SWISS MEDTECH

Information for Swiss Distributors and Importers

Guidance

Designation of a Swiss Authorised Representative under the new MedDO

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Content

Management Summary

This document outlines the provisions regarding Swiss ARs under the revised MedDO and addresses the challenges for the situation without an updated MRA.

The European Medical Device Regulation (MDR) will come into force in less than six months - on 26 May 2021– the same day when the corresponding Swiss Medical Device Regulation (MedDO) enters into effect. It is now a question of political process whether Switzerland and the European Union (EU) will agree on an update of the Mutual Recognition Agreement (MRA) before 26 May 2021; or on a transitional solution whereby the current MRA would continue to apply. The outcome remains uncertain.

As a result, all Swiss distributors of medical devices may have to comply with new regulatory requirements because Switzerland will no longer be part of the EU common market for medical devices. The revised MedDO uses, equivalent to the MDR, the concept of Swiss Authorised Representatives (Swiss AR) that are mandatory for all manufacturers based outside of Switzerland to place medical devices on the Swiss market. Should the MRA not be updated prior to 26 May 2021, the task of the Swiss AR can no longer be fulfilled by an European company (European Legal Manufacturer of European Authorised Representative) as it is done today.

The current version of the revised MedDO has been prepared with a fully functional MRA in mind. Its implementation will be impossible without an updated MRA. Therefore, a further adaption of the MedDO is under way and will be ready in time before 26 May 2021.

The additional efforts for foreign manufacturers to appoint a Swiss AR are considerable. They might therefore decide to withdraw from the Swiss market. As a consequence, financial losses for distributors and a supply shortage of medical devices in Switzerland may result.

The advice from Swiss Medtech to all Swiss distributors of imported medical devices is to start planning for the establishment of a Swiss AR for all foreign legal manufacturers now, but not to implement the measures before the final text of the revised MedDO is made public.

1. Introduction

The regulatory situation

The current European MDD (93/42/EEC) and AIMDD (90/385/EEC) will be replaced by the Medical Device Regulation (EU 2017/745) on 26 May 2021. In order to maintain mutual access to the markets, Switzerland has revised its Therapeutic Products Act TPA [1] and Medical Device Ordinance MedDO[1] and aligned them with the European Medical Device Regulation MDR [2], establishing legal equality. The revised MedDO [3] will come into force on 26 May 2021, the date when the transition period of the MDR ends.

The MedDO, forming the legal basis for medical devices in Switzerland, has been revised and aligned with the MDR in view of maintaining the unrestricted trade and supervision of medical devices between Switzerland and the EU. To create legal certainty and guarantee the equivalence of Swiss law with European law, the Mutual Recognition Agreement MRA [4] between Switzerland and the EU is needed. The MRA is a key element for market access, coordinated market supervision, exchange of information and mutual recognition of conformity assessments. Implementation of all these aspects requires an update of the MRA. Without an updated MRA and the integration of the Swiss system into the European system, it will not be possible to implement the revised MedDO. It is therefore obvious that if the MRA is not updated, the current revised MedDO would have to be adapted again.

Nevertheless, one aspect of the revised MedDO that has to be addressed by the MRA is the role of authorised representative. The MedDO requires any manufacturer not based within Switzerland who wants to place its devices on the Swiss market to designate an authorised representative within Switzerland (Swiss AR). This also holds true for manufacturers from EU/EFTA member states. Only an updated MRA would limit this requirement to manufacturers from third countries, i.e. non-EU/EFTA member states. An update of the MRA would also assure that EU authorised representatives of manufacturers from third countries are recognised by Switzerland, eliminating the need for an additional Swiss AR.

The European Commission links the MRA update to the conclusion on the institutional agreement InstA between Switzerland and the EU. The EU Commission has stated that it will no longer negotiate new market access agreements and will not update existing agreements until the InstA has been concluded. At this moment, Swiss Medtech is presuming that the InstA will most likely not be in place by May 2021 and has therefore commissioned this guidance document.

The balance between product safety and security of supply

The task of the Swiss authorities is to carefully weigh product safety and security of supply against each other. It is not advisable to endanger the security of supply with medical devices in Switzerland. But it is also necessary to ensure the control and market surveillance capabilities of the Swiss authorities.

[1] Throughout this document, ‚MedDO' refers to the revised version, status on 1st July 2020 [3]

The requirements imposed by the MedDO on Swiss ARs and on the foreign manufacturers lead to increased efforts for the latter. These requirements are equivalent to those imposed by the MDR on EU ARs and Non-EU manufacturers. However, while an EU AR is designated for the entire European common market with its 446 Mio. inhabitants, Swiss ARs are only required for the comparatively much smaller Swiss market (population size less than 2% compared to EU). It is therefore possible that many manufacturers will decide to withdraw from the Swiss market rather than incur this additional effort and expense.

As a negative consequence, a loss of sales for Swiss distributors is to be expected. But above all, the security of supply of the Swiss healthcare system regarding medical devices may be jeopardized, which would have a negative impact on patients in Switzerland. This is especially true for products which are sold with low margins, in small volumes and/or are addressing the needs of patients with rare diseases. It is also evident that the introduction of the Swiss AR will increase the costs of medical devices in Switzerland.

On the other hand, the Swiss authorities face the problem that without a renewed MRA which coordinates market surveillance and the exchange of information between the authorities in Switzerland and the EU member states, no legal means are available to control medical devices of foreign manufacturers or to prosecute the manufacturers if necessary. The Swiss AR is therefore an important tool for the authorities to maintain control over the medical device market in Switzerland.

2. Possible scenarios and challenges

Currently, the future situation regarding the need for a Swiss AR is unclear. Assuming that the revised MedDO will come into force on 26 May 2021, this situation mainly depends on the status of the MRA:

- The MRA will be updated before the end of the transition period of the MDR and coming into force of the revised MedDO on 26 May 2021
- The MRA will not be updated when the MDR transition period ends and the MedDO comes into force on 26 May 2021, but will be updated at a later date
- The MRA will not be updated at all or may even be cancelled

The MRA is updated before 26 May 2021

If the MRA is updated in time, it will include provisions to exempt manufacturers from EU/EFTA member states from the need of delegating a Swiss AR. In addition, European ARs of manufacturers from third countries will be accepted as equivalent to Swiss ARs and vice versa. In this case, the situation will be similar as it is today under the current MedDO and MDD.

Regarding the current political situation and the ongoing negotiations concerning the InstA, this scenario is not very likely and should not be relied on.

The MRA is updated after 26 May 2021

During the period between 26 May 2021 and the update of the MRA, the EU would consider Switzerland as a third country (based on the MDR), while Switzerland would consider the EU member states as foreign countries (based on the MedDO). As mentioned, the current version of the revised MedDO is not suitable for a situation without an updated MRA. The MedDO would have to be adapted again to mitigate the consequences with temporary measures.

The scenario that the MRA will not be updated before 26 May 2021, but will be updated at a later date, seems to be the most probable.

The MRA is not updated or cancelled

If it should become clear that the MRA will not be updated at all, or even cancelled, and Switzerland will remain a third country in view of the MDR, the most probable outcome will be that Switzerland will establish its own medical device regulation. This would involve another revision of the relevant legislation, including the MedDO, to establish a legal basis independent of European law and infrastructure. Implementation of such a regulation could take several years. The details of such regulation, i.e. centralised or de-centralised, full-fledged registration processes for all foreign manufacturers or reduced requirements for CE-marked devices etc., are purely speculative.

Despite the long standing and good relationship between Switzerland and the EU, it is still possible that the InstA will never be concluded, preventing an update of the MRA.

Challenges if the MRA is not updated or cancelled

The provisions laid down in the revised MedDO were formulated with an updated MRA in mind. Only an updated MRA will allow the full implementation of the current MedDO. Should the MRA not be updated in time, the implementation of the revised MedDO will lead to additional challenges.

The actor module of Eudamed has been activated on 1 December 2020. The European Commission has published a FAQ which clearly states that Swissmedic will not be registered in the actor module until the MRA is fully updated [5]. This means that Swissmedic does not have access to any market surveillance information in Eudamed. Moreover, registration of Swiss based economic operators, including Swiss ARs, in Eudamed according to article 55 of the MedDO will not be possible without a revised MRA.

From an economic point of view, it is questionable if all manufacturers (either based in Europe or represented by EU ARs) currently selling medical devices in Switzerland will be willing to take on the additional organizational and financial efforts to appoint a Swiss AR. As a result, specific products or whole product ranges might not be available for distribution in Switzerland anymore, which would lead to financial losses for Swiss medical device distributors. A large reduction of the availability of medical devices from foreign manufacturers might endanger the security of supply of the Swiss healthcare system.

Furthermore, if it will become clear that the MRA will be updated sometime after 26 May 2021, the Swiss AR will only be required for European manufacturers for a given period of time, until the revised MRA will make them obsolete again. This might cause some manufacturers to temporarily suspend their sales in Switzerland, rather than delegate an interim Swiss AR.

3. Provisions regarding Swiss Authorised Representatives under the revised MedDO

Article 51 of the revised MedDO states that any manufacturer not based in Switzerland may only place its products on the Swiss market when it has delegated a person based in Switzerland as its authorised representative (Swiss AR).

The current version of the MedDO is very closely aligned with the MDR. The provisions regarding a Swiss AR stated in the MedDO are equivalent to those of the MDR for an European AR. These provisions have already been outlined in a former *Swiss Medtech guidance for compliance with third country requirements* [6].

Designation of a Swiss AR

The MedDO defines an authorised representative as *any natural or legal person established within Switzerland who has received a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligation under this Ordinance*[2,3].

The definition of authorised representative in the MDR differs in that it requires an AR to have '*received **and accepted** a written mandate from a manufacturer'.* However, the MedDO references article 11 of the MDR where it is stated that the mandate '*shall be valid only when accepted in writing by the authorised representative'*.

A Swiss AR will have to be designated for all products of a generic device group of a manufacturer. (Caution: According to the explanatory report of the Federal Office of Public Health FOPH [7], foreign manufacturers may only appoint a single authorized representative in Switzerland, see Art. 51).

According to MedDO article 55, Swiss ARs will have to obtain a *Single Registration Number* SRN [8] and be registered in Eudamed. Note that article 55 will not come into force on 26 May 2021, but at a later date depending on the availability of Eudamed.

Tasks and obligations of the Swiss AR

The Swiss AR shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance with the requirements of the MedDO. The responsibility of this person as well as exceptions and further modalities are in accordance with article 15 of the MDR.

[2] MedDO article 4, paragraph 1.g.

[3] Note that there is no official English text of the revised MedDO yet. All passages from the MedDO referenced in this document have been translated by the author or were taken from other official English documents.

The tasks of a Swiss AR are analogous to those of an EU AR and include:

- Verification of compliance with registration requirements
- Guarantee access to a copy of the technical documentation
- Support of the authorities during audits and product tests
- Reporting of incidents and complaints (Vigilance Report)

Some of the manufacturer's obligations can specifically not be delegated to a Swiss AR:

- Ensuring the conformity of the products
- Maintenance of a risk management system
- Performing clinical evaluations
- Writing and updating of technical documentation
- Preparation of the declaration of conformity
- Maintaining the UDI database
- Maintenance of the manufacturer's quality management system
- Establishment of a post-market monitoring system
- Preparation of labelling and instructions for use
- Definition of necessary corrective measures

Analogous to the European AR, if the manufacturer does not comply with his obligations according to the MedDO, Swiss ARs are jointly and severally liable with the manufacturer for defective products. They are obliged to have sufficient financial cover for damages caused by defective medical devices[4].

Overview of MedDO articles addressing Swiss AR and references to the MDR

MedDO	Reference to MDR
– Art. 51 Duties (of the authorised representative)	– Art. 11 Authorised representative – Art. 12 Change of authorised representative
– Art. 52 Person responsible for regulatory compliance, referencing MedDO Article 49, Paragraphs 2 - 4	– Art. 15 Person responsible for regulatory compliance
– Art. 53 Importer – Art. 54 Distributor	– Art. 13 General obligations of importers – Art. 14 General obligations of distributors – Art. 16 Cases in which obligations of manufacturers apply to importers, distributors or other persons
– Art. 55 Registration of manufacturers, authorised representatives and importers	– Art. 30 Electronic system for registration of economic operators, Paragraph 3 – Art. 31 Registration of manufacturers, authorised representatives and importers
– Art. 16 Product information	– Annex I, chapter III

[4] Art 47d revHMG, BBl 2019 2589

Change of a Swiss AR

If a manufacturer wishes to change their Swiss AR, the detailed arrangements must be clearly defined in an agreement between the manufacturer, the outgoing and the incoming authorised representative in accordance with article 51, paragraph 4 of the MedDO (article 12 of the MDR).

4. Possible additions to the revised MedDO

The current version of the revised MedDO has been prepared with a fully functional MRA in mind. Its implementation will be impossible without an updated MRA. Therefore, a further adaption of the MedDO is under way and will be ready in time before 26 May 2021.

The final text of the revised MedDO will not be made public before April 2021. Therefore, the establishment of a Swiss AR is not feasible before that time.

Some possible additions to the MedDO are discussed below to enable the Swiss distributors to start planning for the establishment of a Swiss AR.

Requirements regarding labelling

The manufacturer must ensure that the information (name and address) of the Swiss AR reaches the end user of the medical device. This can be done in different ways:

- In the ideal case, the Swiss AR would be included in the labelling by the foreign legal manufacturer. This will, however, not represent the most common case as only few manufacturers would be willing to create a separate logistics and labelling process for such a small market as Switzerland.
- In a more common case, the Swiss AR would add a label on the outermost packaging unit.
- In the least laborious case, the information of the Swiss AR would only be included in the accompanying documents. However, this is only applicable if it can be ensured that the information is available to the end user.

The declaration of conformity will have to mention the name and address of the Swiss AR, as well as its *Single Registration Number* SRN.

Requirements regarding access to the technical file

The Swiss AR must ensure that the Swiss authorities have access to the entire technical file of the medical device when they need to assess it in a vigilance case. This can be done in different ways:

- In the ideal case, the Swiss AR would be in possession of the technical files of all medical devices imported from the foreign legal manufacturer. This will, however, not represent the most common case as only few manufacturers would be willing to fully

disclose the technical documentation, potentially including confidential information on design and development, to the Swiss AR.

- In a more common case, the Swiss AR would ensure that the Swiss authorities would have access to the technical file of the medical device whenever they request it. This access needs to be ensured by written mandate, i.e. a contractual agreement with the legal manufacturer.

Transition period for designation of Swiss ARs

The establishment of a transition period for the appointment of a Swiss AR is necessary to allow enough time for the Swiss distributors and the foreign legal manufacturers to plan and execute their actions. If the transition period is sufficiently long, the negative effects on the security of supply may be mitigated. A calculation by Swiss Medtech, based on the results of a survey, leads to the assumption that a minimum transition period of 10 months - without substitute products – is needed. In case substitution of missing products is required, this period would need to be extended to a minimum of 18 months.

It is conceivable to introduce the designation of Swiss ARs in stages, based on the risk classification of the products in a similar fashion to the registration process for CE-marked products in the UK [9] during the transition period after Brexit. For class III medical devices, this transition period is 4 months, for class II devices 8 months and for class I devices 12 months.

It is also conceivable that proven products may benefit from a longer transition period than new products that potentially carry a higher uncertainty and product risk. In this context, MDR products may be referred to as new products, while MDD products would be referred to as proven products, benefiting from an additional transition period.

In a different context, a longer transition period would also allow more time for the political process and hopefully an update of the MRA, making the establishment of a Swiss AR obsolete.

At this point in time, the final additions to the revised MedDO are not yet clear.

5. Recommendation for action

It appears highly probable that the new MedDO will come into force on 26 May 2021 without an updated MRA. This would make the establishment of a Swiss AR mandatory for all manufacturers based outside of Switzerland to continue placing their products on the Swiss market.

Advice to all Swiss distributors and importers of imported medical devices:

Start planning for the establishment of a Swiss AR for all foreign legal manufacturers now, but do not implement the measures before the final text of the revised MedDO is made public (likely in April 2021).

The plan may involve the following steps:

1. Decision who will act as Swiss AR (you as distributor/importer yourself or a third party)
2. Information to all your foreign manufacturers
3. Negotiation with all manufacturers to determine who will continue to supply their medical devices to Switzerland and who may decide to withdraw
4. Search for substitute products for all medical devices that will no longer be available
5. Plan for altered logistics, including labelling
6. Assessment of the impact on your own business and on your customers'

These steps will take a considerable amount of effort and time and Swiss Medtech is trying to negotiate a sufficiently long transition period for you to carry out the work.

References

[1] CC 812.21 Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA)

[2] Regulation (EU) 2017/745 on Medical Devices (MDR)

[3] Swiss Medical Device Ordinance, SR 812.213 (MedDO) of 1. July 2020 (no English text available)

[4] Mutual Recognition Agreement between Switzerland and the EU
EU: Document 02002A0430(05)-20171222, CH: SR 0.946.526.81 (no English text available)

[5] EUDAMED Actor Module FAQs, Nov. 2020, https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/md_actor_module_q-a_en.pdf

[6] Swiss Medtech Guideline for Designation of a European Authorised Representative (in German: https://www.swiss-medtech.ch/sites/default/files/2020-12/Wegleitung_Schweizer%20Hersteller_DE.pdf, in French: https://www.swiss-medtech.ch/sites/default/files/2020-12/Wegleitung_Schweizer%20Hersteller_FR_0.pdf)

[7] FOPH - Explanatory report on revision of medical devices legislation (no English text available)

[8] Swissmedic information sheet: Single Registration Number SRN

[9] MHRA post-transition period information, https://www.gov.uk/government/collections/mhra-post-transition-period-information

Document Release and Change History

Version	Date	Author	Review	Release	Comments
00	15.12.2020	Kaspar Gerber (ISS)	Hansjörg Riedwyl (ISS), Bernhard Bichsel (ISS), Jörg Baumann (SMT)	Daniel Delfosse (Swiss Medtech)	Initial document as «Preliminary Guideline»
01	29.01.2021	dito	dito	dito	"Guidance" with inclusion of the role of Swiss importers