swissmedic

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Strategic objectives 2019–2022

Introduction

Swissmedic, the Swiss authority for the authorisation and supervision of medicinal products and medical devices

Swissmedic, the Swiss authority for the authorisation and supervision of medicinal products and medical devices ("therapeutic products"), is a Federal public law institution with a distinct legal entity. It is autonomous in terms of its organisation and management and has its own budget.

The purpose and remit of Swissmedic are defined in the Therapeutic Products Act (TPA)[1]. Its control and oversight activities ensure that only high-quality, safe and effective therapeutic products are placed on the market, thereby helping to safeguard human and animal health (Article 1 para. 1 TPA).

Specifically, the main tasks of Swissmedic include the approval of clinical trials with medicinal products; the authorisation of medicinal products and batch releases; the issuing of establishment licences for the manufacture of, and wholesale trading in, medicinal products; the designation and monitoring of conformity assessment bodies for medical devices; market surveillance of medicinal products and medical devices (vigilance and market monitoring); monitoring the flow of controlled substances (narcotics); and publication of the Swiss Pharmacopoeia. To enforce the legislation on therapeutic products, Swissmedic can take administrative measures and initiate administrative proceedings, and it also has a duty to inform the public about therapeutic products.

Swissmedic performs safety-related supervisory tasks. It carries out its supervisory activities autonomously and independently (Article 81a para. 1 TPA). The strategic objectives are drawn up by the Agency Council, which then submits these to the Federal Council for approval, as well as an annual report on the achievement of the objectives (Article 72a para. 1 TPA).

Since the freedom to define strategic objectives is restricted by its legal mandate, the strategic objectives primarily address the question of "how" the tasks are to be completed.

[1] Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; CC 812.21)

Context

Rapid scientific and technological change challenges authorities on various levels

The development of innovative technologies goes hand in hand with the rapid advances in digital technology. New forms of evidence generation (patient-reported outcomes, real-world data) are increasingly being used in clinical research. Major advances in diagnostic technology are driving forward personalised medicine ("precision medicine"), particularly in the field of oncology. Apps and wearables have become standard items.

Delimitation issues are becoming ever more important, because it is increasingly difficult to draw the boundaries between the various product categories (medical devices, medicinal products, food products, cosmetics). It is almost impossible to assign new product types and combinations to the current definitions. The growing number of complex products and new technologies requires innovative and more flexible forms of regulation.

At the same time, the processes of legislation are time-consuming and complex and can barely keep pace with technological progress. Thus it is vital to identify technical and scientific developments and their implications for national and international regulation at an early stage.
There are growing expectations that new innovative medicines will be authorised faster and sooner (acceleration of the authorisation procedures and earlier authorisation with less clinical data in connection with "adaptive licensing"). Companies want a more intensive dialogue with the therapeutic products agency during the development process, along the lines of procedures already established in the EU and the USA.

Cooperation between authorities in different countries or groups of countries is steadily expanding. Efforts for greater standardisation and harmonisation are continuing at the international and regional levels. Activities involving collaboration and support are becoming increasingly significant.

Health awareness among the public at large is very high, and the health sector is booming. At the same time, many people are overwhelmed with the content and quantity of health-related information and expect much more transparency, particularly from authorities. The use of social networks is growing, and it is becoming increasingly difficult to distinguish between "true" and "false" information ("fake news"). In light of these developments, credible communication by authorities is essential.

Strategic priorities

1. Programmatic priorities

Efficient and independent control of therapeutic products

Swissmedic carries out its tasks in an environment of potentially conflicting interests. On the one hand, there is the need to protect patients from the risks associated with therapeutic products. On the other, both consumers and patients expect quick access to safe and effective therapeutic products; and, finally, the therapeutic products sector has a legitimate interest in competitive framework conditions. Moreover, the requirements placed on the therapeutic products industry and the intensity of regulation in Switzerland depend on standards that are internationally largely harmonised and, in some cases, laid down in international treaties.

Competent and independent control of therapeutic products is indispensable for the safety of patients and for Switzerland as a location for the pharmaceutical and medical device industries.

Swissmedic fulfils its tasks efficiently, transparently and independently within the framework of the political requirements. In fulfilling its official regulatory activity, Swissmedic consistently adheres to the principle of proportionality and follows international standards, while its supervisory activity involves a risk-based approach.

Swissmedic takes appropriate measures to avoid any conflicts of interest among its organs, employees and expert bodies. Through credible and independent oversight, it strengthens its position as a nationally and internationally recognised therapeutic products authority.

Strategic priorities

2. Task-specific and operational objectives

Objective 1:
Swissmedic provides a substantial contribution to the development of international standards and implements relevant standards.

Harmonised international standards provide an important basis for reducing the workload of authorities and companies and exploiting synergies in the collaboration between authorities. Consequently, Swissmedic continues to place a high priority on participation in international organisations and bodies for the further development of global standards.

Swissmedic defines recognised international standards as standards that reflect the state of the art in science and technology and therefore serve as requirements applicable to the regulated sectors. Standards concerning terminology, the transmission of data or the format of applications are also integrated into the processes and systems of Swissmedic as far as possible.

Strategic priorities

Objective 2:
Reliance on the evaluation results of other authorities and work sharing are intensively used.

The variety and complexity of the evaluation and supervision activities in relation to therapeutic products continue to grow. Given the diversity of tasks and the complexity, it is neither reasonable nor justifiable for authorities to act alone. Therefore, in accordance with TPA Articles 13 (Medicinal products and procedures authorised in foreign countries) and 14 (Simplified authorisation procedures), Swissmedic seeks to rely on the evaluation results of other recognised authorities in cases where the minimum material conditions are satisfied.

At the international level, Swissmedic will also promote initiatives that encourage evaluation under a work-sharing program. In the medium term, a substantial efficiency gain is expected as a result of these measures. In the field of medical devices, Swissmedic also seeks to continue pursuing equivalence with the EU.

Strategic priorities

Objective 3:
Communication with the public is trustworthy and up-to-date.

Aware of the growing interconnectedness, variety and complexity in the therapeutic products sector, Swissmedic must ensure that it shares information with the public in a balanced, impartial manner with the aim of fostering the public's confidence in the authority. It ensures to fulfil its tasks and communicate in a consistent and credible way.

Swissmedic makes use of the latest technologies in its communications, thus enabling differentiated and needs-based exchange with different population groups.

Strategic priorities

Objective 4:
Swissmedic intensifies its cooperation with national decision-makers in healthcare.

The rapid pace of development in the therapeutic products market, particularly in respect of highly-specialised medicinal products for ever smaller patient groups, the increasingly difficult distinction between food products, cosmetics, medical devices and medicinal products, the far-reaching adaptations to the legal framework and the growing pressure on the healthcare costs require closer cooperation with other authorities, politicians, associations and interest groups. Therefore, building on the existing cooperation and its legal mandate, Swissmedic intends to cooperate more intensively in future with decision-makers in Swiss healthcare.

Strategic priorities

Objective 5:
Business processes in the core areas are digitised.

The digitisation of everyday processes continues to grow. Services are no longer tied to traditional office hours. Procedures and processes are greatly supported by IT systems. Swissmedic aims to keep pace with this trend in order to accelerate its internal processes and simplify the dialogue with industry and other authorities.

Swissmedic therefore seeks to digitise its business processes to a large extent, focusing on the processes in its core areas of authorisation, licensing and market surveillance, with the medium-term goal of processing as many business cases as possible online/via the web portal.

Strategic priorities

Objective 6:
Time-critical processes are accelerated.

Swissmedic currently complies with the specified time limits in over 95 percent of all business cases. Over the coming years it will respond to the expectations of patients, consumers and industry concerning accelerated reaction times.

Swissmedic will shorten the duration of the relevant procedures by an average of 10 percent – while maintaining the same level of quality – by accelerating time-critical processes. With respect to the authorisation procedures it aims to match the fastest authorities.

Strategic priorities

Objective 7:
The regulatory systems of low- and middle-income countries are strengthened.

Swissmedic takes its Corporate Social Responsibility (CSR) seriously and, in return for payment and as part of its remit stated in the TPA, provides services for other authorities and international organisations, provided these do not jeopardise its independence or ability to function (Article 69 para. 2 TPA). These are wholly funded by third-party resources (not by the Swiss government or by the companies liable for fees or supervisory levies).

Together with the WHO, SDC and other partners, Swissmedic is involved in regional, continental and global initiatives to promote and strengthen the regulatory systems in low- and middle-income countries[2]. Corresponding initiatives are designed to harmonise, at the regional level, the regulatory principles of authorisation and supervision of therapeutic products based on international standards. This also supports national authorities in building up effective regulatory systems.

[2] As defined by the World Bank (https://data-helpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups)

Financial objectives

Financing for its activities

Swissmedic is managed according to the principles of good business practice and uses its resources efficiently and effectively. It finances its activities through procedural fees, supervisory levies on medicinal products and payments from the Confederation.

The following activities and products are funded exclusively by payments from the Confederation:

- Medicinal products [MP]
  - Legal framework
  - Penal law
- Medical devices [MD]
  - Legal framework
  - Technical standards
  - Information to the general public
  - Vigilance
  - Market surveillance
  - Penal law

Subject to the budget decisions taken by Switzerland's federal parliament, the Confederation funds these products with the following contributions (in CHF millions) as per the 2019 Federal Budget and the Financial Plan for 2020-2022 (BFP 2019).

CHF million	2019	2020	2021	2022
BFP 2019	14.2	14.2	14.4	14.5
Increase for MD (planned)	-	2.5	5.0	5.7

The planned staged increase in the federal contribution by a total of 5.7 million francs a year for the monitoring of medical devices is the result of the new EU MD Regulation, which must be transposed into Swiss Therapeutic Products Legislation as a result of bilateral agreements. This is part of the ongoing revision of the TPA.

The financial resources from the Confederation are used by Swissmedic to provide services efficiently. Surpluses or shortfalls are presented and explained in the reporting process.

Other activities / products are covered by procedural fees and supervisory levies (only on medicinal products) (total income of CHF 75-80 million). These are as follows:

- Medicinal products [MP]
  - Technical standards
  - Information to the general public
  - Information to the therapeutic products sector
  - Authorisation
  - Licensing
  - Vigilance
  - Market monitoring
- Medical devices [MD]
  - Information to the therapeutic products sector
  - Licensing

Financial objectives

Objective 8:
The reserves are increased appropriately.

Article 79 of the Therapeutic Products Act stipulates the option of building up reserves amounting to a maximum of one year's budget in order to finance future investments or cover any losses.

Swissmedic acts in a cost-conscious manner and intends, by the end of the strategy period, to accrue reserves amounting to at least one fifth of a year's budget on the basis of the levy and fee regulations applicable from January 2019.

Personnel and welfare policy objectives

Personnel and welfare policy

Swissmedic pursues a progressive, transparent and socially responsible personnel policy. Attractive and competitive working conditions make it possible to recruit, keep and develop the appropriate and competent staff required for an expert organisation.

Swissmedic respects diversity, particularly as regards gender, age and languages. It employs people who behave with integrity and loyalty and preserve the credibility of Swissmedic.

Management is based on trust, reciprocity, interest and recognition. Professional and personal development and performance, as well as a high degree of flexibility and willingness to change, are promoted at all levels.

Within the specified framework, Swissmedic provides a fair and attractive occupational benefit plan.

Personnel and welfare policy objectives

Objective 9:
At all times, Swissmedic disposes of the competencies needed to fulfil its mandate.

Focusing on medicinal products:
The intensive research and development of medicines targeting cancer and diseases of the central nervous system will produce many new innovative products (known as "advanced therapy medicinal products"). For generating evidence, data from controlled clinical trials is supplemented by data from use in clinical practice ("real-world data"). Swissmedic is constantly expanding its knowledge and capabilities so that it is also able to review these new medicinal products and procedures independently in a scientifically competent manner and using these innovative principles.

Focusing on medical devices:
The new legal requirements with stricter provisions concerning the depth and scope of testing and the monitoring of medical devices, together with the increasingly difficult demarcation between medical devices and medicinal products and new combination products, signify a fundamental change in the situation for Swissmedic.

It will adapt to the new requirements and build up the necessary competencies to fulfil its mandate in an efficient, risk-based manner.

Focusing on digitisation:
Digitisation covers many different aspects, from the use and sharing of data, and the processing of real-world data through to data protection and security. Swissmedic intends to dispose of the competencies required for exchanging information and data in the global network securely and reliably at all times and for processing and evaluating the data for its own purposes.

Personnel and welfare policy objectives

Objective 10:
Resources and competencies in the area of medical devices are built up.

The new Medical Devices Regulation entails additional tasks for Swissmedic. In order to cope with the new tasks, the workforce need to be gradually and substantially increased by 2022 and the necessary competencies acquired.

Cooperation and participation

Cooperation and participation

No financial cooperation or participation exists.

Amendments to strategic objectives and reporting

Amendments to the strategic objectives

If required, the Agency Council can amend the strategic objectives during their period of validity and submit the amended objectives to the Federal Council for approval (Article 70 para. 2 TPA).

Reporting to the Federal Council

The Agency Council prepares an annual report for the Federal Council on the achievement of the strategic objectives (Article 72a para. 1 b TPA).

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