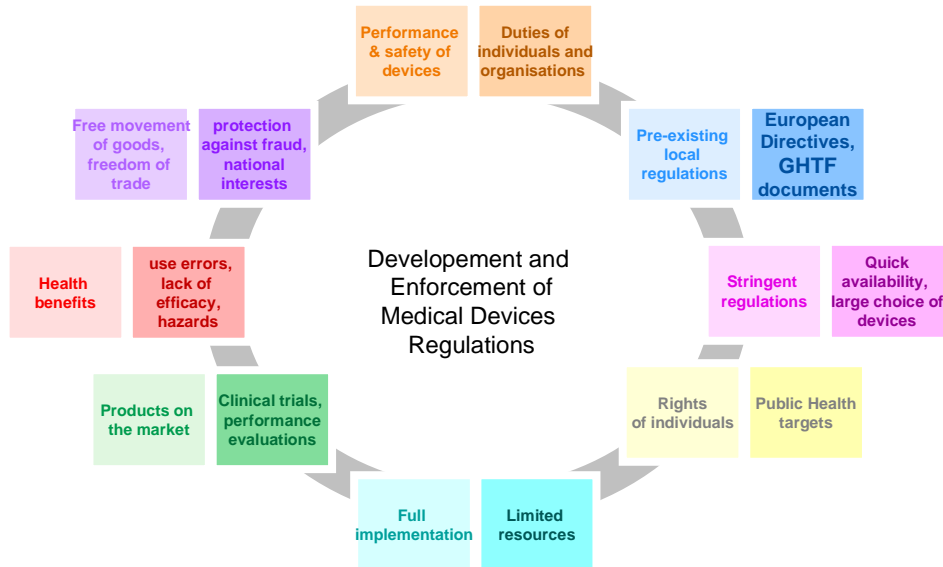


Medical Devices in Switzerland: Regulation and enforcement of regulatory requirements by Swissmedic



Legislation and Competent Authority

The Mission

To guarantee that only high-quality, safe, and effective therapeutic products are placed on the market in Switzerland.

New Federal regulations

The Federal Law on Therapeutic Products (LTP), which came into force on 1 January 2002, replaces the previous Cantonal Drugs Convention and existing Federal regulations. The LTP summarizes, updates and completes the control regulations for therapeutic products. Swissmedic, the new Swiss Agency for Therapeutic Products, is responsible for enforcing these new regulations at Federal level. It was founded on the merger of the Intercantonal Office for the Control of Medicines and the Therapeutic Products Section of the Swiss Federal Office of Public Health. Decisions by Swissmedic are legally binding, which guarantees that they will be implemented simultaneously throughout Switzerland. This solution meets the growing demand for health care protection and quality guarantees at international level.

Swissmedic, the Agency in brief

Swissmedic is a public institution of the Swiss government, in the third circle of the administrative model. It has its own legal personality. The Agency's core legal basis is the Federal Law on Medical Products and Medical Devices (the Law on Therapeutic Products, LTP).

Swissmedic started to operate when the Law on Therapeutic Products came into force on 1 January 2002. Swissmedic is an independent public institution. It is affiliated to the Federal Department of Home Affairs. Swissmedic employs roughly 240 full-time staff. 14 full-time staff are dedicated to medical devices.

It is financed from fees, payments from the Federal government in return for services of public interest, and from services rendered to third parties. The public services are described in a service mandate from the Swiss Federal Council and in an annual service agreement with the Federal Department of Home Affairs.

The Agency is managed according to the principles of good business practice to ensure the efficiency of its control activity.

The Agency's various activities are organized according to the needs of its partners. These comprise patients, consumers, authorities and organizations in Switzerland and abroad, the pharmaceutical industry, medical professionals and the media.

Enforcement activities

Information

National information activities are of major importance for spreading knowledge about regulatory requirements and health hazards, thus helping individuals and companies concerned to meet duties and minimise risks. Major information activities of Swissmedic in the medical devices sector are currently focusing on:

- users: medical institutions (e.g. hospitals) and their staff, the medical community, the public
- companies: small and medium sized companies in the medical devices sector; staff in charge of the development, manufacturing, control, and distribution of medical devices

Swissmedic develops and maintains a comprehensive set of guides, fact sheets and aids in several languages. Swissmedic also organizes and participates to seminars and trainings. These documents and activities can be viewed in or downloaded from the Internet (select <http://www.swissmedic.ch/md.asp>).

In addition to general information activities, Swissmedic answers about 170 specific questions asked by stake holders every month, including roughly 150 questions of companies, 30 questions of hospitals, professionals using medical devices and the public, and 20 questions of national and international authorities, notified bodies and standards organisations (data 2001).

Vigilance

The scope of vigilance activities is an early identification of health hazards due to medical devices and the implementation of corrective actions that will avoid repetitions of incidents. During 2001, Swissmedic received nearly 500 vigilance signals, including 147 reports of incidents that happened within Switzerland, 188 recalls of products and 48 other corrective actions. In 2002, the national vigilance system extends to professional users of devices. Corresponding staff will be designated in all Swiss hospitals and coached by Swissmedic.

Market surveillance and inspections, control of Swiss conformity assessment bodies

Swissmedic is responsible for market surveillance and the coordination of market surveillance activities for medical devices within Switzerland. All manufacturers and distributors of medical devices may be subject to such activities. The Agency closely collaborates with local health authorities for the surveillance of sales outlets and professionals using medical devices. Swissmedic is also actively participating to European working groups on market surveillance and notified bodies overview, and to different study groups of the Global Harmonization Task Force.

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