IMDRF International Medical Device Regulators Forum | 26th Session

Regulatory Update Switzerland

Markus Wälti

Head of Division Medical Devices Vigilance

Swissmedic, Swiss Agency for Therapeutic Products

Key changes to regulatory framework

Revision of MedDO and IvDO

EU IVDR amendment: Equivalence with EU Regulation on Medical Devices ensured

swissdamed – swiss database on medical devices

The first of two modules of the swissdamed medical devices database went live on 6th August

swissdamed is the new Swissmedic database for registering economic operators and medical devices, including in vitro diagnostic medical devices, on the Swiss market.

Academic clinical trials with medical devices

Application for fee reduction for clinical trials with medical devices (clinical investigations and performance studies)

Expiry of COVID-19 Ordinance 3

Dispensing of coronavirus self-tests still possible from 1 July 2024

Amendments to ordinances relating to the Human Research Act (HRA)

Adapting human research legislation in response to technological and social changes

Key changes to guidance documents

swissdamed

swissdamed Privacy Notice and Terms of Use (new – 06.08.2024)

swissdamed Service Agreement (new – 06.08.2024)

swissdamed User Guide Actors (new – 31.07.2024)

Healthcare institutions

Obligations of professional users and third parties in connection with the maintenance of medical devices
* only available in German, French and Italian, but not in English (new – 03.07.2024)

Clinical trials

Clinical investigations with medical devices (updated - 01.07.2024)

Performance studies with IVD (updated – 01.07.2024)

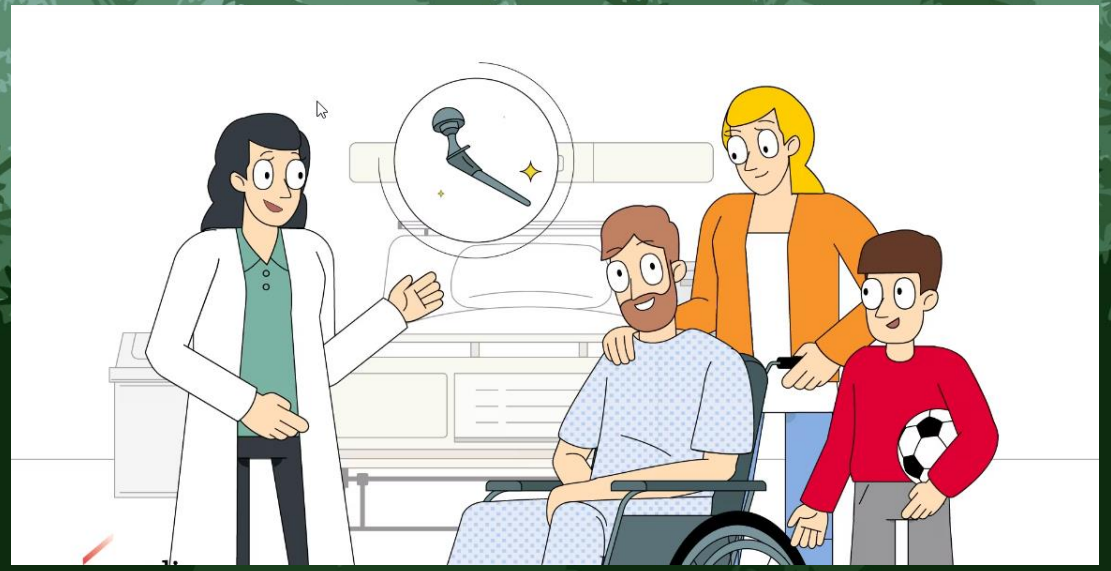
Application for fee reduction (new – 01.07.2024)

Application fee reduction self-declaration (new – 01.07.2024)

Materiovigilance – every report counts!

Serious incidents involving medical devices: find out in the video why every report counts!

As a professional user, you are contributing to making medical devices safer! Report every serious incident promptly – because every report counts! 📣



For reporting obligations for users and economic operators see: Reporting incidents & FSCAs

SEATTLE WASHINGTON "The Emerald City" The City of Flowers

U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

swissdamed

- Swiss database for medical devices and responsible stakeholders
- Transparency for service providers
  - The platform **will** allow healthcare facilities, medical professionals, and other users to search for specific products and economically responsible entities
- A central element for the future, data-supported, and data-focused market surveillance of medical devices.
- First productive application on Swissmedic public cloud infrastructure https://www.swissdamed.ch/

swissdamed - swiss database on medical devices

Goals | Actors | Devices

One of the main goals of the new Medical Device Regulation is to increase transparency and to ensure the complete traceability of products throughout the entire supply chain. In the event of problems, appropriate measures can thus be taken quickly. swissdamed, as a centralised system, was designed for this purpose and serves to collect and process the information on Swiss Economic Operators and Medical Devices. The public and professionals benefit equally from access to published information.

Search for actors and devices

Search for actors

Search for a manufacturer, authorised representative, importer or system procedure pack producer.

Search for devices

The search for UDI-DI and medical device data will be available with Release 2.

Support

Find relevant documents and information about swissdamed.

Go to Support

Release note

06.08.2024

Release 1.0: The swissdamed “Actors” module is live, enabling registration of companies and economic operators, including actor and user management (e.g. for setting up user accounts or updating actor data).

All release notes

Search for actors

The search for actors allows you to search and retrieve all records that contain the search terms you enter. At least one search criterion is mandatory.

Company name

CHRN

UID

If you don't know the UID-number of the company, you can find it in Zefix

Actor type: All

City

Country: All

Actor status: Registered

Clear search | Search

4096 Records found:

Actors (3735) | Mandates (foreign manufacturers) (361)

View	Actor type	CHRN	UID	Name ↑	Address	Postal code	City	Country
	IM							Switzerland
	IM							Switzerland
	AR							Switzerland
	AR							Switzerland
	IM							

News on International activities

- On 27 March 2024, Swissmedic signed a new grant agreement with the Bill & Melinda Gates Foundation.

  Under terms of this agreement, both parties commit to supporting regulatory authorities in low and middle-income countries for a further three years, thereby improving access to healthcare in the targeted regions and countries.

- Regulatory training in Bern, CH
  - Last course: 27.05. - 31.05.2024
  - Next course: 21.10. - 25.10.2024

Swissmedic's Activities in IMDRF

IMDRF MC and Working Groups
Management Committee (as Official Observer)
Adverse Event Terminology
Artificial Intelligence/Machine Learning-enabled
Good Regulatory Review Practices
Quality Management Systems
Software as a Medical Device
Clinical Evidence for IVD Medical Devices

Lin
k

IMDRF WG AET Meeting in Bern

The IMDRF Adverse Event Terminology Working Group meeting took place at Swissmedic from 23 to 26 April 2024.

Eleven international authorities took part to advance the harmonized coding of adverse events involving medical devices.

SEATTLE WASHINGTON "The Emerald City" The City of Flowers

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

LinkedIn

Meetings, Workshops & Trainings

Datum	Organisator	Veranstaltung, Ort
13.05.2024	Schweizerische Gesellschaft für medizinische Kosmetik SGMK (Swiss Society for Medical Cosmetics)	«Beauty on the lake» - event for products without medical purpose, Zürich, CH
25.05.2024	Bern University of Applied Sciences (bfh), Department of Engineering and Information Technology	Certificate of Advanced Studies: Regulatory Affairs in Life Sciences, Bern, CH
27.05. - 31.05.2024	Swissmedic-WHO	Regulatory training course for regulatory authorities, Bern, CH
03.06.2024	Swissmedic	Roundtable on Medical Technology (RTMT), Bern, CH
18.06. - 19.06.2024	IG WiG – Interessenvertretung für die Wiederaufbereitung im Gesundheitswesen (Interest Group for Reprocessing in Healthcare)	18.6.: «Good Practice for Reprocessing Endoscopes», Lyss, CH / 19.6.: SGSVS 20th «Swiss Conference on Sterilisation», Biel, CH
25.07. - 27.07.2024	Bill & Melinda Gates Foundation	Kigali, Ruanda
27.08. - 30.08.2024	Taiwan Food and Drug Administration, Ministry of Health and Welfare, R.O.C.	2024 Conference on International Medical Device Regulations and APEC CoE Center of Excellence Workshop, Taipei, Taiwan

U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF

International Medical Device Regulators Forum

Markus Wälti, Swissmedic

Markus.waelti@swissmedic.ch