EU-Swiss MRA
Accessing the EU market under the transitional provisions of article 120 of the MDR

Brussels, 9th August 2021

Background

The EU and Switzerland have been successfully trading seamlessly in medical technologies for well over 20 years under the Mutual Recognition Agreement (MRA) which included the Medical Devices Directive (MDD, 93/42/EEC).

However, the EU and Switzerland have been unable to finalise an updating of the MRA to cover all aspects of the Medical Devices Regulation (MDR, EU 2017/745). This in practice leaves a number of open questions on how to proceed with the implementation of article 120 of the MDR (transitional provisions) for those manufacturers who rely on Switzerland to access the EU market, in one of the following ways:

- Manufacturer based in Switzerland
- Authorised Representative based in Switzerland, with manufacturer in a third country
- Manufacturers hold a certificated issued by the Swiss notified body SQS

Following the entry into application of the MDR, devices could continue to be placed on the EU market either through full compliance with MDR provisions or using the transitional provisions (sometimes known as the grace period) detailed in article 120 of the MDR. This document focuses on those transitional provisions.

The Commission has issued a note on this issue on 26th May 2021 – however the note did not provide a legal framework for the conclusions which it had reached and so MedTech Europe requested an independent memorandum from Sidley Austin to clarify the situation.

The summaries below are all based on ensuring manufacturers are complying with the applicable EU requirements and are able to fulfil their obligations in line with good regulatory practices. All the information below is based on the actual MDR and MDD texts as well as the memorandum from Sidley Austin.

Regarding medical devices under article 120 of the MDR (Grace Period)

In order to benefit from article 120 of the MDR all of the relevant provisions need to be met. In practice the following considerations apply:

- The device remains in compliance with the requirements of the directive (MDD or AIMD) and is covered by a valid notified body certificate. No significant changes in the design or intended purpose of the device.
- Registration of economic operators and devices according to the MDR applies.

- Post market requirements of the Regulation corresponding to activities in post-market surveillance, market surveillance and vigilance apply.

Even though the MRA between the EU and Switzerland has not been updated to fully reflect the EU MDR, the MRA in its current form remains in full force and effect. This is a crucial aspect of both the Sidley Austin Memorandum and the overall legal framework under which medical devices will operate going forward.

It is in particular important to note that Swiss legacy devices[1]are guaranteed access to the EU/EEA market in the same way as other devices. This is supported by the MRA which clearly states that certificates and declarations of conformity issued under the MRA must continue to be recognised by both the EU and Switzerland.

Quoting directly from the Sidley Austin Memorandum:

> *Devices must be granted access to the EU/EEA market under the same conditions as all other Legacy Devices, and, with regard to reports, certificates, authorisations and conformity marks issued under the MRA, exactly as had been the case between 26 May 2017 and 26 May 2021. It follows directly from the MRA, which has remained in full force and effect after 26 May 2021, that Swiss Legacy Devices must be granted full "Article 120 MDR rights":*

Regarding Authorised Representatives.

Article 120 requires that all economic operators be registered under the MDR.

Devices placed on the market with a Swiss manufacturer or manufacturers with a Swiss Authorised Representative (AR) would be in compliance with the MDD, as the MRA remains in force, thus meeting the requirement of article 120 that the devices remain in compliance with the Directive. This recognition of this is explicitly pointed out in the Sidley Austin Memorandum as follows:

Quoting directly from the Sidley Austin Memorandum (emphasis added)

> ***The EU and its Member States must recognise existing registrations of Swiss manufacturers and of Swiss authorised representatives in Switzerland, and may not require the appointment of an additional EU authorised representative ("EU AR")*** *nor may they require relabelling of products to reflect the addition of an EU AR;*

However, it is also true that all manufacturers based in Switzerland, or who rely on a Swiss AR will have to eventually establish an AR in the EU as their devices move from transitional provisions to full compliance with the MDR.

In Summary: All manufacturers based in Switzerland or with an Authorised Representative established in Switzerland under the MDD or AIMD can now establish an Authorised Representative

[1] In this context, Swiss legacy devices are those which under the MDD or AIMD were placed on the market by a Swiss legal manufacturer without an AR or placed on the market by a third country manufacturer with a Swiss AR, or were covered by a Swiss NB certificate.

under the MDR according to MDR rules on a voluntary basis and register this Authorised Representative according to MDR rules. For these manufacturers an Authorised Representative will become compulsory when devices transition to the MDR.

Regarding labelling of devices.

Article 120 requires compliance with labelling requirements (and in fact all other essential requirements) of the MDD or AIMD. Not with requirements of the MDR. There is in fact no requirement under article 120 to update labels in order to benefit from article 120, even if the AR under the MDD is not the same as the AR under the MDR.

In addition, as the experience following the withdrawal of the UK from the European Union has shown, it takes approximately two years for labelling changes to be fully implemented. This means that at best devices under the transitional provisions of article 120 will only be placed on the market for 12 months, probably less, as they transition to full MDR compliance (and a new set of labels).

Quoting directly from the Sidley Austin Memorandum (emphasis added)

> *The EU and its Member States must recognise existing registrations of Swiss manufacturers and of Swiss authorised representatives in Switzerland, and may not require the appointment of an additional EU authorised representative ("EU AR")* ***nor may they require relabelling of products to reflect the addition of an EU AR;***

In Summary: Labels on devices benefitting from article 120 transitional provisions need to display the Authorised Representative under the MDD or AIMD. The AR on the label needs to continue to respond to queries as required under the MDD or AIMD. Thus no label change is needed with regards to the AR for Swiss legacy devices.

Regarding devices covered by a certificate issued by a Swiss notified body.

Though the EU Commission in its note points out that certificates issued by Swiss notified bodies under the Directives should be considered as no longer valid, there seems to be no legal basis for this statement.

Quoting directly from the Sidley Austin Memorandum:

> ***The*** *EU and its Member States must continue to permit EU sales of all MDD devices with a valid certificate issued by a Swiss conformity assessment body prior to 26 May 2021 and may not require an EU CE certificate as a condition for importation.*

Exactly like all other certificates issued by notified bodies issued under the MDD, certificates issued by Swiss notified bodies under the MDD should be considered valid until their expiration date, or until the 26th of May 2024, whichever comes first.

In Summary: Devices covered by a valid Swiss notified body certificate may benefit from the transitional provisions of article 120.

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