

Swissmedic – Schweizerisches Heilmittelinstitut (Swiss Agency for Therapeutic Products)

Your Objectives:

At the end of the lesson, you will be able to state the functions and importance of *Swissmedic*, and to discover who does what for this industry.

Swissmedic, the Swiss Agency for Therapeutic Products, assumes responsibility for the licensing and monitoring authority of medicinal products in Switzerland. Based in Berne, [Swissmedic](https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products/patients-and-users.html) started operations on 1st January 2002 as successor to the Inter-cantonal Control Agency for Medicinal Products (ICS). It is affiliated with the Federal Department of Home Affairs (FDHA*).

Switzerland is contingent upon the approval of *Swissmedic* for all medicinal products (for human and animal consumption) introduced to the local market. The governmental institution is also responsible for market surveillance of pharmaceuticals and medical devices.

When approving new medicinal products, *Swissmedic* administers internationally applicable criteria. The medical preparations may only be sold if their quality, [health] safety and effectiveness have been scrutinizingly inspected and proven efficacious.

Examination of pharmaceuticals is complex and often takes several years**. If the criteria for approval are met, *Swissmedic* issues an approval, specifies the type of sale (prescription required delivery points) and appoints the specialists as well as the patient information. Product registration is to be assumed by the applicant and must be renewed every five (5) years.

Much like any **foreign state authority**, in charge of telecommunications services and devices, *Swissmedic* has the authority to check the import of medicinal products on the respective manufacturer's and halt sales and to recall products within Switzerland, if necessary.

* The FDHA deals with a wide range of issues, from social insurance, the health system and statistics to gender equality, culture, and meteorology. Current major topics for the FDHA are old-age pensions and health.

** According to Swissmedic, it takes on average 10 to 12 years for a medical products life cycle: <https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products/patients-and-users.html>

«Values and conduct» on the Swissmedic-website:

(source: <https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products/guiding-principles.html>)

«Integrity»

We take an impartial and loyal standpoint with regard to our legal mandate on the one hand and the expectations of our stakeholders on the other. We show integrity and perform our tasks in the public interest.

«Quality»

We maintain a high level of expertise and deploy it in the interests of the effective performance of our tasks. We work efficiently, are mindful of risks and take prompt decisions.

«Transparency»

Our actions are transparent and reproducible. We communicate our decisions clearly and in a manner that is appropriate to the audience.

«Commitment»

We support each other in our daily work and improve ourselves continuously. Challenges spur us on to do better, and we do not shirk difficult decisions.

«Respect»

We interact in a respectful manner and conduct an open dialogue. In doing so, we create trust and nurture a corporate culture of respect and appreciation.

Search site for product information: <https://www.swissmedicininfo.ch/?Lang=EN>