IMDRF International Medical Device Regulators Forum

swissmedic

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About Swissmedic 1/2

Mission:

Our competence: for therapeutic products you can trust

We are the Swiss authority for the licensing and monitoring of therapeutic products. We perform the mandate conferred upon us by law and work with partner authorities at home and abroad.

We ensure that the therapeutic products we approve are of faultless quality, effective and safe. In doing so we make a significant contribution to safeguarding human and animal health and to maintaining Switzerland's role as a location for business and research.

→ https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products/guiding-principles.html

About Swissmedic 2/2

Swissmedic is an autonomous organisation associated with the FDHA (the Federal Department of Home Affairs)

Swissmedic finances its activities through procedural fees, supervisory levies and payments from the federal government (Art. 77 para. 2 TPA).

The following tasks and activities are funded solely by payments from the federal government in accordance with the Therapeutic Products Act (Art. 77 para. 2^{bis} TPA):

- Legislation
- Enforcement of provisions of criminal law
- Surveillance of medical devices

Working Areas related to Medical Devices 1/4

The existing laws and regulation in place for Medical Devices

Therapeutic Products Act (TPA)
812.21

Human Research Act (HRA)
810.30

Medical Devices Ordinance (MedDO)
812.213

Ordinance on In Vitro Diagnostic Medical Devices (IvDO)
812.219

Ordinance on Clinical Trials with Medical Devices (ClinO-MD)
810.306

Full text of mentioned acts and ordinances see here:
→ https://www.fedlex.admin.ch/en/cc/internal-law/81

Policy for implementation of IMDRF documents 2/4

As a long-term contributor to GHTF and EU documents, Swissmedic has aligned itself with the principles of the IMDRF and fully applies them.

Examples (non-exhaustive):

Same definitions (e.g. for manufacturer, medical device, custom-made devices), equivalent principles for classification, conformity assessment bodies conduct regulatory reviews, full reliance on international standards.

For placing a device on Swiss market, it must comply with MedDO / IvDO, meet general safety and performance requirements set out in Annex I EU-MDR or EU-IVDR and bear either the CE-mark or the Swiss MD-marking.

Information on Swiss Medical Device Industry 3/4

67’500 employees generated CHF 20.8 billion in revenue in 2021

Switzerland imported medical devices worth CHF 6.0 billion and Swiss MedTech companies exported goods worth CHF 11.9 billion

- The resulting trade surplus of CHF 5.9 billion represents 11.5% of the entire trade surplus of Switzerland.

Medical technology is traditionally one of the most research-intensive industries. Requirements for proving clinical efficacy and safety have increased, and consequently require more resources

- The weighted share of manufacturer expenditure for R&D in 2021 is 10.4%

Information for the year 2022 should be available in September
→ https://www.swiss-medtech.ch/en/documents#jahresberichte

Participation in Global Harmonization Activities 4/4

In partnership with the World Health Organization (WHO), Swissmedic devised a training course for regulatory authorities in low- and middle-income countries. Such courses are part of the WHO's programme to improve its member states' regulatory systems.

Swissmedic is a member of IMDSM (international medical device safety meeting) with monthly information exchange.

- Data protection laws and the resulting difficulties in sharing information are the biggest challenge so far.

Information on national and international collaboration of Swissmedic:
→ https://www.swissmedic.ch/swissmedic/en/home/about-us.html

Relevant Updates 1/2

MedDO and IvDO will be updated to reflect the changes to EU-MDR & IVDR in relation to Regulation (EU) 2023/607 of 15 March 2023 (extension of transition periods for “**legacy devices**” and removal of sell-off period).

MedDO will also be revised in relation to '**groups of products without an intended medical purpose**' to incorporate and align with changes made in the EU since December 2022.

swissdamed - the Swiss database on medical devices - will be publicly accessible for actor data from the beginning of 2024, and voluntary device registration is expected to be available from summer 2024.

Relevant Updates 2/2

Updated “Swiss Good Practice for the Reprocessing of medical devices”

- For healthcare facilities, that reprocess medical devices (available only in German, French and Italian, but not in English)

“Good Practice of maintenance in medical technology (brochure for hospitals)” is planned to be updated as well. Due to the very good feedback on the previous GP documents, 2 more, namely a “Good Practice for reporting serious incidents, one for hospitals and one for labs” are planned until the end of 2025.

New training concept for reprocessing, maintenance and vigilance in healthcare facilities to be implemented by year-end.

Relation with IMDRF Activities

Swissmedic has a total of 570 employees, 65 of whom work directly with medical devices. 10 of the 65 employees are actively involved in 5 of the 8 active IMDRF working groups, and 6 are nominated for 3 working groups that have completed their work items for the time being.

Swissmedic believes that international harmonization of medical device surveillance guidelines is becoming increasingly important due to the global nature of the medical device industry, the need for patient safety and quality assurance, the desire for efficiency and cost savings, the importance of collaboration and information sharing, the drive for global standards and interoperability, rapid technological advances, and the influence of international cooperation and trade agreements.

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Thank you/Questions

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https://www.swissmedic.ch/ (direct link medical devices)