swissmedic

Strategic objectives 2023-2026

Preliminary remarks

The strategy for 2023-2026 was developed with recognised strategy development methods that have demonstrated their usefulness in practice. Swissmedic worked on the basis of an environmental scenario described as *rapid scientific and technological change challenges authorities on various levels*.

Developments in technology and science

The development of innovative technologies goes hand in hand with rapidly increasing digitalisation. Nucleic acid technology is expected to boost development. The development and deployment of mRNA vaccines demonstrated the capabilities of this technology. Research into and development of new innovative medicinal products based on this technology will rapidly intensify. At the same time, conventional molecules derived synthetically and using biotechnology can be developed faster and manufactured more efficiently. Enormous progress in diagnostic capabilities, given further impetus by the use of everyday devices (apps, wearables) newly deployed for diagnostic purposes, is leading to increasingly personalised forms of therapy and, as a result, to the growing orphanisation of therapeutic products.

Regulation, development and expectations

The discrepancy between regulation of the therapeutic products market and the speed of scientific and technological developments is becoming ever more striking. The growing number of complex products and new technologies requires new, more innovative forms of regulation. Moreover, delimitation issues are gaining in importance as it becomes increasingly difficult to draw lines between the different product categories (therapeutic products, medical devices). At the same time, legislative processes are time-consuming because of their complexity. It is therefore vital to identify technical and scientific developments and their implications for national and international regulation at an early stage, not least because of the need to maintain the role of Switzerland as an attractive location for economically viable research and development activities.

The public expects new innovative therapeutic products to be made available as fast as possible without compromising on safety, efficacy or quality and expects the supply of these products to be reliable. The companies operating in the medicinal products and medical devices sector would welcome a dialogue with the authorities during the development process.

Relationship with the EU and international collaboration

The relationship between Switzerland and the EU, a major trading and research partner, is unclear. The EU requires progress to be made with the institutional agreement before the necessary update of the Mutual Recognition Agreement (MRA) can take place, so this has not happened yet.

Preliminary remarks

Collaboration with the EU on the surveillance of medical devices is therefore not currently possible. The Federal Council approved a number of mitigating measures in 2021 so that Switzerland can be supplied with safe medical devices even in the absence of an updated MRA and to enable Swissmedic to intervene in the market as needed to protect patients. The changes maintain the equivalence of the Swiss provisions with those operating in the EU, leaving open the option of updating the MRA at a later date.

At the same time, cross-agency national and international collaboration is becoming increasingly important in enabling Swissmedic to play the role required of it as a modern therapeutic products agency and to anticipate the need for new regulations in a timely manner. Activities towards greater standardisation and harmonisation are continuing intensively at the international level.

Developments in society, communication and fake news

Society is becoming increasingly individualised. The number of groups with a wide variety of different and in some cases contradictory calls for dialogue with and information from the authorities is growing.

The expectation of receiving transparent, fast and understandable information is additionally clashing with the need to safeguard official secrecy. The use of social networks continues to grow, 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.

Continuity of the strategy

The strategic objectives for 2023-2026 follow on from the achievements of the preceding strategy period. The period was marked internationally by the increasing harmonisation of requirements and greater collaboration between the therapeutic products authorities, which will continue to intensify in the future. At the national level the exchange with decision-makers in the healthcare sector and communication with the public were greatly expanded. The work done during the pandemic helped to increase public perception of Swissmedic as a scientifically autonomous and economically and politically independent authority.

Progress achieved in recent years in process optimisation and digitalisation will be continued with greater intensity. This also applies to dialogue and collaboration with the various stakeholder groups.

Strategic objectives 2023-2026 of the Swiss Agency for Therapeutic Products (Swissmedic)

of 16 September 2022

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[1] Publication in BBl 2022 3130

Introduction

Swissmedic ensures that only high-quality, safe and effective therapeutic products are placed on the market to protect the health of humans and animals.

Swissmedic, the Swiss authority for the authorisation and surveillance of medicinal products and medical devices (therapeutic products), is a public institution of the federal government and a legal entity in its own right. 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 of 15 December 2000[2] (TPA). The monitoring and surveillance activities performed by Swissmedic ensure that only high-quality, safe and effective medicines are placed on the market. In this way Swissmedic helps to protect the health of humans and animals (Art. 1 para. 1 TPA). Swissmedic furthermore assists the federal government in its efforts to ensure the safe and orderly supply of therapeutic products throughout Switzerland.

Specifically, the main tasks of Swissmedic include the approval of clinical trials with therapeutic 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.

Cross-agency national and international collaboration is becoming increasingly important in enabling Swissmedic to play the role required of it as a modern therapeutic products authority. At the same time, the relationship between Switzerland and the European Union (EU), a major trading and research partner, is unclear. The EU requires progress to be made with the institutional agreement before the necessary update of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 21 June 1999[3] (Mutual Recognition Agreement, MRA) can take place, so this has not happened yet. Collaboration with the EU on the surveillance of medical devices is therefore not currently possible.

[2] SR 812.21
[2] SR 0.946.526.81

Introduction

The Federal Council approved a number of mitigating measures in 2021 so that Switzerland can nonetheless be supplied with safe medical devices and to enable Swissmedic to intervene in the market as needed to protect patients.

The institutional autonomy of Swissmedic allows it to set its own priorities in the implementation of its legal mandate. These priorities are set out in the form of strategic objectives and reviewed every four years. They are submitted to the Federal Council for approval in accordance with Article 70 TPA. The strategic objectives serve as guidelines for Swissmedic in its operational management. Every year, the Swissmedic Agency Council sets priorities for the implementation of the strategy in the coming year, and these are incorporated into the annual objectives for individual organisational units.

Strategic priorities

1. Programmatic priorities

Efficient and independent surveillance of therapeutic products

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

A competent and independent control of therapeutic products guarantees the safety of patients and is important for Switzerland as a location for pharmaceuticals and medical technology. Subject to the legal requirements, Swissmedic performs its tasks efficiently, transparently and independently.

In fulfilling its official regulatory remit, Swissmedic consistently adheres to the principle of proportionality and follows international standards. Its supervisory remit involves a risk-based, international approach.

Swissmedic is one of the leading therapeutic products agencies worldwide. Within international organisations it makes a substantial contribution to the refinement of therapeutic products regulation and takes on leadership roles.

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

2. Task-specific and operational objectives

Swissmedic has stepped up its supervisory and surveillance activities in the therapeutic products market.

Swissmedic ensures compliance with the legal requirements in the therapeutic products sector. Its supervisory and surveillance activities ascertain the conformity and safety of products. If violations occur, Swissmedic takes measures to restore a state of legal compliance, thus making a major contribution to patient safety.

Swissmedic is increasing the number of annual inspections connected with clinical trials performed annually and the number of inspected hospitals and economic operators in the medical devices sector. More vigilance inspections are being performed in a risk-based approach and are also carried out before authorisation is granted.

Expanded penal powers with tougher options for sanctions underpin Swissmedic's positioning as a serious enforcement authority.

Strategic priorities

Swissmedic is known to the public as a trustworthy authority.

Swissmedic ensures that everyone in Switzerland who uses therapeutic products for themselves or for other people or animals for prevention or cure can trust these products.

Swissmedic communicates credibly using defined platforms. Swissmedic adapts the content of communication and the channels used to the target groups. Swissmedic regularly verifies the success of its efforts in order to refine its public relations work, thus strengthening the public's trust in the public service provided by Swissmedic.

By involving patient and consumer organisations, Swissmedic can take a differentiated approach to the needs of these central groups and can tailor communication more effectively to their concerns. At the same time, Swissmedic promotes understanding of its role as a therapeutic products agency and supports the common interest in patient safety.

Strategic priorities

In specific areas, Swissmedic works together with other authorities and medical professionals.

As a relevant part of the Swiss healthcare system, Swissmedic promotes good collaboration with the system partners.

There is a regular dialogue with medical professionals and representatives of the federal government and the cantons. Swissmedic's expertise is highly valued in expert circles and is incorporated into therapeutic product-related topics. The aim of collaboration is to contribute to improving the healthcare system in Switzerland.

Strategic priorities

Swissmedic supports the development of novel therapeutic products and helps ensure swift access to innovative therapies.

Research into and the development and market launch of a new innovative therapeutic product are complex activities. Scientific and technological challenges are compounded by the need to take numerous regulatory requirements into account.

Intensive research is ongoing into novel therapy options for rare and serious diseases. There is great interest in such forms of therapy; many universities, start-ups and small and medium-sized enterprises are launching research projects in this field. Contact with the research community enables Swissmedic to become acquainted with new therapeutic products and technologies at an early stage. It provides scientific and regulatory advice for innovative research projects.

Swissmedic develops internationally agreed, appropriate regulations for new innovative technologies that are not yet regulated.

Swissmedic works with international partners (e.g. Access Consortium, the U.S. Food and Drug Administration [FDA], Project Orbis) to accelerate market access process for medicinal products with great innovative potential. Swissmedic is expanding its dialogue with the research-based therapeutic products industry and the academic research community and is involved in international committees to promote extensive regulatory harmonisation.

Strategic priorities

Swissmedic implements Swiss medical device regulations on an internationally networked basis.

Medical devices regulation in Switzerland is internationally compatible and ensures the same level of protection as in the EU.

Swissmedic is expanding its international collaboration (e.g. within the Access Consortium, with the British Medicines and Healthcare products Regulatory Agency and with the FDA in the USA) and, as a member of the International Medical Device Regulators Forum, is involved in the development of global standards for medical devices.

Data exchange based on international treaties facilitates the effective surveillance of the medical devices market.

The expanded portfolio of tasks (including the creation of an in-house database, new approval and surveillance functions) is summarised in a task structure.

Strategic priorities

Swissmedic uses state-of-the-art digital technologies.

Swissmedic has the technological capabilities required to collaborate with the therapeutic products industry, other authorities and other countries on a data-focused basis. It operates a modern enterprise information management system. The working infrastructure consists of a sensible combination of private and public clouds.

The open data architecture and structure are compatible with national and international standards. Artificial intelligence in the form of machine learning or natural-language processing is deployed wherever this is sensible.

The implemented data protection and information security measures and business continuity management ensure the integrity, legal conformity and availability of data.

Strategic priorities

Swissmedic is an agile and data-focused authority.

Swissmedic is a knowledge-based organisation well-versed in the wide variety of scientific and regulatory disciplines found in the therapeutic products sector. A continuous exchange and processing of analogue and digital information form the basis of and are the precondition for Swissmedic's ability to perform.

The use of new digital technologies means that far more data from a variety of sources are available and can be networked.

Swissmedic supports the interoperability of data and standards in the Swiss healthcare system and in international collaboration with authorities and organisations.

Work processes are digitally transformed and data-driven. Swissmedic promotes its employees' digital skills and assists them in working with innovative new business models and ways of thinking.

Financial objectives

Financial objectives

General

Swissmedic finances its activities through procedural fees, supervisory levies and payments from the federal government (Art. 77 para. 2 TPA).

The following tasks and activities are funded solely by payments from the federal government in accordance with the Therapeutic Products Act (Art. 77 para. 2bis TPA):

- Legislation
- Enforcement of provisions of criminal law
- Surveillance of medical devices

The financial resources from the federal government are used by Swissmedic to provide services efficiently. Surpluses or shortfalls are presented and explained in reports.

Funding of tasks relating to medical devices

While there is no legislative basis for supervisory levies, surveillance of medical devices will be funded entirely by procedural fees and payments from the federal government.

Funding of tasks relating to market access for medicinal products

At least 85% of the tasks and activities relating to market access (authorisation and approval of medicinal products) are funded by procedural fees.

Reserves

Swissmedic built up its reserves during the last strategy period. They totalled some CHF 100 million as at the end of 2022.

In the new strategy period the emphasis is no longer on building up reserves but on investing in the renewal and transformation of the IT infrastructure. These investments will be financed from the reserves where necessary (Art. 79 TPA).

Personnel and welfare policy objectives

Personnel and welfare policy objectives

Swissmedic pursues a progressive, transparent and socially responsible personnel policy. Attractive and competitive working conditions enable us to recruit and keep the appropriate and competent staff required for an expert organisation and to offer them opportunities for career development.

Swissmedic's personnel policy promotes equality of opportunities and the diversity of its staff. Modern, flexible working conditions ensure the compatibility of work and private life. The policy offers employees appropriate development prospects. It combines a working atmosphere based on trust and respect, a fair personnel assessment system and transparent communication, generating a high level of job satisfaction and identification of employees with Swissmedic, their employer.

Autonomy, competence, a sense of belonging, a high level of willingness to change and agility are promoted at all levels.

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

Cooperation and participation

Cooperation and participation

No financial cooperation or participation exists.

Amendments to strategic objectives and reporting

Amendments to strategic objectives and reporting

The Agency Council may modify the strategic objectives following an annual review. The amendments must be submitted to the Federal Council for approval (Art. 70 para. 2 TPA).

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

Annex: Indicators and key figures

1.1 Programmatic priorities

Indicators	Key figures	Target
PZ1-1: International positioning of Swissmedic	CIRS ranking of the median throughput time for new active substances (NAS)	Top 5
PZ1-2: Participation in steering committees of international organisations	No. of seats on steering committees of international organisations	At least 3

1.2 Task-specific and operational objectives

Strategic objective: ***Swissmedic has stepped up its supervisory and surveillance activities in the therapeutic products market.***

Indicators	Key figures	Target
St1-1: Inspections of clinical trials of medicinal products	Proportion of clinical trials inspected / year	20% (currently: 10%)
St1-2: Inspections of clinical trials of medical devices	Proportion of clinical trials inspected / year	20% (currently: 5%)
St1-3: Inspected hospitals	Proportion of hospitals inspected / year	10% (currently: 5%)
St1-4: Inspected economic operators in the medical devices (MD) sector	No. of economic operators inspected (decreasing, constant, increasing)	increasing
St1-5: Pharmacovigilance inspections of medicinal products	No. of inspections (decreasing, constant, increasing)	increasing
St1-6: Expertise in expanded options for penal sanctions (penalties)	Revised criminal provisions in the TPA	In force (from 1.1.2027)

Strategic objective: ***Swissmedic is known to the public as a trustworthy authority.***

Indicators	Key figures	Target
St2-1: Evaluation of "Image as a trustworthy authority" by stakeholders	No. of points (0-100)	At least 85 (currently: 78)
St2-2: Contact with patient and consumer organisations	No. of contacts with patient and consumer organisations (decreasing, constant, increasing)	increasing

Strategic objective: ***In specific areas, Swissmedic works together with other authorities and medical professionals.***

Indicators	Key figures	Target
St3-1: Exchange/dialogue with medical professionals	No. of events (decreasing, constant, increasing)	increasing
St3-2: Events and collaboration with representatives of the federal government and cantons	No. of events and collaborative activities (decreasing, constant, increasing)	increasing
St3-3: Evaluation of "familiarity with the tasks done by Swissmedic" by medical professionals	Percentage of medical professionals surveyed who are familiar with the tasks done by Swissmedic	At least 75% (currently: ~50%)

Strategic objective: ***Swissmedic supports the development of novel therapeutic products and helps ensure swift access to innovative therapies.***

Indicators	Key figures	Target
St4-1: Advice to universities, start-ups, research groups, etc.	No. of new contacts / year	At least 5 (currently: 0)
St4-2: Scientific Advice Meetings, medicinal products	No. of meetings (decreasing, constant, increasing)	increasing
St4-3: Stakeholder evaluation of "Swissmedic as a promoter of innovations"	No. of points (0-100)	At least 75 (currently: 59)
St4-4: Authorisation procedures in conjunction with international partner authorities	No. of procedures (decreasing, constant, increasing)	increasing
St4-5: Reduction of the throughput time for authorisation of new innovative medicinal products	Reduction in per cent	Minus 10% (compared with 2021)

Strategic objective: ***Swissmedic implements Swiss medical device regulations on an internationally networked basis.***

Indicators	Key figures	Target
St5-1: International treaties on data exchange for supervision and surveillance of medical devices	No. of corresponding international treaties on data exchange	At least 3 (currently: 0)
St5-2: Membership of the International Medical Device Regulators Forum (IMDRF)	Swissmedic is a member of the IMDRF (yes/no)	Yes (currently: no)
St5-3: swissdamed database to support the interoperability of data and standards in collaboration with international partners	A database with structured data about economic operators and medical devices exists (yes/no)	Yes (currently: no)

Strategic objective: ***Swissmedic uses state-of-the-art digital technologies.***

Indicators	Key figures	Target
St6-1: Swissmedic applications based on open data structures and compatible international standards	Proportion of Swissmedic applications in the core processes authorisation, approval and market surveillance	50% (currently: 0%)
St6-2: Swissmedic applications supported by artificial intelligence (AI)	No. of AI-supported Swissmedic applications in routine operation	5 (currently: 0)
St6-3: Data protection and information security	No. of critical data protection and information security incidents / year	<5 (currently: n.a.)

Strategic objective: ***Swissmedic is an agile and data-focused authority.***

Indicators	Key figures	Target
St7-1: Progress towards digital maturity	Maturity level (Level 1 – level 5)	Level 4 (currently: level 1)

2. Financial objectives

Indicators	Key figures	Target
F-1: Surveillance of medical devices funded by federal contribution	Degree of cost recovery in per cent	100%
F-2: Market access for medicinal products funded by procedural fees	Degree of cost recovery in per cent	>85%
F-2: Reserves (current)	Amount (CHF million)	At least CHF 80 million

3. Personnel and welfare policy objectives

Indicators	Key figures	Target
P-1: Employees' job satisfaction	No. of points (0-100)	> 78
P-2: Employees' commitment	No. of points (0-100)	> 85
P-3: Fluctuation (terminations by employees and by Swissmedic)	Fluctuation rate in per cent	<8%
P-4: Part-time working	Proportion of part-time working (up to 89%) in per cent	>50%
P-5: Women in management positions	Proportion of women in management positions in per cent	>40%

Indicators	Key figures	Target
V-1: Risk exposure of the Swissmedic pension fund	Actuarial funded status in per cent	>110%
V-2: Attractiveness of the Swissmedic pension fund	Return on retirement capital in per cent	>Minimum interest rate

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