SWISS MEDTECH

Information for Swiss Health Institutions

Guidance

Direct procurement of foreign medical devices by healthcare professionals in Switzerland

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Contents

Recommendation

The Medical Devices Ordinance[1] allows professionals to procure devices directly from abroad for use without placing them on the market.

It is important to note that in the case of direct procurement, individual professionals and health institutions automatically assume full functional responsibility, i.e.: no Swiss economic operator is responsible for any procedural or safety-related issues, and the readiness for delivery depends exclusively on the foreign supplier.

The direct procurement of devices from abroad is associated with considerable risks related to supply and liability. **Swiss Medtech therefore recommends that healthcare professionals and health facilities should always obtain their devices from Swiss manufacturers and/or distributors and only resort to direct procurement in isolated exceptional situations.**

It is also important to note that direct procurement is subject to specific conditions, namely that

a) they should be viewed as emergency procurements only, and that the uninterrupted supply of other – even identical – devices should not be affected;

b) healthcare professionals can also procure such devices themselves;

c) healthcare professionals only seek assistance in procuring such devices in association with their own health institution – i.e., hospital, physician's office, or other healthcare organization;

d) healthcare professionals also use the directly procured devices themselves; and

e) healthcare professionals assume professional responsibility for the full compliance of their directly procured devices.

[1] Medical Devices Ordinance MedDO of July 1, 2020 (German, MepV), SR 8112.213 (as amended on May 26, 2021).

1 Objective

According to the Swiss Medical Devices Ordinance MedDO[2] (German MepV), which aligns Swiss law with the new European Medical Devices Regulation (MDR)[3], professionals can procure CE-marked medical devices (hereinafter referred to as 'devices') directly from abroad and use these in Switzerland without them being placed on the domestic market. The new requirements for national testing, registration and documentation for imports do not apply for devices obtained in this manner.

The following section defines what is meant by this type of procurement by professionals, what responsibility they must bear, and in what form they may delegate procurement activities. Information on the conceivable effects on the continuity of supply and possible consequences in the event of non-compliance with legal requirements is also covered.

2 Further details

2.1 Legal basis

Swiss legislation governing therapeutic products provides only general statements on the procurement of devices; the focus is mainly on the safety and efficacy of products that are placed on the market. This makes Article 3 of the Therapeutic Products Act TPA (German HMG)[4] all the more important. This Article stipulates that all parties involved in the handling of devices are obliged to prevent any risk to the health of humans and animals.

For direct procurements from abroad, the provisions regulating implementation are found in Article 70 of the MedDO. The first paragraph states:

> *«Any professional who directly uses a product from abroad without placing it on the market, is responsible for the conformity of said product.»*

The Explanatory Report[5] on the revision of the MedDO of 1 July 2020 also refers to Article 70:

> *«Paragraph 1: Anyone who imports devices from abroad is considered an importer under the EU MDR and must fulfil the associated obligations for placing products on the market. As imported devices are used directly by professionals within health institutions, any process involving the placing of devices on the market is eliminated. This added paragraph to the MedDO takes these special circumstances into account, whereby the responsibility for the conformity of the imported and directly used product lies with the professionals.»*

[2] Cf. Medical Devices Ordinance (FN 1).

[3] Ordinance (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices (MDR), OJ L 117, 5.5.2017.

[4] Federal Law of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) SR 812.21 (in the version of 1 January 2022)

[5] Comprehensive revision of the Medical Devices Ordinance and Ordinance on Clinical Trials with Medical Devices (new Medical Devices Regulation), Explanatory Report, FDHA/FOPH, July 2020, https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/heilmittel/meprrevision/erlaeut_juli2020.pdf.download.pdf/2020-07-01_DE_Erlaeuterungen.pdf (viewed 17.12.2021) in German

The terms 'professionals' and 'health institution' used in this context must be defined precisely to ensure the clarity of this section of the ordinance and report. Concerning the term 'health institution', reference can be made to the MedDO in Article 4, Para. 1, Subpara. k. which states:

> *«Health institution: refers to an organization whose primary purpose is to provide care or treatment to patients, or to promote public health;»*

Further elaboration of the term 'health institution' in the above-mentioned Article 4 can be found on page 16 of the Explanatory Report[6].

Additional information on the direct procurement of devices from abroad can be found in the updated Swissmedic «Procurement of medical devices in health institutions»[7] information sheet. Section 7 focuses on the topic of «Medical devices imported from abroad by professionals». It begins with the following statement:

> *«If a professional (in this context including health institutions) imports conforming medical devices **from abroad** and **uses them directly** without making them available on the market, the devices are not considered to be placed on the market in Switzerland. Accordingly, from the standpoint of medical devices legislation, the professional or health institution does not assume the role of importer, i.e. they are not subject to the testing, registration or documentation obligations that apply to importers …»*

Both the explanatory report and, in particular, the information sheet emphasizes that the newly defined requirements do not apply to devices imported under these conditions, as they will not be placed on the market in Switzerland. Furthermore, the information sheet specifying that professionals must not fulfil any «testing, registration and documentation obligations», refers to the standard registration requirements for Swiss agents and Swiss importers regarding product labelling, declarations of conformity, and instructions for use that must be verified for imports.

2.2 Healthcare professionals

According to Article 70 of the MedDO, professionals in Switzerland are permitted to procure and use devices directly from abroad. This does not necessarily mean that the product must be placed on the Swiss market. However, the Article can only be properly understood if the term 'professional' is clearly described. As the term is not specifically defined for the area of medical devices, both at the legal level of the TPA or at the ordinance level of the MedDO, references found in other legal texts can be useful.

[6] Cf. Explanatory Report, FDHA/BAG, April 2021 (FN 5).

[7] Information sheet 'Procurement of medical devices in healthcare facilities', MU600_00_006d / V3.0 / com /mk /07.01.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/mu600_00_006d_mb_beschaffung_mep.pdf.download.pdf/MU600_00_006d_MB_Beschaffung_von_Medizinprodukten_in_Gesundheitseinrichtungen.pdf (viewed 12.1.2022)

MedDO Annex 2 equates the Swiss term 'professional' with the European term 'healthcare professional'. Furthermore, in Switzerland, the terms 'user' and 'layperson''[8] refer directly to the EU law of the MDR. In this, the 'user'[9] is referred to as:

> *«any healthcare professional or lay person who uses a medical device.»*

If we now substitute and apply the term 'healthcare professional' used in the EU area for the Swiss term 'professional', we now have a common term for 'users' that can also be applied in Switzerland:

> *«Healthcare professionals or lay persons who use a medical device».*

In this way, healthcare professionals can be clearly defined for the purposes of the MedDO. The following applies:

> *«Healthcare professionals are all users of a medical devices who do not belong to the category of laypersons.»*

2.3 Healthcare professionals' responsibility for conformity

The Swiss version of the current MedDO is closely aligned with the MDR. This purpose of this is described in Section 1.3 of the current MedDO Explanatory Report[10]:

> *«The alignment of Swiss medical device law with the new EU regulations is aimed at improving the safety and quality of medical devices in Switzerland as well...»*

It is therefore logical that any decisive reason for revision concerning the introduction of the MDR in the EU is also relevant for Switzerland. With the latest revision, the EU aims to achieve a «*uniformly high level of health and safety protection for EU citizens who use these devices*». This is described in the corresponding introduction page[11] of the EU Commission (see paragraph «The main reasons behind this change»):

> *«The new regulations will ensure ...a consistently high level of health and safety protection for EU citizens using these devices... ».*

In line with this guiding principle, the formulation of the MDR includes requirements aimed at a broader range than for the actual manufacturers of medical devices. Other economic and healthcare players involved were also assigned detailed responsibilities. Consequently, Switzerland has also followed this principle in its formulation of the current MedDO.

With regard to the direct procurement of foreign medical devices by healthcare professionals, Section 7 of the current version of the Swissmedic information sheet on procurement[12] explains:

[8] MedDO, Art 4, Para 2, reference to MDR, Art 2, Paras 37 and 38.
[9] MDR, Art 2, Nummer 37
[10] Cf. Explanatory Report, FDHA/BAG, April 2021 (FN 5).
[11] New Regulations, https://ec.europa.eu/health/md_sector/new_regulations_en, (viewed 17.12.2021)
[12] Cf. Procurement of medical devices in health institutions (FN 7).

> *«**The professional who imports and directly uses a medical device is responsible for its conformity**. A procuring professional, or the procuring health institution where the professional works, must therefore check and ensure that such a device carries a conformity marking recognised by the MedDO, and that a conformity assessment procedure has been carried out …»*

Consequently, products used in Switzerland without being placed on the market must also meet specific conformity requirements of the MedDO. These include the aforementioned, easily verifiable formal aspects of the CE- (or MD-) conformity markings and their certificates.

Importantly, the following section of the above-mentioned information sheet also states:

> *«Swissmedic explicitly points out to professionals and their healthcare institutions importing devices **without** Swiss authorised representatives that these devices may not be covered by the legal liability statement in Art. 47d TPA [Author's note: financial coverage and liability by manufacturer and authorized representatives], and that no Swiss economic operator is responsible for formal and safety-related aspects …. **In this situation, the professionals and the healthcare institutions take full responsibility for ensuring the information flow, obtaining any required information, implementing the corrective actions and clarifying questions of legal liability** …».*

This places an obligation on healthcare professionals to also address the possible risks of such direct procurement. The necessary risk assessments must show that healthcare professionals are able to assess the content of the manufacturers' conformity assessments. This requires both regulatory and technical expertise. A thorough assessment of possible risks requires a comprehensive understanding of the conformity assessments carried out by manufacturers.

2.4 Third party commissioning options

Legislators explicitly address healthcare professionals in Article 70 of the MedDO, which provides for the possibility of procuring medical devices directly from abroad.

When healthcare professionals seek administrative and/or logistical assistance from third parties, they must ensure that no transfer of ownership, possession, or other rights in Switzerland resulting in the 'making available on the market'[13] of corresponding products takes place. Consequently, third-party assistance may only be provided within organizations to which the healthcare professional is directly associated. Swissmedic emphasizes this interpretation in the aforementioned procurement information sheet. The first sentence of Section 7 refers explicitly to healthcare professionals who «use the devices directly».

With its wording, Swissmedic clearly expresses that a distribution of the products (making them available on the market), and consequently also a transfer of the procurement to other organizations, is not foreseen in the present procurement model – as this would result in a

[13] MedDO, Art 4, Para. 1, Letter a

putting into circulation of these products in Switzerland. If forwarding companies or intermediaries were commissioned with the procurement, this would consequently imply a subsequent «making them available on the market». According to the MedDO, all these organizations would then automatically have to assume the tasks and responsibilities of importers[14] and, if applicable, also dealers[15] and authorized representatives[16].

However, 'transfers' can occur even in cases of procurement and applications occurring internally within an organization. Under certain circumstances, a hospital which assists its affiliated physicians by procuring products can result in these devices being «placed on the market» in Switzerland. The same applies to cases of centralized procurement for associated health institutions within a specific association or network.

3 Potential risks

3.1 Continuity of supply

Direct ordering of products from abroad is now a routine procurement practice in many health institutions. Foreign sources are often used by such facilities to bridge availability problems in national supply chains – resulting in situations equivalent to parallel importation. Undoubtedly, the direct procurement of devices from abroad model is also employed to ensure the continuity of supply.

Problems could arise, however, if the direct procurement of foreign medical devices by health institutions were to cause foreign manufacturers to downsize their warehouses within Switzerland, and/or the eliminate Swiss distributors – which would inevitably lead to further reductions in security of supply and quality of service.

Problems could also arise if foreign manufacturers ignore the new MedDO requirements in cases involving direct procurement. This could arise when Swiss healthcare professionals who procure devices (and who are required by the authorities to assume responsibility for compliance) request that manufacturers release technical and clinical data (see also 2.3, last paragraph). Such a request, however, could hardly be met without additional confidentiality agreements.

Regulatory requirements may also lead to a termination of the procurement model under discussion. A foreign manufacturer can be obliged by its Notified Body to take corrective measures, for example, if its distribution partners do not provide supplies to healthcare professionals in Switzerland in a sufficiently transparent manner.

[14] MedDO, Art 53
[15] MedDO, Art 54
[16] MedDO, Art 51, Art 52

3.2 Possible consequences of non-compliance

The model under discussion – direct product procurement from abroad – means that health institutions will have to adhere to narrowly defined framework conditions. Violations of these requirements could result in the imposition of corrective measures by monitoring authorities. It is also possible that the processes defined for this purpose and the competence of healthcare professionals will also lead to objections. This in turn could cause corrections and delays in the procurement of these – and possibly also other – products.

Criminal proceedings may be initiated in the event of intentional non-compliance with the requirements of the 'procurement of devices from abroad' model. The following penal provisions are listed in the TPA[17] Article 86, Para 1:

> *«A penalty of imprisonment of up to three years or a fine shall be imposed on anyone who intentionally:*
>
> *...d. Places on the market, exports or uses medical devices that do not comply with the requirements of this Act or uses medical devices without fulfilling the necessary specialized and operational requirements; ...»*

[17] Cf. Therapeutic Products Act TPA, German HMG (FN 4).

4 Conclusion

Healthcare professionals in Swiss health institutions may procure products directly from abroad and use them without placing them on the market. However, it is only possible for economic operators to waive the testing, registration, and documentation obligations for Switzerland if the framework conditions set out in the context are fully met. Potential problem areas are likely to be the transfer of conformity responsibility to healthcare professionals, and the challenges to uninterrupted supply capacities.

As attractive as it may appear due to the waived obligation to appoint and declare Swiss authorized representatives and importers, this procurement model can only be seen as an **emergency option** – at most to be used according to the framework conditions for a health institution. As presented in the Swissmedic information sheet on procurement[18] in the second to last paragraph of Section 7:

> *For the reasons already stated, healthcare professionals and institutions should usually procure products from a Swiss manufacturer or that have a Swiss authorised representative and **only directly use products from abroad without a Swiss authorised representative in justified exceptional cases**.*

As a rule, already standardised and established procurement processes will also continue to apply to foreign products as well.

Document approval and modification history

Version	Date	Author	Revision	Approval for release	Comments
01	17.03.2022	Peter Studer (confinis AG)	n.a.	Daniel Delfosse (Swiss Medtech)	First creation

[18] Cf. Procurement of medical devices in health institutions (FN 7).

ANNEX

Impact on the various stakeholders

The direct procurement of foreign products will affect the various parties in different ways. According to Art 70, Para 1 of the MedDO, it is important to note:

Stakeholder	Consequences	Section
Healthcare professionals in Switzerland	- Assume responsibility for directly procured products conformity, requires technical and regulatory know-how - Source any additional required technical and clinical data – validate the manufacturer's conformity assessment - Assume responsibility in the event of any safety and performance inconsistencies or discrepancies in instructions for use - Manage any necessary corrective measures – including possible legal consequences, if applicable - Provide procurement support solely within an organization's own internal structures, i.e. only in health institutions where the professionals themselves are employed – without placing devices on the market	3.1 3.2 3.3 3.4 4.2
Swiss health institutions (e.g. hospitals, medical practices, and laboratories)	- Ensure continuity of supply of devices from foreign suppliers and foreign manufacturers - Provide procurement support only to professionals employed by them – without placing devices on the market - Understand the consequences of non-compliance	3.4 4.1 4.3
Swiss importers and Swiss dealers	- May not directly procure devices without fulfilling additional testing, registration and documentation requirements – as their core activities result in placing or making devices available on the market in Switzerland	3.4
Swiss Authorized Representatives	- Core functions do not involve the trading of devices - If involved in product trading, must also assume the role of Swiss importer or Swiss dealer.	-
Foreign manufacturers	- Ensure the continuity of supply of its devices to Switzerland - Willing to provide Swiss professionals with additional data (some potentially confidential) required to validate the conformity assessment	3.3 4.1
Foreign dealers	- Provide support to ensure the continuity of supply of devices to their foreign suppliers and foreign manufacturers - Support Swiss professionals in obtaining any additional required data (some potentially confidential) required to validate the manufacturer's conformity assessment	3.3 4.1