION AGREEMENT (MRA) FOR MEDICAL DEVICES

Until now, Switzerland has been participating in the European Union internal market for medical devices through a specific chapter of the EU-Switzerland Mutual Recognition Agreement (MRA). The medical devices chapter of the MRA has provided for recognition of conformity assessment certificates between the European Union and Switzerland based on equivalent regulations. This has facilitated seamless trade of medical devices between the parties.

The new Medical Devices Regulation (EU) 2017/745 becomes fully applicable on 26 May 2021, replacing the previous Medical Devices Directives 90/385/EEC and 93/42/EEC. Absent an update, this new Medical Devices Regulation is not included, in its relevant parts, in the medical devices chapter of the MRA.[1]

The MRA is one of the key agreements between the EU and Switzerland, facilitating bilateral trade in a number of key sectors such as machinery, motor vehicles and medical devices. It is essentially a "single market access" and "dynamic alignment" with EU rules agreement, two principles which are also at the core of the Institutional Framework Agreement[2] in negotiation with Switzerland since 2014. 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 absence of a deal on the Institutional Framework Agreement, a full update of the MRA cannot be considered, including the medical devices chapter.

However, and although we do not expect large 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

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1 It is noted that the medical devices chapter of the EU-Switzerland MRA also covers trade of *in-vitro* diagnostic medical devices, based on the Directive 98/79/EC and the corresponding Swiss legislation. This part of the chapter continues to apply until the date of application of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

2 The Institutional Agreement encompasses five key existing bilateral agreements that allow Switzerland to participate in the internal market. They relate to free movement of persons, mutual recognition of industrial standards, agricultural products, air transport and land transport. Future agreements (e.g. on electricity or public Health) will fall under this scope, once negotiated. For all of these agreement, the Institutional Framework Agreement sets out crucial horizontal rules and procedures that ensure the uniform interpretation and application of the agreements concerned, a "dynamic" takeover of the EU *acquis* by Switzerland, state aid discipline and an effective dispute settlement mechanism.

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 falling under the new Medical Devices Regulation, 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.

The following consequences as of 26 May 2021 should therefore be noted by stakeholders:

- For all new devices, Swiss manufacturers will be treated as any other third country manufacturer intending to place their devices on the EU market. In particular, new Swiss medium and high-risk devices must be certified by conformity assessment bodies established within the EU.

- Existing certificates issued under the MRA by conformity assessment bodies established in Switzerland will no longer be recognised as valid in the EU.

- For existing certificates issued under the MRA by conformity assessment bodies established in the EU, Swiss manufacturers and third country manufacturers whose authorised representative was previously established in Switzerland, must designate an authorised representative established in the EU.

- On 19 May 2021, the Swiss Federal Council adopted an amendment to the Swiss Ordinance on Medical Devices establishing conditions for trade of medical devices covered by EU issued certificates on the Swiss market. This includes the recognition of existing certificates issued under the MRA by conformity assessment bodies established in the EU and transitional timelines for the designation of a representative in Switzerland for EU/EEA manufacturers of medical devices.

To address the consequences set out in this notice, market participants (e.g. affected manufacturers, EU importers and distributors, authorised representatives) as well as EU market surveillance and customs authorities in Member States are required to act in accordance with the Medical Devices Regulation (EU) 2017/745:

- Since existing certificates issued under the MRA by conformity assessment bodies established in Switzerland will no longer be recognised as valid in the EU as of 26 May 2021, to ensure that medical devices are certified by an EU conformity assessment body where such certification is required on the basis of the applicable conformity assessment procedure;

- to ensure compliance with the requirements for economic operators, in particular the need for an EU authorised representative;

- to comply with the requirements on registration and labelling of products.

Any possible further developments regarding the EU-Switzerland MRA for medical devices will be communicated in due course.