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Entry into force of the revised Swiss Medical Devices Ordinance and its implications for the medtech industry

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As of today, the revised Swiss Medical Devices Ordinance enters into force. Simultaneously, the EU Medical Device Regulation becomes legally effective. Since the Mutual Recognition Agreement between Switzerland and the EU was not updated in due time, Switzerland is now treated as a third country from an EU-perspective and *vice versa*. Read about the consequences below.

Current situation between Switzerland and the EU

Thanks to the Mutual Recognition Agreement (**MRA**) with the European Union (**EU**), Switzerland participated as equal trading partner in the EU[1] internal market for medical devices. An update of the MRA would have been necessary in order to maintain facilitated reciprocal market access between Switzerland and the EU due to the total revision of the Swiss and the EU legislation regarding medical devices, both of which enter into force as of today. However, the European Commission is linking the full update of the MRA to progress on the institutional agreement. Thus, the update has not yet been completed despite the postponed entry into force of the EU Medical Device Regulation (**MDR**) and the revised Swiss Medical Devices Ordinance (**revMedDO**) for one year (see our previous newsletters of April/May 2020 here and here). Yet, it remains Switzerland's primary objective to be recognised as an equivalent trading partner in the EU internal market. Negotiations between Switzerland and the EU are still ongoing, led by the Swiss State Secretariat for Economic Affairs (**SECO**). According to Swiss Medtech, it remains to be hoped that at least a partial update of the MRA with defined transition periods will soon be agreed upon. However, it could also be that the MRA will not be updated at all.

1 EFTA member states are also covered hereinafter when referring to the EU.

Recent Developments in Switzerland

The revMedDO enters into force as of today, composed of the version adopted on 1 July 2020 and the amending enactment published by the Swiss Federal Council on 19 May 2021 (full German text here and here, explanatory reports here and here). The amendments were necessary because the previous version of 1 July 2020 was based on a fully updated MRA.

In order to avoid significant barriers in the supply chains of medical devices between Switzerland and the EU, to improve cooperation in market surveillance and to enable the assurance of patient safety, the Swiss Federal Council has decided at its meeting of 19 May 2021 on measures reflected in the amending enactment (media release here).

Legal Implications of the amending enactment

As a consequence of the non-updated MRA, the Swiss and European medtech industries have to cope with significant additional efforts. The most important measures of the Swiss Federal Council to mitigate the negative effects of the delayed MRA-update are (non-exhaustive):

i. Unique device identification (UDI):
Medical devices must be assigned an UDI before being placed on the market.

The obligations and requirements associated with the UDI principally remain the same, but the information must now be reported to Swissmedic, as Switzerland will not have access to the EUDAMED database until further notice. However, this reporting obligation will only come into force at a later, not known date (see notes to "Entry into force" below). Within the transition period, the reporting obligation according to the previous MedDO applies. The reporting obligation must be fulfilled by manufacturers, distributors of combinations or persons who assemble systems or treatment units based in Switzerland. The reporting obligation concerns the placing on the market of both, MDD-[2] and MDR-compliant products.

ii. Issue and content of certificates of conformity:
Certificates issued by notified bodies according to the MDR are treated in the same way as those issued by Swiss notified bodies, provided that the qualification of the notified bodies and the assessment procedure applied meet the Swiss requirements.

iii. Appointment and duties of the Swiss authorised representative (Swiss AR):
Manufacturers domiciled in the EU (or manufacturers from a third country who have established an authorised representative in the EU) must appoint a Swiss AR for devices placed on the market after 26 May 2021 within the following deadlines (including product labelling):

- until 31 December 2021 for class III devices, class IIb implantable devices, and all active implantable devices;
- until 31 March 2022 for non-implantable class IIb devices and class IIa devices;
- until 31 July 2022 for class I devices, systems and treatment units.

What is new is that manufacturers or persons who assemble systems and treatment units domiciled in the EU are allowed to provide access to the technical documentation either by keeping a copy available at the Swiss AR or by contractually guaranteeing that it will be handed over to Swissmedic upon request within 7 days.

iv. Registration of Swiss economic operators:
The relevant information must be registered by the manufacturers or their Swiss AR and the importers to Swissmedic within 3 months of a product being placed on the market for the first time (economic operators who have placed MDR-compliant products on the market before 26 May 2021, must be registered by 26 November 2021; for economic operators who place MDR-compliant products on the market after 26 May 2021, the registration obligation applies from 26 May 2021 with a deadline of 3 months from the first placing on the market). Swissmedic allocates an identification number to the economic operators after checking the information. The registration of the named economic operators is only carried out once. Changes must also be reported to Swissmedic within one week. Persons placing systems or treatment units on the market for the first time must now also notify Swissmedic of their name and address within 3 months and, if applicable, the details of their Swiss AR.

v. Documentation obligation and review of safety reports:
The documentation obligation and the obligation to submit the safety report at the request of the competent authority remain unchanged. Instead of transmission via EUDAMED, both have to be submitted to Swissmedic.

vi. Summary of Safety and Clinical Performance (SSCP) report:
The data of the SSCP should be publicly accessible, even if economic operators or notified bodies from Switzerland do not have access to EUDAMED. Therefore, it is now the responsibility of the manufacturers to publish the SSCP report (e.g. on their website).

vii. Notification obligations (vigilance):
Manufacturers or their Swiss AR who supply products in Switzerland, as well as persons who supply/assemble systems or treatment units in Switzerland, must notify to Swissmedic all serious incidents that occur in Switzerland and the measures taken. Furthermore, Swiss AR must submit trend reports on serious incidents in Switzerland and abroad and final reports without being asked to do so. Swissmedic is granted the power to impose health protection measures in the event of non-compliance with the notification obligations.

viii. Entry into force:
The entry into force was adapted, as all provisions of the revMedDO - with the exception of the provisions relating to the registration of the UID - enter into force on 26 May 2021.

Conclusion

As of today, Switzerland transitions to third country status under the MDR from an EU-perspective and *vice versa*. On 19 May 2021, the Swiss Federal Council has adopted measures (media release here) to the revMedDO in order to mitigate the negative effects, e.g. extended transition periods for the designation of a Swiss AR.

2 Medical Device Directive 93/42/EEC, which is being replaced by the MDR as of 26 May 2021.