Avoiding distortion of trade in medical devices between EU and Switzerland based on the situation

Brussels, 12 February 2021

Summary

Trade in medical devices between the EU and Switzerland relies on the Mutual Recognition Agreement (MRA) signed between both parties. This MRA does not cover most of the provisions of the Medical Devices Regulation (MDR) and will in effect cease to function as a means to facilitate trade between the EU and Switzerland for medical devices on the 26th May 2021 with the entry into application of the MDR unless the MRA is updated before this point.

Currently the EU and the Switzerland are negotiating an update to the interinstitutional framework agreement (IFA) which provides the framework for the multiple recognition agreements between the EU Switzerland. Before the IFA negotiations are concluded it seems unlikely that the MRA on medical devices will be updated.

In practice this means that the MedTech industry cannot assume that the MRA between the EU and Switzerland on medical devices will be in place by the date of entry into application of the MDR by May 26th this year and that therefore Switzerland will become a third country for the purposes of the implementation of the MDR.

Impact – need to avoid discrimination for Swiss manufacturers and manufacturers in third countries with a Swiss authorised representative.

This in practice will result in Switzerland becoming a third country under the MDR – however due to the existing relationship it is important that measures be taken to ensure that Swiss manufacturers and manufacturers which have an authorised representative in Switzerland under the MDD are not discriminated against.

For manufacturers both in the EU and in third countries, if they have a valid certificate under the MDD they can continue to place devices on the EU market provided they comply with the transitional provisions as outlined in article 120 of the MDR on the basis of the valid MDD certificate, up until 26 May 2024.

It has been suggested that due to the nature of the legal provisions in the MRA and in the MDR, that manufacturers based in Switzerland or in third countries with a Swiss Authorised Representative may not benefit fully from the transitional provisions laid down in article 120 of the MDR in spite of having a valid MDD certificate.

It is important that the uncertainty around the devices covered by such certificates be clarified or it could lead to a significant disruption in supply of those devices after May 2021.

In particular the following patients would be impacted:

- Patients in emergency care suffering from acute kidney injury – this is a common complication of COVID-19, as devices used in renal replacement therapies and their consumables would be affected.
- Patients requiring cancer and dialysis treatments – infusion pumps, dialysis systems and related consumables needed for the treatment of these patients would be impacted.
- Trauma patients – patients suffering from trauma, in particular those needed specialist surgery such as joint reconstruction, craniomaxillofacial interventions or spinal surgery would be impacted.
- Ophthalmology patients – notably those patients requiring implants for cataract and vitreoretinal surgery.

Concerns

In order to benefit from the full transitional provisions laid down in article 120 of the MDR it is important that there is confirmation from the Commission that the holders of the following certificates, all of which are lawful and valid under the existing legislation, would be able to benefit from the relevant transitional provisions:

- Certificates issued under the MDD or the AIMD which list a Swiss manufacturer with no authorised representative in the EU.
- Certificates issued under the MDD or the AIMD which list a manufacturer in a third country and an authorised representative in Switzerland.
- Certificates which are issued by Swiss notified bodies under the MDD.

It should be noted that due to the uncertainty about the future of the MRA manufacturers based in Switzerland have been establishing authorised representatives in the EU for compliance with the MDR. In practice though it has not been possible to update the relevant MDD certificates as the lack of notified body capacity has resulted in notified bodies not being available to update valid certificates. For those manufacturers based in Switzerland who have established an authorised representative in the EU, there should be no penalty should the MRA be signed in the future – i.e. it should be possible for them to continue operating with an AR in the EU.

We remain at the disposal of the Commission for any further discussions and clarifications so as to resolve these urgent questions as quickly as possible.