

## 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  authority of medicinal  in

Switzerland. Based in Berne, *Swissmedic* started operations on 1<sup>st</sup> 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

products (for  and animal consumption) introduced to the local

market. The governmental institution is also responsible for market surveillance of

and medical devices.

When approving new medicinal products, *Swissmedic* administers internationally applicable

. The medical preparations may only be sold if their quality,

[health]  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  , specifies the type of

sale (prescription required delivery points) and appoints the specialists as well as the

information. Product registration is to be assumed by the applicant and must be renewed every five (5) years.

Much like any **foreign state** , 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  and statistics to gender equality, , 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  : <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  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  interest.

### «Quality»

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

### «Transparency»

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

### «Commitment»

We  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  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.swissmedicinfo.ch/?Lang=EN>

### Aufgabe Lückentext:

**Folgende Wörter bitte in den Lückentext einfüllen.**

**Jedes Wort kommt einmal vor.**

**Bitte Gross- und Kleinbuchstaben beachten.**

approval, authority, criteria, cycle, culture, human, impartial, monitoring, medicinal, products, pharmaceuticals, patient, performance, public, respectful, safety, system, support, transparent