swissmedic

ANNUAL REPORT 2025

Mission

Our competence – for therapeutic products you can trust.

CONTENTS

6 Foreword
6 Together through a year of radical change

8 Swissmedic at a glance
8 Core tasks of Swissmedic
9 Our stakeholders
10 People, culture and values
11 External experts
12 Organisational chart

13 Strategy and sustainability
13 Strategic objectives 2023–2026
14 Sustainable development
16 Stepping up surveillance of therapeutic product safety: Focus on collaboration

17 Governance
17 Corporate Governance
17 Organisation
18 Agency Council
20 Management Board
21 Risk management and compliance

22 Medicinal Products – **Standards product group**
22 Legal Framework product
22 Technical Standards product

24 Medicinal Products – **Information product group**
24 Informing the General Public product
24 Informing the Therapeutic Products Sector product

27 Medicinal Products – **Market Access product group**
27 Authorisation product
27 Overview
28 First authorisations
30 Authorisation procedures
31 Human medicinal products
33 Special human medicinal product and transplant product categories
34 Complementary and herbal medicines
35 Veterinary medicinal products
36 Appeals procedure
37 Medicinal products: facts and figures
38 Licensing product
38 Overview
39 Establishment licences
39 Licences under Article 4 NarcA
39 Licences for clinical trials
40 Import licences for vaccines and blood products
40 Certificates for medicinal products and ATMPs
41 Batch assessment and plasma pool tests

42 Laboratory analyses and test method development
42 Inspections
45 Other monitoring activities
45 Appeals procedure
46 Establishment licences in facts and figures

47 Medicinal Products – **Market Surveillance product group**
47 Overview
48 Vigilance product
48 Human medicinal products vigilance
49 Signals and safety reports
50 Introduction of Safety Update – Updates to Information for healthcare professionals
50 Introduction of mandatory identification of safety-relevant information
50 Vigilance for veterinary medicinal products
51 Market monitoring of medicinal products product
51 Quality defects and batch recalls
52 Out-of-stock products
52 Control of advertising
53 Measures against illegal medicinal products
54 Appeals procedure

55 Medicinal Products – **Penal Law product group**
55 Penal Law product

58 Medical Devices – **Standards product group**
58 Legal Framework product
58 Technical Standards product

59 Medical Devices – **Information product group**
59 Informing the General Public product
59 Informing the Therapeutic Products Sector product

61 Medical Devices – **Market Access product group**
61 Licensing product
61 Placing on the market
61 Clinical trials
62 Export certificates
62 swissdamed – medical device database
63 Medical devices: facts and figures

64 Medical Devices – **Market Surveillance product group**
64 Vigilance product
64 Materiovigilance
65 Market Monitoring product
65 Independent monitoring
65 Market monitoring procedures
66 Notified bodies and inspections
66 Hospital inspections
66 Appeals procedure

67 Medical Devices – **Penal Law product group**
67 Penal Law product

68 Balance sheet

69 Income statement

70 Statement of comprehensive income

70 Cash flow statement

71 Statement of changes in equity

72 Annex
72 Operating activities
72 Summary of the main accounting principles
77 Risk assessment and risk management
78 Valuation uncertainties
78 Notes on the balance sheet
78 1 Cash and cash equivalents
78 2 Receivables from sales and services
79 3 Financial assets
80 4 Fixed assets
81 5 Real estate
82 6 Intangible assets
83 7 Right of use
84 8 Other commitments
84 9 Deferred income
84 10 Other current provisions
85 11 Pension provision
90 Notes on the income statement
90 12 Procedural fees and income pursuant to Article 69 Therapeutic Products Act
90 13 Personnel
91 14 IT
91 15 Financial income
91 16 Financial expense
92 Other notes
94 Report of the statutory auditors

FOREWORD

Lukas Bruhin, Chairman of the Agency Council
Dr Philippe Girard, Acting Executive Director

Together through a year of radical change

2025 will go down as a turning point in Swissmedic's history. Personnel changes at the helm of the Management Board and in the Agency Council, the deterioration of the financial situation and the digital transformation led to radical adjustments.

The financial year was one of strong performance. Swissmedic fulfilled its legal mandate reliably and efficiently, even under challenging conditions. This is particularly evident in the high adherence to regulatory deadlines, through which Swissmedic continues to be one of the most efficient regulatory authorities at the international level. External evaluations of authorisation times in 2025 also confirmed this.

Changes to management and governance
While the generational transition at the helm of our organisation had long been planned, the health of Executive Director Raimund Bruhin necessitated its early implementation on a temporary basis. We wish him well in his retirement and would like to thank him for his many years of service to Swissmedic. Philippe Girard took over operational management with effect from October.

With its appointment of Vincenza Trivigno as the new Executive Director from January 2026, the Federal Council has set the course for the future. It has also confirmed and effected a partial change in the composition of the Agency Council: The new members from 2026 are Milena Folletti and Virginie De Biase. We sincerely thank the departing members Olivier Guillod and Giovan Maria Zanini for their many years of commitment. Monika Rüegg Bless has been appointed the new Vice Chair of the Agency Council.

Worsening financial situation
Swissmedic's financial strain was clearly evident in autumn 2025. The situation is attributable to a range of factors and worsened considerably in the year under review for three key reasons: the shortfall in the funding of areas by federal contributions, the reduction in the supervisory levies for medicinal products, and a sharp rise in overall costs. Rising staff and material costs as well as essential investments in digitalisation, IT infrastructure and new regulatory requirements were all contributory factors.

Under the Acting Executive Director and with the involvement of the Management Board, we analysed this development in the late autumn and adopted a strict consolidation and stabilisation programme. It includes measures on the cost side as well as short-term adjustments to the income side within the legal framework.

We are also involved in political discussions on creating a legal basis for user-pays funding of medical device surveillance – specifically in the form of a supervisory levy. From Swissmedic's perspective, this type of provision is required for sustainable financing of the public authority market surveillance mandate in the future.

We deeply regret that a reduction in headcount will be necessary in this context. Our social partnership has proven its value in this difficult phase. It was crucially important to the Agency Council, Management Board, employee committee and social partners that the restructuring be organised in as socially acceptable a manner as possible.

Performance mandate, quality and digital transformation
The technical completion of the change in IT provider from FOITT to Swisscom, which was executed successfully, was a key milestone.

Through the further development of the swissdamed database, we created the possibility of registering medical devices and significantly improved transparency on the medical devices available in Switzerland.

Swissmedic sent out a strong quality signal with the successful SAS reaccreditation of the GMP/GDP inspectorate. There were no non-conformities, and the high level of expertise and the effectiveness of quality management were confirmed.

We were able to further strengthen our position at international level: In the autumn, Swissmedic took over the Chair of the Assembly at the International Council for Harmonisation (ICH). Swissmedic was also accepted as a member of the Management Committee of the International Medical Device Regulators Forum (IMDRF), thereby increasing our direct influence on the future regulation of medicinal products and medical devices.

Lukas Bruhin

Philippe Girard

Outlook

The focus in 2026 will be on stabilisation. The 2025 deficit of almost 32 million francs should signal the turning point.

While we will continue to allocate our reserves to finance the necessary digital transformation, this targeted drawdown should end once a limit of around 30 million francs is reached. Based on cost-saving measures that have already been introduced and the planned action on the income side – particularly the further development of supervisory levies – we aim to then increase reserves again gradually in order to maintain and strengthen Swissmedic's financial independence and capacity to act in the long term.

Thank you

Our employees are behind everything Swissmedic does. We would like to express our particular thanks to them. They have demonstrated extraordinary professionalism, loyalty and dedication in a year of uncertainty and cost-saving measures. This commitment is the basis on which we will develop Swissmedic further together.

SWISSMEDIC AT A GLANCE

Core tasks of Swissmedic

As the Swiss Agency for Therapeutic Products, Swissmedic is scientifically independent and politically neutral. As part of its economic and safety-related supervisory tasks, it ensures that therapeutic products (medicinal products and medical devices) on the Swiss market are high-quality, safe and effective in accordance with the legal bases.

Specifically, the main tasks of Swissmedic, in accordance with the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act), comprise the authorisation of medicinal products; market surveillance (vigilance and market monitoring); the approval of clinical trials of therapeutic products; the issuing of establishment licences for the manufacture of, and wholesale trading in, medicinal products; batch release; the designation and supervision of conformity assessment bodies for medical devices; monitoring the flow of controlled substances (narcotics); and publication of the Swiss Pharmacopoeia. Swissmedic has a duty to provide public information about therapeutic products. It can also impose administrative measures and initiate administrative proceedings for the purposes of enforcing therapeutic products legislation.

The key achievements and figures for financial year 2025 are reported by product group and product for medicinal products and medical devices from page 22 onwards.

Under Article 68 of the Therapeutic Products Act, Swissmedic has its own budget and manages its own accounts. More than 83 percent of the Agency's income comes from fees and supervisory levies; the remainder comes from payments from the federal government. Swissmedic is an expert organisation. Accordingly, personnel expenses account for approximately 70 percent of operating costs.

The 2025 financial statements with accompanying commentary start on page 68.

Its service portfolio is divided into the following product groups (PG) and products (P):

Standards PG
- Legal Framework (P)
- Technical Standards (P)

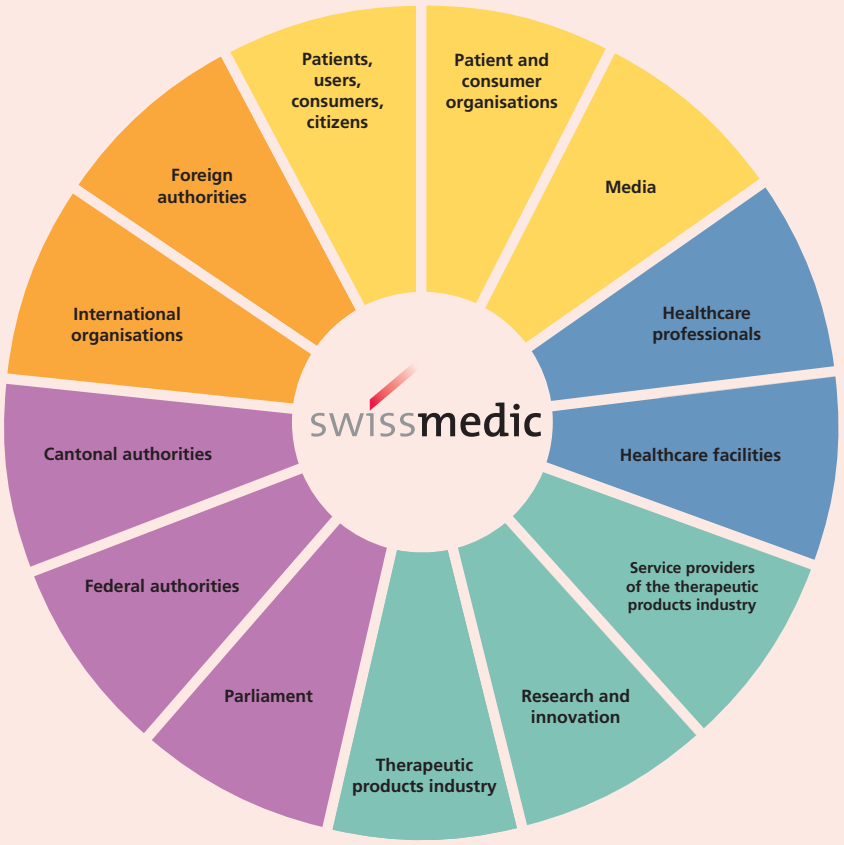
Information PG
- Informing the General Public (P)
- Informing the Therapeutic Products Sector (P

Market Access PG
- Authorisation (P)
- Licensing (P)

Market Surveillance PG
- Vigilance (P)
- Market Monitoring (P)

Penal Law PG
- Penal Law (P)

Our stakeholders



The stakeholder map shows that Swissmedic fulfils its mandate in a broad-ranging environment characterised by varying needs and expectations.

Collaboration with various stakeholder groups is institutionalised at national level – for example with the Association of Cantonal Pharmacists, Federal Office of Public Health, Federal Food Safety and Veterinary Office and the Cantons as part of the Expert Panel for Delimitation Questions, with patient and consumer organisations or the therapeutic products industry and its associations. Swissmedic also intends to step up dialogue with healthcare and medical professionals. Contact with specialist oncology societies, paediatricians and vets was strengthened during 2025.

Swissmedic and Switzerland attach great importance to international bilateral and multilateral cooperation. Swissmedic makes an active contribution to the harmonisation of regulatory requirements through its active involvement with the following organisations and committees (listed alphabetically):

- Access Consortium (therapeutic products authorities of Australia, Canada, Singapore, the United Kingdom and Switzerland)
- Council for International Organizations of Medical Sciences (CIOMS)
- European Directorate for the Quality of Medicines & HealthCare (EDQM)
- European Patients' Academy on Therapeutic Innovation (EUPATI)
- European Pharmacopoeia Commission
- Global Coalition for Regulatory Science Research (GCRSR)
- International Coalition of Medicines Regulatory Authorities (ICMRA)
- International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- International Medical Device Regulators Forum (IMDRF)
- International Medical Device Safety Meeting (IMDSM)
- International Pharmaceutical Regulators Programme (IPRP)
- Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- World Health Organization (WHO)

People, culture and values

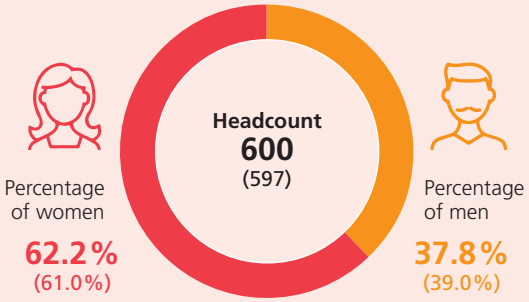
The people who work at Swissmedic have a wide range of qualifications in medicine, pharmaceutics, science, engineering, physics, statistics, IT and law, as well as technical, paramedical, commercial and many other backgrounds. All of them use their skills and commitment and work in compliance with the legal bases to ensure that only high-quality, safe and effective therapeutic products are placed on the market to protect the health of humans and animals.

The reduction in headcount was started in 2025 and temporary positions were cut. During the year under review, a maximum of 520 full-time equivalents was reached; as at the end of the year, this figure was 512.1 full-time equivalents. As stated previously, Swissmedic took measures to reduce its operating expenses; as part of this, headcount will be reduced in 2026 and 2027 by around 45 full-time equivalents compared to the end of 2025.

Swissmedic has the staffing resources to pursue strategic objectives such as supporting rapid access to innovative treatments or closer monitoring of the therapeutic products market, and to successfully deal with its wide-ranging and in some cases new tasks. According to the international benchmarking study by the Centre for Innovation in Regulatory Science (CIRS), Swissmedic is the smallest of the leading therapeutic products authorities.

A competent and independent control of therapeutic products guarantees the safety of patients and is important for Switzerland as a hub 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. The way Swissmedic employees conduct themselves is defined by core values: integrity, quality, transparency, commitment and respect.

Key figures: human resources
(Previous year's figures)



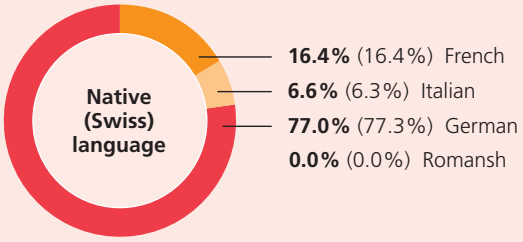
512.1 Full-time equivalents (510)

Percentage of women in executive positions (46.8%) **45.7%**

47.9 Average age (47.0)

Part-time working (up to 89%) (47.4%) **47.8%**

2.8% Fluctuation rate (2.5%)



External experts

When required, Swissmedic augments its own expertise by consulting external experts in medicine, pharmacy, science and other disciplines.

Swissmedic Medicines Expert Committees
The Human Medicines Expert Committee (HMEC) and the Veterinary Medicines Expert Committee (VMEC) are two advisory committees that assist Swissmedic with authorisation documentation reviews, the market surveillance of medicinal products and medical devices, and other procedures. The Agency Council elects the members of both committees for a four-year period of office. The 2024 elections resulted in a rejuvenation of the committees and greater diversity.

The HMEC also gained external experts in the areas of gender medicine and patient advocacy. It commenced its activities on 1 January 2025 under the new Chair, Prof. Dr. med. Dr. phil. Andreas Wicki.

The HMEC met nine (previous year: nine) times and issued 22 (25) recommendations, mainly on applications for new authorisation of medicinal products and additional indications. In addition, HMEC members carried out 28 (38) assessments of parts of dossiers and 24 (35) individual expert opinions were obtained.

The VMEC, chaired by Dr. Barbara Knutti, met six (five) times and issued 16 (12) recommendations. The applications concerned the new authorisation of veterinary medicinal products, additional indications and new target animal species, new routes of administration and resistance monitoring with regard to a clinical/preclinical condition for authorised veterinary medicinal products. VMEC members also delivered 34 (32) individual expert opinions.

A list of members of both committees, their vested interests and the rules put in place to guarantee the experts' neutrality are published on Swissmedic's website.

Members of the HMEC/VMEC and their vested interests

Expert Commission for Radiopharmaceuticals
The Expert Commission for Radiopharmaceuticals (ECRP) employed by the Federal Council is made up of external experts from universities and hospitals across Switzerland. It assesses applications for authorisation and applications for variations. Since radiopharmaceuticals are subject to the Radiological Protection Ordinance as well as to the Therapeutic Products Act, decisions are made on a consensus basis between the ECRP, Swissmedic and the Federal Office of Public Health.

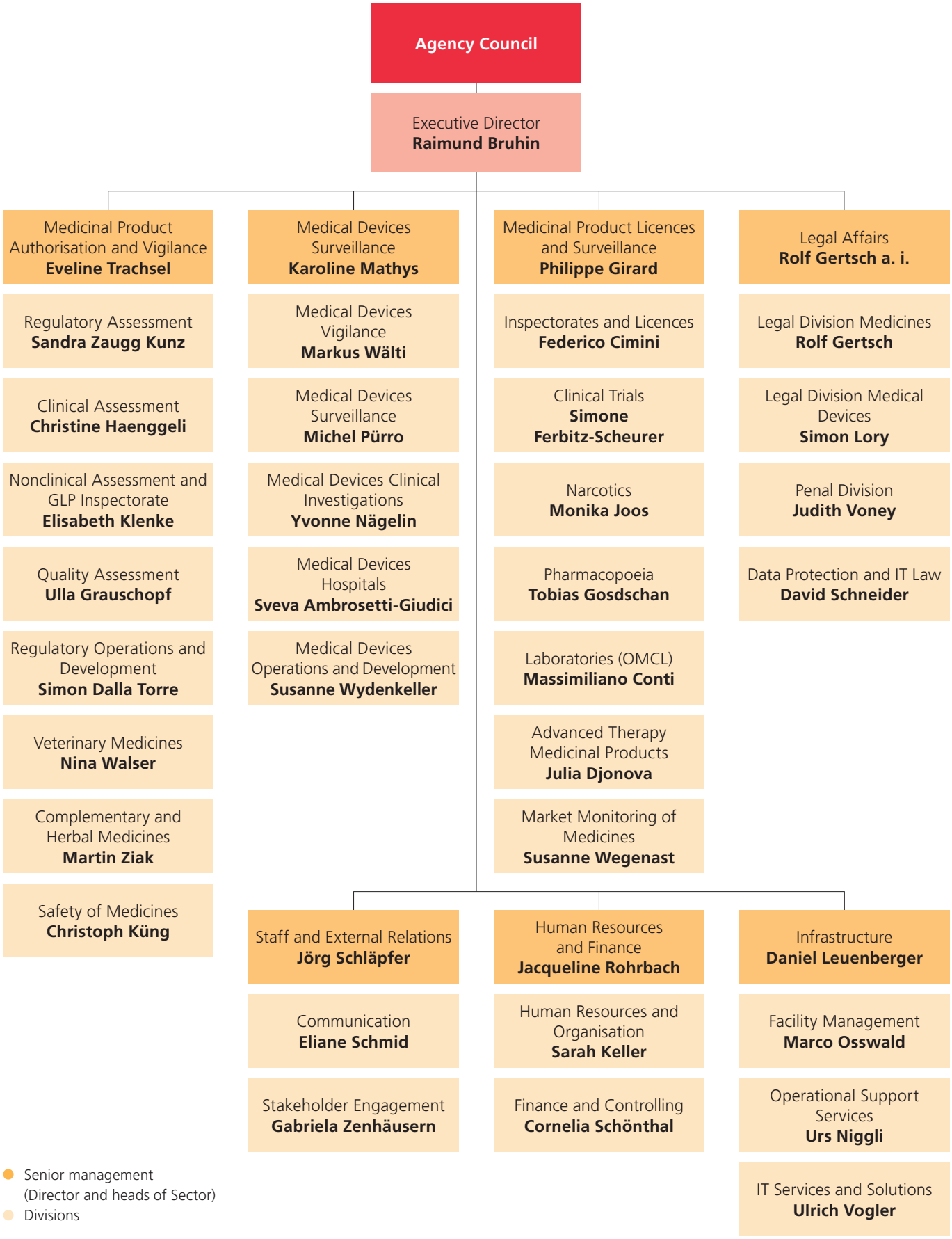
Pharmacopoeia experts
Around 130 Swiss specialists from industry, the universities, community and hospital pharmacies, drugstores and authorities contribute to the preparation of the Pharmacopoeia. The experts work firstly in the Swiss pharmacopoeia expert groups convened by Swissmedic and secondly in the specialist committees coordinated by the EDQM in Strasbourg for the European Pharmacopoeia (Ph. Eur.).

The Swiss Pharmacopoeia (Ph. Helv.) is prepared by five specialist committees. The Ph. Helv. texts are approved by the Swiss Pharmacopoeia Commission. A total of 72 (72) mandates are currently held across all Swiss pharmacopoeia committees.

The regular elections to appoint experts to the Ph. Eur.'s specialist committees were held in 2025. These elections take place every three years. Swiss experts currently hold 106 (107) of the approximately 1,000 mandates in the active Ph. Eur. expert and working groups, of which there are around 60. The tasks are overseen by the European Pharmacopoeia Commission, which is made up of delegations from the Ph. Eur. member states. The Swiss delegation is appointed by the Federal Council and is led by the Head of Swissmedic's Pharmacopoeia Division.

Pharmacopoeia Boards

Organisational chart



STRATEGY AND SUSTAINABILITY

Strategic objectives 2023–2026

The institutional autonomy of Swissmedic allows it to set sustainable and necessary regulatory priorities in the implementation of its legal mandate. These are set out in the form of strategic objectives. In accordance with Article 72a of the Therapeutic Products Act, the Agency Council draws up these objectives, submits them to the Federal Council for approval and reports annually on their fulfilment.

The focus areas of the strategic objectives for 2023–2026 are as follows:

- Stepping up supervisory and surveillance activities in the therapeutic products market
- Supporting the development of novel therapeutic products and helping ensure swift access to innovative therapies
- Contributing to implementation of medical device regulations on an internationally networked basis
- Working in specific areas with other authorities and healthcare professionals
- Being known to the public as a trustworthy authority
- Using state-of-the-art digital technologies and promoting the transformation into a data-focused, agile authority

The following milestones were achieved during 2025:

- Continuation of the joint focus campaign with the Cantons on inspection of healthcare institutions and cosmetic studios that use medical devices (specifically "fillers")
- Establishment of new methods for analysis of non-authorised GLP-1 products
- Introduction of identification of Direct Healthcare Professional Communications to help increase medicinal product and patient safety
- Hosting of more than 100 Scientific Advice Meetings by the Innovation Office and issuing of specific development recommendations for ATMPs
- Shortening and optimisation of deadlines in international procedures, for known active substances according to Art. 13 TPA and in the labelling phase
- Introduction of a fast track for processing applications for clinical trials with a high medical need (pilot project)
- Revision in collaboration with medical societies and associations of good practices for reprocessing of flexible, thermolabile endoscopes
- Go-live of the second registration module (for medical devices) of the swissdamed database
- Acceptance as a member of the Management Committee of the IMDRF
- Taking over of the Chair of the Assembly at the International Council for Harmonisation (ICH)
- Approval of the 2025–2028 strategy of the Access Consortium, including the aim of strengthening collaboration in the area of GxP inspections
- Stepping up of dialogue with medical experts in the areas of oncology and materiovigilance; development of new guidelines (good practice) for materiovigilance with experts in the field
- Publication of the first annual report on Good Clinical Practice (GCP) inspections
- A survey on Swissmedic's reputation in seven stakeholder areas
- Digitalisation of import and export licences for narcotics
- Successful migration of IT applications to the new provider, Swisscom
- Go-live of other applications on new platforms
- Completion of the "Transformation of Swissmedic Platforms" project and transition to regular operation

Strategic objectives

Sustainable development

The UN's 2030 Agenda defines 17 global sustainable development goals with 169 targets. Swissmedic is making an active contribution to the achievement of four of these global goals:

Under the Memorandum of Understanding between the Gates Foundation, the Federal Department of Home Affairs and the Federal Department of Foreign Affairs, Swissmedic is committed to strengthening regulatory systems in low- and middle-income countries with the aim of supplying people with high-quality, life-saving medicinal products as quickly as possible.

Training courses to expand capacity and promote dialogue between regulatory authorities from these countries continued in 2025. A total of 41 people from ten regulatory authorities took part in the biannual regulatory training. Furthermore, four inspectors received training on specific GMP (Good Manufacturing Practice) topics. Two products were authorised in 2025 under the Swissmedic procedure for collaborative assessment of medicinal products to combat diseases in the Global South (MAGHP procedure): a paediatric medicinal product against malaria (Riamet Baby) and an ocular anaesthetic (Visiclor, Eye Gel). Swissmedic continues to support regional and continental initiatives for regulatory harmonisation in Africa and to operationalise the African Medicines Agency (AMA).

(Target: Achieve access to safe, effective, quality and affordable essential medicines and vaccines for all)

Swissmedic has been promoting equal opportunities for many years by offering attractive employment conditions and part-time working. The percentage of women in executive positions was around 46 percent in 2025; the equivalent figure for the Management Board was 43 percent. Women and men are paid the same for the same or equivalent work, and this was confirmed by the second independent gender pay gap review, conducted in March 2024. The total share of female employees in 2025 was 62 percent.

(Target: Ensure women's full and effective participation and equal opportunities for leadership at all levels of decision-making in political, economic and public life)

SUSTAINABLE DEVELOPMENT GOALS

Innovation and digital transformation are important focal areas of Swissmedic's strategic objectives.

Since 2023, Swissmedic has operated an Innovation Office to accompany and support the development of innovative therapeutic products. The current focus is on advanced therapy medicinal products (ATMPs). The Office provides expertise and advises researchers in universities and start-ups on developments in manufacturing processes or the conditions that need to be met for a clinical trial or authorisation application to be approved. Early-stage dialogue helps those involved meet regulatory and scientific requirements faster and avoid costly errors. This happens through Scientific Advice Meetings and informal dialogue while projects are in progress. The close cooperation and continual knowledge sharing enable Swissmedic to process and approve applications for promising treatments quickly.

(Target: Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation)

Swissmedic's three buildings are fitted with photovoltaic installations, which generated 236,000 kWh of electricity (previous year: approx. 227,000 kWh).

To promote sustainable mobility, electric car charging stations are available at the buildings on Hallerstrasse and Freiburgstrasse.

Swissmedic systematically uses recyclable paper in all Sectors and in doing so is supporting resource-friendly business practices and reducing its environmental footprint.

(Targets: Sustainable management and efficient use of natural resources)

Stepping up surveillance of therapeutic product safety: Focus on collaboration

Medicinal products and medical devices are key tools in healthcare. In line with legal requirements, Swissmedic ensures that only high-quality, effective, safe medicinal products are authorised. By contrast, medical devices do not undergo an official authorisation procedure. They must meet basic safety and performance requirements and comply with regulations so that they can be placed on the market in the EU and Switzerland.

After market access, all therapeutic products – medicinal products and medical devices – are subject to continuous surveillance in order to recognise any risks swiftly, take corrective action and ensure the safety of the products and as a result patient safety throughout the entire life cycle. In light of the strategic objective of stepping up surveillance of therapeutic products, Swissmedic strengthened implementation of its surveillance and enforcement concept in 2025.

In medical devices, preventive measures such as information for economic operators to better enable them to assume their responsibility, a video to improve reporting discipline among medical device users and good materiovigilance practice in hospitals were published. In addition, collaboration on surveillance with the cantonal enforcement authorities was stepped up further in 2025. Alongside a joint campaign on fillers (medical devices to smooth out wrinkles), Swissmedic performed, evaluated and published numerous inspections of various market players as part of planned focus campaigns. For-cause inspections were also increasingly carried out to clarify the facts in cases of suspicion reports.

Inspection activities in hospitals were also stepped up and specific recommendations to improve the situation were published.

International cooperation

International cooperation is extremely important for monitoring of the Swiss therapeutic products market. Swissmedic exchanges information and new findings on therapeutic product safety with numerous foreign supervisory authorities (including EU member states, the USA and the Access Consortium partner authorities of Australia (TGA), Canada (HC), Singapore (HSA) and the United Kingdom (MHRA)) in regular meetings. This helps to identify new risks more quickly and implement corrective actions.

In medicinal product manufacturing, Swissmedic took an active role in all international bodies in which international GMP standards and their implementation are discussed, interpreted and – if required – further developed (EMA Inspector Working Group, PIC/S committee and sub-committees, PIC/S EMA joint drafting groups). In this way, Swissmedic was able to help shape the international GMP standards and ensure compliance with and enforcement of them in Switzerland. The foreign inspection programme was also expanded. GMP-compliant manufacturing was inspected at various production sites in India and China.

The Swissmedic OMCL laboratory has strong international links and is actively involved in a number of expert groups to ensure and further improve medicinal product safety for humans and animals in Switzerland.

Focus areas include cell and gene therapies, mRNA and other vaccines, immunological veterinary medicinal products and blood products. The laboratory was designated a Centre of Expertise for nitrosamine analysis by the European Directorate for the Quality of Medicines & HealthCare (EDQM). Swissmedic performs analyses for numerous partner countries.

Clinical trials inspections

More inspections were carried out of ongoing clinical trials both for medicinal products and medical devices. Swissmedic further stepped up monitoring in connection with clinical trials with medicinal products in 2025 through GCP inspections. In total, Swissmedic performed three for-cause inspections. Due to severe non-compliances identified either during application processing or inspections, Swissmedic withdrew the authorisation for one clinical trial in the year under review and interrupted recruitment of new study participants in two further cases.

An inspection was performed in Greece in collaboration with the Greek regulatory authority for the first time.

In 2025, the GCP/GVP Inspectorate took part in an MHRA inspection as an observer to find out whether the Access Consortium can collaborate on authorisation-relevant GCP inspections and harness synergies in the future.

GOVERNANCE

Corporate Governance

Organisation

Swissmedic is a public institution of the Swiss Confederation and a legal entity in its own right. It is independently organised and managed, has its own budget and manages its own accounts. As a decentralised administrative unit with economic and safety-related supervisory tasks, it is attached to the Federal Department of Home Affairs. Its statutory bodies are the Agency Council, Management Board and auditors. Individuals may only belong to one of these bodies.

The Federal Council appointed Ernst & Young AG (EY) as auditors for the period 2024 to 2027. EY has already held this role for two periods of office.

Swissmedic is divided into the following seven Sectors: Medical Devices Surveillance, Medicinal Product Authorisation and Vigilance, Medicinal Product Licences and Surveillance, Legal Affairs, Staff and External Relations, Human Resources and Finance, and Infrastructure. The Sector heads are members of the Management Board and report directly to the Executive Director.

Swissmedic is represented in international bodies (EU GCP Inspectors Working Group), cooperates actively in working groups (PIC/S GCP expert circles (EC): Risk Adapted Approaches Group, Data Governance Group) and participates in the PIC/S Joint Visits Programme. Through these activities, Swissmedic aims to harmonise clinical trials monitoring with other regulatory authorities.

One for-cause inspection was performed as part of monitoring activities of pharmacovigilance systems of companies holding authorisations. Swissmedic ordered measures to restore legally compliant status in one case. Swissmedic is also represented in international bodies (EU GVP Inspectors Working Group und EMA Junior GVP Group) and in the PIC/S GVP EC Best Practices Working Group in the area of pharmacovigilance.

Agency Council

The Agency Council consists of a maximum of seven members who are elected by the Federal Council. The Cantons have the right to propose three members for consideration. The Federal Council also nominates the Chair. Members are elected for a four-year period of office and may be re-elected for two further periods of office. The Federal Council elected the following for the 2022–2025 period of office on 16 November 2021:

- **Lukas Bruhin**, Chairman; attorney-at-law; partner in Arioli Law, owner and general manager of Layout Consulting GmbH
- **Giovan Maria Zanini**, Vice Chairman; Cantonal Pharmacist, Canton of Ticino
- **Daniel Betticher**, Prof. Dr. med.; President of the Fribourg Cancer League, former Chief Physician at Fribourg hospital
- **Lukas Engelberger**, Dr. iur.; member of the Cantonal Council and Head of the Health Department, Canton of Basel-Stadt
- **Olivier Guillod**, Prof. Dr. iur.; Emeritus Professor, Institute of Health Law, University of Neuchatel
- **Monika Rüegg Bless**, regional governor (Statthalter) and Head of the Department of Health and Social Affairs of the Canton of Appenzell Innerrhoden
- **Marie-Denise Schaller**, Prof. Dr. med.; former Chief Physician in the Department of Adult Intensive Care, Lausanne University Hospital

At the end of this period of office, Olivier Guillod and Giovan Maria Zanini reached the term limit and stepped down from the Agency Council. They have been replaced by Milena Folletti and Virginie de Biase.

Agency Council members' CVs and an up-to-date list of their vested interests can be found on Swissmedic's website along with the Council's business regulations.

In its capacity as a strategic body, the Agency Council represents Swissmedic's interests vis-à-vis the Federal Department and the Federal Council. Its duties and responsibilities are set out in Article 72a of the Therapeutic Products Act. In particular, the Agency Council develops the strategic objectives and submits them to the Federal Council for approval; prepares an Annual Report for Swissmedic's owner; oversees the Management Board and ensures appropriate internal control and risk management systems are in place; approves business planning and the statement of estimates; and issues regulations guaranteeing the neutrality of experts mandated by Swissmedic.

The Agency Council appoints a strategy committee, a finance and controlling committee, an appointments and remuneration committee, and a committees committee from among its ranks. In the year under review, the digitalisation committee was added to ensure the Agency Council is updated regularly on Swissmedic's progress with digitalisation. The committees deal with matters falling within their area of responsibility and submit them to the full Agency Council.

Important issues in 2025 once again included the political, regulatory and financial trends in the medical devices sector (equivalence of Switzerland's regulation with its

Olivier Guillod, Lukas Bruhin, Monika Rüegg Bless

EU counterpart, funding surveillance), the development of pharma regulation in the EU and its impacts on Switzerland, international trends in the development and authorisation of innovative medicinal products (use of AI, improvement in framework conditions for clinical studies, optimisation of authorisation processes, CIRS study) and the Confederation's report on economic supply. The Agency Council also dealt with the digital transformation process and in general with measures to improve Swissmedic's financial situation. In the period under review, the partial revision of annexes to the TPL-RO and its entry into force were approved for February 2026. The reappointment of the Swissmedic Medical Expert Committees (SMEC) was concluded during the reporting period. One of the tasks the Agency Council addresses each year is the disclosure of Council members' vested interests and Management Board members' other occupations and public offices held.

Remuneration for the Agency Council in 2025 totalled CHF 225,000 (previous year: CHF 200,000) including expenses. The increase is due to additional meetings of the Agency Council and its committees, particularly in connection with deciding on a successor for the outgoing Executive Director.

Of this figure, CHF 64,000 (CHF 58,000) was paid to the Chairman.

Agency Council

Lukas Engelberger, Daniel Betticher, Giovan Maria Zanini

Daniel Betticher, Marie-Denise Schaller

Management Board

The Management Board is Swissmedic's executive body and is responsible for operational aspects. It is led by the Executive Director, and its tasks, competences and responsibilities under law derive from Article 73 of the Therapeutic Products Act. In particular, it manages business, issues official decisions, prepares business planning, the statement of estimates and other decision-making materials for submission to the Agency Council, represents the Agency externally and discharges the duties not assigned to a different body.

The Management Board consists of the Executive Director and the seven Sector heads.

- **Raimund Bruhin**, Dr. med.; Executive Director
- **Philippe Girard**, Dr. sc. nat.; Deputy Executive Director, Head of Medicinal Product Licences and Surveillance Sector
- **Helga Horisberger**, Head of Legal Affairs Sector (until 31.08.2025), **Rolf Gertsch**, Acting Head of Legal Affairs Sector (from 01.09.2025)
- **Daniel Leuenberger**; Head of Infrastructure Sector
- **Karoline Mathys Badertscher**, Dr. pharm.; Head of Medical Devices Surveillance Sector
- **Jorg Schlapfer**, Dr. med. vet., PhD; Head of Staff and External Relations Sector
- **Barbara Schütz Baumgartner**, Head of Human Resources and Finance Sector (until 30.04.2025), **Jacqueline Rohrbach**, new Head of Human Resources and Finance Sector (from 01.05.2025)
- **Eveline Trachsel**, Dr. sc. nat.; Head of Medicinal Product Authorisation and Vigilance Sector

Executive Director Bruhin announced at the start of 2025 that he would be retiring in February 2026. However, he had to step down from operational management earlier than planned for health reasons. His deputy, Philippe Girard, provisionally took over management of Swissmedic from October 2025.

Barbara Schütz Baumgartner, the longstanding Head of Human Resources and Finance, retired at the end of May 2025. The Head of Legal Affairs, Helga Horisberger, took on a new professional challenge at the end of August 2025.

The Management Board confirms compliance with the Swissmedic Code of Conduct annually and publishes its members' CVs and details of any other occupations and public offices held by members on the Swissmedic website.

The remuneration paid to the Management Board is subject to the Swissmedic Personnel Ordinance. The total remuneration paid to the Management Board was CHF 2,401,221 (previous year: CHF 2,197,878), of which CHF 347,484 (CHF 338,954) was paid to the Executive Director.

Management Board

Philippe Girard, Raimund Bruhin

Karoline Mathys Badertscher, Eveline Trachsel

Helga Horisberger, Jörg Schläpfer, Barbara Schütz Baumgartner, Daniel Leuenberger

Risk management and compliance

Swissmedic operates a comprehensive risk management system with the appropriate processes and tools. Given the current lack of clarity surrounding Switzerland's relations with the EU, the Agency Council again classified the revised EU pharmaceutical regulation as a strategic risk during 2025. The Agency Council also identified additional risks connected to rapid access to new innovative treatments in Switzerland and the positioning of Swissmedic in the employment market for top executives and senior experts. Various measures were taken to mitigate these risks to the greatest possible extent.

As part of its comprehensive risk management activities, Swissmedic operates an internal control system (ICS), which focuses on finance-related business processes. The ICS is reviewed annually in terms of the risks identified and assessed, as well as the effectiveness of the risk-minimising controls conducted, and modified if necessary. The auditors confirmed the existence of the ICS in their management letter of November 2025 and reported that the level of documentation was appropriate for Swissmedic's size and complexity.

Swissmedic operates an Information Security Management System (ISMS) that complies with ISO 27001 as part of its comprehensive risk management activities. This system creates a binding framework, within which information security risks are systematically identified, assessed and addressed through appropriate technical and organisational measures. This is done with the aim of protecting business-relevant information against loss, theft or misuse and ensuring compliance with legal requirements (including FADP and ISA) as regards confidentiality, integrity and availability. Strategic control of information security was further strengthened in 2025. The migration of the IT infrastructure and expansion of the Security Operations Center significantly improved transparency and compliance. The requirements of ISO 27001 have largely been met and confirm a high level of security.

Codes of conduct for the Agency Council, employees and external experts ensure that Swissmedic exercises due neutrality in fulfilling its duties. Vested interests are published and compliance with the codes of conduct is reviewed at intervals and training is given. The annual audits of risk management, ICS and compliance with the codes of conduct carried out by the Agency Council and the Management Board did not require any measures, apart from those already initiated to improve earnings.

Rolf Gertsch, Jacqueline Rohrbach

MEDICINAL PRODUCTS – **STANDARDS PRODUCT GROUP**

Legal Framework product
Technical Standards product

Revision of the Therapeutic Products Act

The Therapeutic Products Act, which has been in force since 2002, is currently undergoing its third revision. This revision addresses three areas: digitalisation in the medication process (electronic prescribing, medication plan, electronic system to calculate medicinal product dosages), advanced therapy medicinal products (ATMPs) and extensive alignment of the rules for veterinary medicinal products with the modified EU legislation. The Federal Council submitted the draft to Parliament on 3 September 2025. The responsible committee will begin the detailed consultation in early 2026.

New ordinances and revision of existing ordinances

The following Federal Council ordinances are currently being drafted or revised:
- Therapeutic Products Ordinance
- Medicinal Products Licensing Ordinance
- Ordinance for Devitalised Cells and Tissues

Revision of Agency ordinances

Preparations for the revision of the Fees Ordinance (FeeO-Swissmedic) were made during 2025. In addition to the introduction of a fee for registering devices, systems and procedure packs in the area of medical devices, the hourly rate for the time-based fee, which has been unchanged since 2002, will be increased. The revision is expected to enter into force during 2026.

In addition, various annexes to the Ordinances issued by the Agency Council are reviewed each year in light of the current state of the art in science and technology and amended as necessary. In 2025, the annexes to the Ordinance on the Simplified Licensing of and the Notification Procedure for Complementary and Phytotherapeutic Products (KPTPO) and the Therapeutic Products Licensing Requirements Ordinance (TPLRO) were revised and came into force on 1 July 2025 and 1 February 2026, respectively.

Revision of the Narcotics Lists Ordinance

To counteract the threat posed by new developments, particularly new synthetic drugs, Swissmedic regularly reviews the lists associated with the Narcotics Lists Ordinance and applies to the Federal Department of Home Affairs to have them updated if necessary.

In the year under review, details of substances and precursors which are newly subject to control internationally were added to Annexes 1–3 and 5–7 of the Narcotics List Ordinance with effect from 15 May.

Memorandum of Understanding

Swissmedic and the US Food and Drug Administration (FDA) signed a Confidentiality Commitment (23 May 2025 and 4 June 2025, respectively), defining the exchange of non-public information and business secrets within the scope of the collaboration between the authorities. The commitment was based, among others, on the Mutual Recognition Agreement (MRA) in the area of good manufacturing practice for therapeutic products signed in January 2023.

In addition, Swissmedic signed a Memorandum of Understanding (MoU) with the Swedish Medical Products Agency on 19 May 2025. The signing of this MoU underscores both authorities' shared commitment to efficient, science-based therapeutic products regulation and lays the foundation for closer collaboration on regulatory questions concerning medicinal products and medical devices.

Pharmacopoeia

The pharmacopoeia that is valid in Switzerland consists of the European Pharmacopoeia (Pharmacopoea Europea, Ph. Eur.) and the Swiss Pharmacopoeia (Pharmacopoea Helvetica, Ph. Helv.). It contains legally binding quality requirements for common, known medicinal products and pharmaceutical excipients, as well as for certain medical devices. The requirements are risk-based and reflect the current state of science and technology.

Switzerland was among the founding members of the Ph. Eur. in 1964 and has since played an active role. In addition to the 39 member states in Europe, more than 30 other countries and organisations are incorporated as observers into the work of the European Pharmacopoeia. They ensure that the European Pharmacopoeia also plays an important role at global level. Supplements 11.6, 11.7 and 11.8 to the 11th edition of Ph. Eur. came into effect during 2025. The monographs and general chapters of the Ph. Helv. are constantly updated as part of the process of ensuring that the publication always reflects the latest scientific findings. The existing revision programmes were continued, and the revised requirements will be incorporated into the next edition.

The Ph. Helv. celebrated its 160th anniversary in 2025. Swissmedic also brought into effect an urgent amendment to the Good Manufacturing Practice rules for medicinal products in small quantities in the Ph. Helv. on 1 June 2025. This clarified the distinction under therapeutic products legislation between manufacture and preparation for administration.

Explanatory video about the pharmacopoeia

MEDICINAL PRODUCTS – **STANDARDS PRODUCT GROUP**

Informing the General Public product
Informing the Therapeutic Products Sector product

Informing the general public

Part of Swissmedic's legal mandate under Article 67 of the Therapeutic Products Act is to provide information for the general public.

Swissmedic publishes information on its website, in various newsletters and through its social media channels. It also publishes Visible, a mass-audience magazine, which appeared with slightly differing layouts in printed and online versions in the year under review and gives a detailed insight into Swissmedic's work. The online version includes videos. Production of Visible was discontinued for resource-related reasons in autumn 2025.

Visible

During 2025, Swissmedic released one podcast episode on veterinary medicine. Production of podcasts was then discontinued for resource-related reasons.

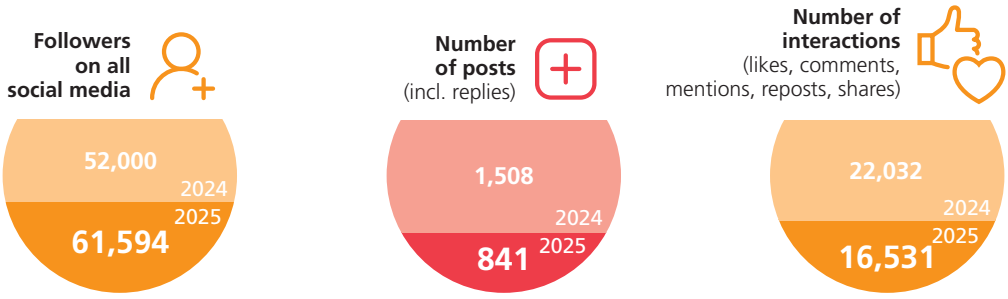
In September, Swissmedic published a statement on the use of paracetamol during pregnancy on its website, emphasising that the benefit-risk balance remains positive.

As a basis for its stakeholder management, Swissmedic commissioned gfs.bern to carry out an image survey of just under 1,300 people from various stakeholder areas. This found that a clear majority in all groups believe that Swissmedic plays an important role in Swiss healthcare and that its decisions can be trusted. The assessments from stakeholders with a high degree of contact with Swissmedic were particularly positive. Those from healthcare and medical professionals and the cantonal authorities were more critical. There is potential for optimisation in the areas of efficiency, communication and decreasing bureaucracy. The findings were taken into account in planning the stakeholder management for 2026.

Social media

Swissmedic made targeted use of social media to provide information to and raise awareness among the public in 2025. The focus was on content with direct benefits for patients and healthcare professionals, particularly regarding medicinal product safety, regulatory questions and international authorisation procedures. Swissmedic also offered in-depth insights into its specialist work and expertise. These included portraits and interviews with experts.

Swissmedic left the platform X in the third quarter. Despite the loss of this platform, the total number of followers on all channels rose again significantly. Swissmedic has been on the microblogging platform Bluesky since 2025.



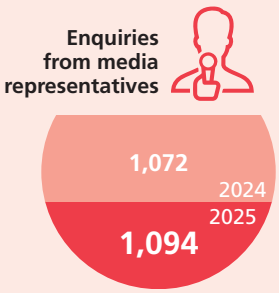
Press relations

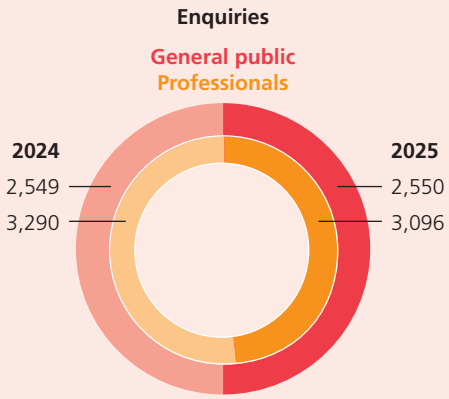
Media interest in Swissmedic remained high during 2025. The Swiss Agency for Therapeutic Products mainly attracted attention in matters regarding enforcement and market surveillance: The media covered results concerning illegally imported or falsified medicinal products, and reported on focus campaigns (e.g. on fillers) and criminal judgements, particularly in prominent cases. Editors also frequently reported on medicinal products for weight loss (GLP-1 receptor agonists). Individual media reports also addressed the distinction between information and unlawful advertising of medicinal products.

Topics conveying the role and performance of Swissmedic also attracted attention: The international CIRS study and the annual benchmarking study led to numerous articles, as did the annual report on hospital inspections and the pilot phase on accelerated processing of clinical trial applications. The appointment of Vincenza Trivigno as the new Executive Director was also widely reported. The media were critical of the annual loss in 2024 and internal criticism of the investment in digitalisation and the working environment. They reported widely, but neutrally, on both Swissmedic press releases on the measures to improve earnings. Swissmedic gave a total of 28 interviews and background briefings in 2025.

Enquiries

Swissmedic answers questions from lay-people, healthcare professionals and other specialists, and other stakeholders. Over 5,600 enquiries were received in 2025. The general public was primarily interested in issues such as falsified slimming products from the internet or importing melatonin. The topics covered by the questions from specialists included cannabis for medical purposes, clinical trials, establishment licences and authorisation under Article 13 of the Therapeutic Products Act.





Requests under FoIA

2024 2025

No. of applications

48
25

Time requirement (in hours) **for processing requests**

1,092
988

Political business items involving medicinal products

2024 2025

Parliamentary proposals

58
43

Other business items in which Swissmedic was involved

70
63

Transparency/FoIA

The Federal Act on Freedom of Information in the Administration (Freedom of Information Act, FoIA) gives everyone the right in principle to access official documents. This right can be restricted or refused in order to protect overriding public or private interests.

The number of FoIA requests decreased by around 50 percent compared to 2024. However, the time required for processing requests remained high, mainly due to the scope of the requests received. Partial or full access was granted in most cases.

One appeal regarding freedom of information requests is currently pending before the Federal Administrative Court and one arbitration procedure with the Federal Data Protection and Information Commissioner (FDPIC).

Parliamentary proposals

Swissmedic acted as lead agency on five (previous year: eight) parliamentary proposals. A postulate calling for a review of the current implementation rules for importing small quantities of medicinal products was accepted.

Swissmedic representatives attended the meetings of various parliamentary committees throughout the year, providing information on matters such as potential simplifications of the authorisation process for patent-expired medicinal products.

Professionals

The information channels that Swissmedic uses to communicate with professionals are the Agency's website, various newsletters, and training and information events.

The round table meetings are an important forum for dialogue with the therapeutic products industry and industry associations. They were held for stakeholders in the areas of regulatory affairs, e-submissions (previously electronic Common Technical Dossier (eCTD)), GMP/GDP, complementary and herbal medicinal products (CHM), veterinary medicinal products (on topics including supply issues) and medical technology in the year under review.

A round table meeting on innovation was held with multidisciplinary stakeholder representatives on the topic of advanced pharma manufacturing. The strengths and weaknesses of Switzerland as a pharmaceutical production location and the role of Swissmedic were discussed. Participants from industry, technology, biotechnology, science and Innosuisse as well as Swissmedic experts mentioned Switzerland's attractiveness as a production hub and its international positioning.

Swissmedic was the host of the Global Summit on Regulatory Science in 2025. 200 international experts from regulatory authorities, science and industry discussed the scientific basis of future regulatory systems.

As every year, Swissmedic also held training courses for international GMP inspectors and cantonal therapeutic product inspectors and organised the Medicrime meeting with representatives from federal and cantonal authorities in the fight against illegal therapeutic products.

MEDICINAL PRODUCTS – **MARKET ACCESS PRODUCT GROUP**

Authorisation product

Overview

In 2025, 10,734 (previous year: 10,297) authorisation applications and applications for variations were submitted for human and veterinary medicinal products, and 11,000 (10,855) were completed. Of the 40 human medicines with new active substances authorised, Swissmedic processed 36 (90 percent) within the prescribed time limits. The median delay for the remaining four was 16 calendar days. The median turnaround time for the 40 applications was 392 (444) calendar days. 98 (112) meetings for applicants were held before or during the authorisation process. At the end of 2025, 2,967 (3,478) applications were in progress.

Applications received	2025	2024
First authorisations of innovative medicinal products	125	136
First authorisations of non-innovative medicinal products	245	209
Extensions	57	57
Major variations	1,336	1,308
Minor variations	7,359	6,952
Other applications	1,612	1,635

Applications completed	2025	2024
First authorisations of innovative medicinal products	131	102
First authorisations of non-innovative medicinal products	261	215
Extensions	69	69
Major variations	1,803	1,801
Minor variations	7,202	6,965
Other applications	1,534	1,703

First authorisations

Human medicinal products with a new active substance

	Medicinal product	Active substance(s)	Indication
Oncology and haematological malignancies	Balversa	Erdafitinib	Urothelial cancer
	Blenrep	Belantamab mafodotin	Multiple myeloma
	Datroway	Datopotamab deruxtecan	Breast cancer
	Elahere	Mirvetuximab soravtansine	Ovarian, fallopian tube or primary peritoneal cancer
	Hetronifly	Serplulimab	Lung cancer
	Itovebi	Inavolisib	Breast cancer
	Lazcluze	Lazertinib	Lung cancer
	Nexpovio	Selinexor	Multiple myeloma
	Vanflyta	Quizartinib	Acute myeloid leukaemia
	Vyloy	Zolbetuximab	Stomach cancer
	Zynyz	Retifanlimab	Merkel cell carcinoma
Endocrinology and metabolism	Imcivree	Setmelanotide	Obesity associated with Bardet-Biedl syndrome (BBS)
	Lynkuet	Elinzanetant	Vasomotor symptoms in post-menopausal patients
	Sephience	Sepiapterin	Phenylketonuria
	Tepezza	Teprotumumab	Thyroid eye disease
	Voxzogo	Vosoritide	Achondroplasia
	Yorvipath	Palopegteriparatide	Hypoparathyroidism
Neurology and psychiatry	Briumvi	Ublituximab	Multiple sclerosis
	Imaavy	Nipocalimab	Myasthenia gravis
	Qalsody	Tofersen	Amyotrophic lateral sclerosis (ALS)
	Rystiggo	Rozanolixizumab	Myasthenia gravis
	Wainzua	Eplontersen	Polyneuropathy associated with amyloidosis
Dermatology	Filsuvez	Refined dry extract from birch bark	Epidermolysis bullosa
	Litfulo	Ritlecitinib	Alopecia areata
	Nemluvio	Nemolizumab	Atopic dermatitis
	Relfydess	Botulinum toxin type A (strain I01)	Glabellar lines
Diagnostics	PulmoProDiff	Carbon monoxide, helium	Investigating lung function
	Pylclari	Piflufolastat (18F)	Diagnosis in prostate cancer
	RoTecPSMA	Trofolastat	Diagnosis in prostate cancer

	Medicinal product	Active substance(s)	Indication
Cardiology and nephrology	Beyonttra	Acoramidis	Transthyretin amyloid cardiomyopathy (ATTR-CM)
	Jeraygo	Aprocitentan	Arterial hypertension
	Obgemsa	Vibegron	Overactive bladder
Haematology and haemostaseology	Andembry	Garadacimab	Hereditary angioedema
	Ekterly	Sebetralstat	Hereditary angioedema
	Piasky	Crovalimab	Paroxysmal nocturnal haemoglobinuria (PNH)
Infectious diseases and vaccines	Capvaxive	Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B de-O-acetylated, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, 35B polysaccharide conjugated to Corynebacterium diphtheriae CRM197 protein	Prevention of Streptococcus pneumoniae infection
	mRESVIA (respiratory syncytial virus mRNA vaccine)	mRNA-1345	Prevention of respiratory syncytial virus (RSV) infection
Gastroenterology	Bylvay	Odevixibat	Progressive familial intrahepatic cholestasis
	Lyvdelzi	Seladelpar	Primary biliary cholangitis
Pulmonology	Alyftrek	Vanzacaftor, tezacaftor, deutivacaftor	Cystic fibrosis

Veterinary medicinal products with a new active substance

	Medicinal product	Active substance(s)	Indication
Vaccines	BTVPUR ad us. vet.	Bluetongue virus, serotypes 1, 2, 4, 8, inactivated	Inactivated vaccine for active immunisation of cattle and sheep against blue tongue disease
	Poulvac Procerta HVT-IBD ad us. vet.	Live recombinant turkey herpes virus expressing the VP2 protein of HVT-IBD	Live vaccine for active immunisation of day-old chicks and embryonated chicken eggs against Marek's disease and the infectious bursitis virus
	Protivity ad us. vet.	Mycoplasma (Mycoplasmopsis) bovis strain N2805-1, live attenuated	Attenuated live vaccine against Mycobacterium bovis in cattle
	BULTAVO 3 ad us. vet.	Bluetongue virus, serotype 3, strain Bio-93:BTV3, inactivated	To stimulate active immunity against blue tongue virus in vaccinated animals (sheep and cattle)
Dermatologicals	Zenrelia ad us. vet.	Ilunocitinib	Dermatological product for dogs
	Numelvi ad us. vet.	Atinvicitinib	Dermatological product for dogs
Nervous system	Tessie 0.3 mg/mL ad us. vet.	Tasipimidine	For short-term relief of situational anxiety and fear in dogs

Authorisation procedures

Various authorisation procedures are available to applicants. Swissmedic differentiates between procedures with standard time limits and various fast-track procedures. In addition, it differentiates between standard procedures and reliance procedures.

Authorisation under Article 13 Therapeutic Products Act

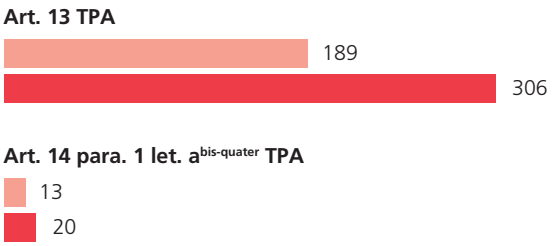
The authorisation procedure under Article 13 TPA is a reliance procedure. If a medicinal product or procedure has already been authorised in a country with comparable medicinal product control, Swissmedic takes account of the results of the associated review.

Authorisation under Article 14 Therapeutic Products Act

The procedure under Article 14 paragraph 1 letter $a^{bis\text{-}quater}$ TPA is also a reliance procedure. Under this procedure, it is possible to request simplified authorisation of new and known active substances that have already been authorised in other countries for many years or with which practical experience has been acquired in other countries over a period of many years.

Number of applications submitted under reliance procedures

2024 2025



Fast-track authorisation procedure

It is possible to request a fast-track authorisation procedure for new authorisations, extensions and new or modified indications if the following three conditions are all fulfilled: The medicinal product is expected to be successful in treating or preventing a serious disease; authorised medicinal products do not provide alternative or satisfactory treatment options; and the medicinal product holds out the prospect of a significant therapeutic benefit.

Temporary authorisation procedure

It is possible for temporary authorisation to be granted under certain conditions defined by law in order to make medicinal products for the treatment of life-threatening diseases available as quickly as possible. Under these conditions, any clinical documentation that is missing when the application is reviewed only has to be provided after the official decision has been issued. Swissmedic assesses the data retrospectively, and if its verdict is positive, the temporary authorisation is lifted. Swissmedic can issue temporary authorisations at applicants' request or ex officio. In the former case, the fast-track review time limits are applied.

Procedure with prior notification

Applicants can request a procedure with prior notification for products with new active substances or indication extensions if they provide three to six months' advance notification of submission and Swissmedic has sufficient staffing capacity. A PPN is 20 percent faster than the normal procedure.

International procedures (Access and Orbis)

The Access Consortium (therapeutic products authorities of Australia, Canada, Singapore, the United Kingdom and Switzerland) reviews authorisation applications on a work-sharing basis. In Orbis, applications are reviewed in parallel with the US Food and Drug Administration (FDA) and other regulatory authorities.

Human medicinal products

New authorisations and extensions

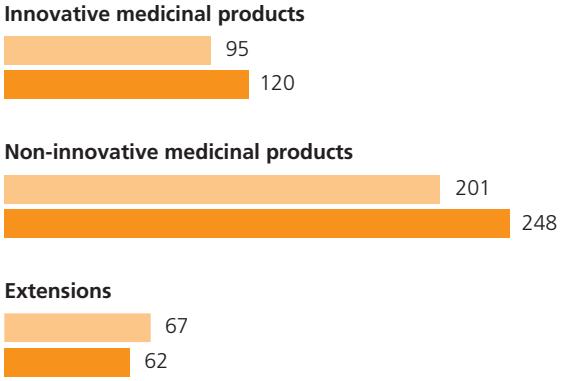
New authorisation of human medicinal products is granted following a comprehensive review of the documentation submitted by the applicant on safety, efficacy and quality. The authorisation procedure distinguishes between innovative medicinal products (new active substances and extensions such as new pharmaceutical forms) and non-innovative medicinal products (known active substances).

Activities

Compared with 2024, 18 percent more applications for new authorisation of innovative and non-innovative medicinal products, as well as for authorisation extensions, were processed and completed.

Number of applications completed

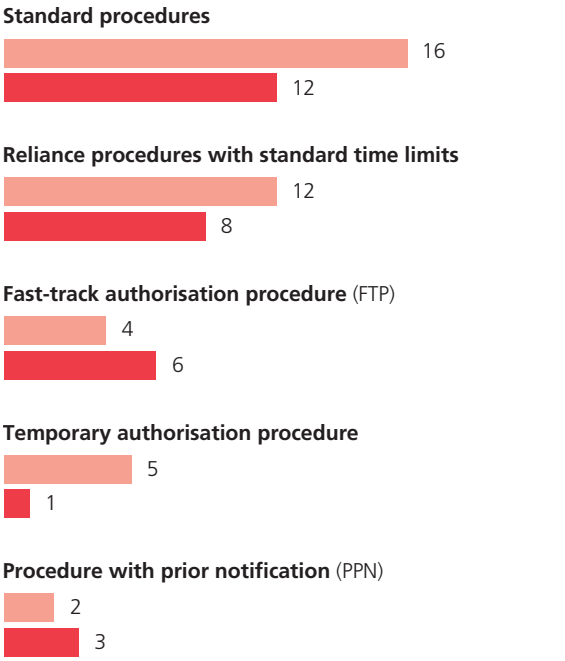
2024 2025



40 (46) innovative human medicinal products with new active substances were authorised in 2025. Authorisation was granted under various procedures. Fast-track procedures were used for 50 percent of applications. The median turnaround time (companies' time and Swissmedic's time) was 392 (444) calendar days. The resulting turnaround time for the Access procedures was 395 (328) calendar days, while that for the Orbis procedures was 321 (329) days.

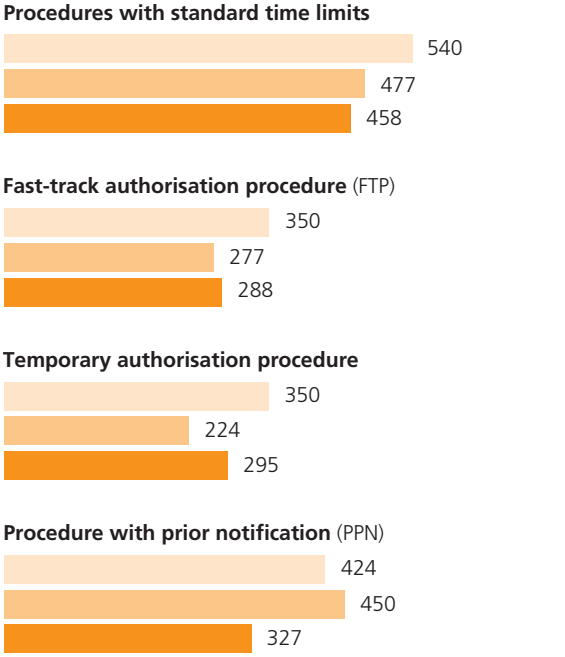
Number of new authorisations of human medicinal products with new active substances by procedure (multiple procedures possible)

2024 2025



Median turnaround time in calendar days for different authorisation procedures for human medicinal products with new active substances compared with time limits specified in guidance document

Time limit 2024 2025



29 percent of applications for indication extensions were processed under the fast-track procedure. The median turnaround time for all procedures was 331 (316) calendar days.

Number of authorised indication extensions
(multiple procedures possible)

2024 **2025**

Standard procedures
44
72

Reliance procedures with standard time limits
4
5

Fast-track authorisation procedure (FTP)
1
7

Temporary authorisation procedure
3
2

Procedure with prior notification (PPN)
3
4

International procedures (Access and Orbis)
17
21

Major variations

Major variations (type II variations) may affect the efficacy, safety and quality of the medicinal product in question and must not be implemented until they have been approved by Swissmedic. Type II variations include such items as additional indications, substantial changes in active substance or finished product manufacturing processes, or changes in recommended dosage.

Activities

Type II variations increased by 4 percent. A total of 1,712 (1,639) were completed.

Number of completed type II variations

2024 **2025**

Additional indications
76
117

Change in recommended dosage
21
40

All other type II variations
1,542
1,555

Minor variations and other applications

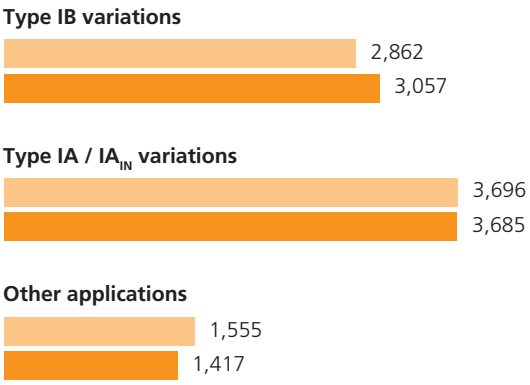
In the case of minor variations, a distinction is made between type IB variations, which have to be notified prior to implementation, and type IA / IA_{IN} variations, which can be reported after the fact. The remaining applications are for authorisation renewals, quality conditions, discontinuation of authorisation or no-marketing/marketing discontinued notifications.

Activities

The number of completed applications in this category was largely unchanged year-on-year at a total of 8,159 (8,113).

Number of completed variations
(Collective applications were counted as one application)

2024 **2025**



Special human medicinal product and transplant product categories

Advanced therapy medicinal products (ATMPs)

In view of the special risks involved and to ensure patients are protected, products for novel therapies (cell therapy, tissue cultures, gene therapy and products such as oligonucleotides or mRNA) are subject to more specific rules than conventional medicinal products. Under the Transplantation Act, they are equivalent to medicinal products and therefore also subject to the Therapeutic Products Act.

Activities

Three ATMPs with new active substances were authorised during 2025, the same number as in 2024. These were: two antisense oligonucleotides and one vaccine (respiratory syncytial virus, RSV). One in-vivo gene therapy application was withdrawn. 170 variations, including two indication extensions, were completed.

Orphan drugs

Swissmedic recognises orphan drug status – i.e. status as a treatment for a rare disease – if applicants either prove that the medicinal product in question can be used to diagnose, prevent or treat a rare, life-threatening or chronically debilitating disease that affects at most five out of 10,000 people in Switzerland, or that it has been granted this status in a country with comparable medicinal product control (particularly the EMA or FDA).

Activities

Orphan drug status was recognised in 41 (32) cases. 27 (29) innovative new applications were authorised as orphan drugs.

Biosimilars

Biosimilars are biological medicinal products that are sufficiently similar to reference products that have already been authorised by Swissmedic and which refer to the originator product's documentation.

Activities
24 (five) authorisation applications for biosimilars were completed and approved.

Paediatric medicinal products

Applicants must submit their Paediatric Investigation Plan (PIP) for all medicinal products with new active substances and for additional indications of these products to Swissmedic and develop their medicinal products for use in children in line with these plans.

Activities
20 (28) applications for verification of complete fulfilment of PIP conditions were completed and approved in 2025. In addition, 17 (20) paediatric trials were authorised.

Vaccines

Vaccines are administered to healthy people as a preventive measure. The requirements associated with protecting the public are particularly stringent. Interdisciplinary dialogue within Swissmedic and internationally guarantees a broad-based assessment of the efficacy and safety of these products.

Activities
Two (five) new vaccines were approved in 2025.

Manufacturing processes for non-standardisable medicinal products

Swissmedic also authorises manufacturing processes for products whose origins and biological variability mean they cannot be standardised in the same way as normal medicinal products. Accordingly, such products are always subject to the authorisation requirement under Article 9 paragraph 1 of the Therapeutic Products Act.

Activities
Eight manufacturing processes for non-standardisable medicinal products (eye serum preparations) were being processed in 2025. One variation of a pathogen inactivation process was also completed.

Complementary and herbal medicines

Swissmedic ensures that the main authorisation requirements for complementary and herbal medicines (CHMs) are respected. CHMs can be authorised by the simplified procedure. Quality, safety and tolerability must be guaranteed in each case.

Complementary medicinal products

Complementary medicinal products comprise homeopathic, anthroposophic and Asian (Ayurvedic, Chinese or Tibetan) medicinal products. In addition to medicinal products with a stated indication, a substantial number of products with no indication are authorised for individual therapy. This generally takes place under a notification procedure, under which there is no legal obligation to provide proof of efficacy.

Activities
Four (16) applications for the new authorisation of complementary medicinal products with indication were completed in 2025.

As in 2024, there was a significant rise in completed new authorisations of single products without indication (homeopathic and anthroposophic medicines, and Chinese medicinal products).

Completed new applications for complementary medicinal products

2024 2025

Medicinal product with indication under simplified procedure

16

4

Simplified authorisation with reduced dossier

1

6

Single products without indication under notification procedure

414

867

Combined products without indication under notification procedure

65

71

Herbal medicinal products

Herbal medicinal products are medicinal products with specified indications, containing only herbal active substances or preparations and which are not classified as complementary medicines. Under the simplified authorisation procedure, proof of efficacy and safety can be provided in the form of bibliographic evidence. Simplification does not extend to quality documentation.

Activities

Four (four) applications for new authorisation were completed under the simplified authorisation procedure in 2025, including two (one) co-marketing medicinal products.

Veterinary medicinal products

New authorisations

New authorisation of veterinary medicinal products is granted in line with the legal requirements following a comprehensive review of the safety, efficacy and quality documentation submitted by the applicant. The authorisation procedure distinguishes between innovative (new active substances) and non-innovative medicinal products (known active substances).

In addition, medicinal products for use in livestock are assessed for their effect on the safety of foodstuffs, and the authorisation procedure specifies the medicinal product residue levels that can be tolerated in foodstuffs such as meat, milk, eggs or honey.

Activities

24 (21) applications for new authorisations were completed in 2025, four of which involved immunological veterinary medicinal products.

Number of applications completed

2024 2025

Innovative veterinary medicinal products

7

11

Non-innovative veterinary medicinal products

14

13

Seven (three) of the 11 innovative new authorisations involved veterinary medicinal products with new active substances. The median turnaround time (Swissmedic's time and companies' time) for veterinary medicinal products with new active substances was 453 calendar days. Of the 24 new authorisations, ten were authorised under Article 13 of the Therapeutic Products Act.

Variations

Activities

A total of 558 (570) applications for variations were processed and completed.

Number of applications completed

2024 **2025**

Additional indications

7
8

All other type II variations / assessed as "major"

156
90

Type IB variations / assessed as "minor"

200
197

Variations without assessment

207
263

Appeals procedure

Applicants have a period of 30 days in which to lodge appeals against administrative decisions issued by Swissmedic with the Federal Administrative Court (FAC). FAC verdicts can be contested before the Federal Supreme Court (FSC).

Activities

One (two) official decision connected with authorisation procedures was contested before the Federal Administrative Court in 2025. Three (four) cases are currently still pending before the Court. Two (zero) appeals were dismissed in 2025.As in 2024, no cases are still pending before the Federal Supreme Court.

Medicinal products: facts and figures

Number of authorisations by type of product

Number of authorisations	2025	2024
Human medicinal products	**5,773**	**5,744**
Synthetics	4,767	4,765
Biotechnologicals	505	457
Vaccines	62	65
Blood products	65	67
Radiopharmaceuticals	56	56
Allergen products	253	269
Bacterial and yeast products	23	23
Antidotes / antivenins	42	42
Transplant products	**31**	**20**
Complementary and herbal medicines	**13,141**	**12,313**
Phytopharmaceuticals	365	377
Homeopathics	590	587
Anthroposophics	322	325
Ayurvedic medicinal products	1	1
Tibetan medicinal products	4	5
Other alternative treatments	5	5
Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication	11,854	11,013
Chinese medicines with no indication	0	0
Lozenges	**27**	**31**
Veterinary medicinal products	**754**	**749**

Number of authorisations by dispensing category

Number of authorisations	2025	2024
A Single dispensing on medical/veterinary prescription	1,642	1,623
B Dispensed on medical/veterinary prescription	4,207	4,173
D Dispensed after expert advice	1,884	1,892
E Dispensed without expert advice	138	155

One (previous year: one) medicinal product is still assigned to dispensing category C (in pharmacies without a medical prescription) because the reassignment process could not be completed.

Licensing product

Overview

Number of authorisations	2025	2024
Establishment licences	1,093	1,111
Licences for handling controlled substances	407	419
Licences for the cultivation of cannabis for medical purposes	35	29
Import / export permits for controlled substances	5,307	5,368
Licences for new clinical trials of medicinal products	162	144
Licences for new clinical trials of ATMPs	13	15
Import licences for vaccines and blood products	1,314	1,242
Batch assessment and plasma pool tests	5,281	5,609

Number of inspections	2025	2024
GLP (Good Laboratory Practice) inspections	7	13
GCP (Good Clinical Practice) inspections	83	66
GVP (Good Vigilance Practice) inspections	16	17
GMP/GDP (Good Manufacturing/Distribution Practice) inspections	88	95
Microbiological laboratory inspections	34	30
Inspections for third parties	20	21
Autologous cell and tissue inspections	8	6

Deadline compliance	Result	Target
Establishment licences	100 %	97 %
Licences for handling controlled substances	99.5 %	95 %
Import / export permits for controlled substances	100 %	95 %
Licences for new clinical trials of medicinal products	99 %	95 %
Licences for new clinical trials of ATMPs	100 %	95 %
Import licences for vaccines and blood products	100 %	95 %

Establishment licences

Companies that manufacture or distribute medicinal products or ATMPs in Switzerland (wholesale, import, export and trade abroad) or which act as brokers or agents for medicinal products require an establishment licence. Furthermore, laboratories that conduct microbiological testing for the identification of communicable diseases (patient diagnosis, screening and environmental analytics) are required by the Federal Act on Combating Communicable Human Diseases (Epidemics Act) to obtain an establishment licence from Swissmedic

Establishment licences for medicinal products and ATMPs

Activities

705 (previous year: 706) establishment licences were issued, extended, modified or revoked during 2025.

Establishment licences for microbiological laboratories

Activities

Swissmedic processed 72 (60) applications from microbiological laboratories for new establishment licences or changes to or renewal of existing licences.

Licences under Article 4 NarcA

Companies and individuals that handle controlled substances or cultivate cannabis for medical purposes must obtain an establishment licence from Swissmedic. A licence issued on a case-by-case basis is required to import and export controlled substances. Licence holders must keep accounts of all transactions involving controlled substances and also accounts of cultivation activities. These records must be used to prepare annual statements, which are then submitted to Swissmedic. The Agency examines these annual statements and forwards a consolidated report to the International Narcotics Control Board (INCB) at UNO in Vienna in accordance with international agreements.

Activities

Swissmedic processed 230 (210) applications for new establishment licences or changes to or renewal of existing licences and examined the annual statements of 522 company sites for the report to the INCB.

Licences for clinical trials

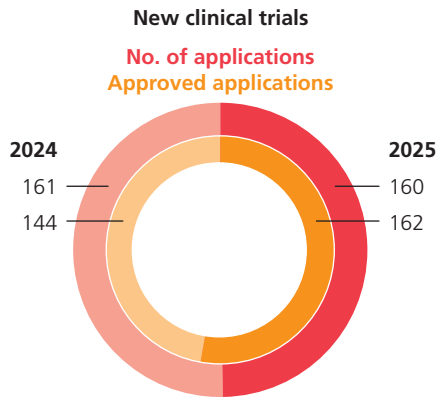
Clinical trials with medicinal products

Clinical trials are used to systematically gather information on medicinal products when used in humans. Swissmedic verifies whether the quality and safety of the investigational medicinal product are guaranteed. Clinical trials may only be carried out in Switzerland if they have been approved by a cantonal ethics committee and by Swissmedic.

Activities

Swissmedic received 161 (160) applications for new clinical trials of medicinal products during 2025. Nine (nine) involved first-in-human trials. A total of 162 (144) clinical trials were approved, 11 (six) of which involved a medicinal product and medical device in combination. Since the launch of the pilot project for fast-track assessment of first-time applications on 1 July 2025, 12 relevant applications have been submitted to Swissmedic. Ten applications met the criteria for fast-track assessment. Of these, seven were assessed within the shortened deadlines by the end of the financial year. Three applications were not yet completed.

In addition, Swissmedic processed 2,635 (2,594) other applications (variations to ongoing clinical trials) or notifications (end-of-trial notifications, Annual Safety Reports and end-of-trial reports) as well as 124 (124) reports of suspected unexpected serious adverse reactions (SUSARs).



Clinical trials with ATMPs, medicinal products for gene therapy and genetically modified organisms

Documents submitted in connection with clinical trials involving innovative novel products are subject to special requirements. The products require innovative trial designs that take account of their specific properties. Furthermore, their complexity and diversity entail a large number of risks that could impair their safety and efficacy and therefore have to be considered when dossiers are prepared.

Activities

Swissmedic approved 13 (15) applications for new clinical trials. These focused primarily on innovative investigational medicinal products for the treatment of cancer or genetic diseases and were complex in design.

In addition, 129 (151) amendments to ongoing clinical trials were approved.

Import licences for vaccines and blood products

Activities

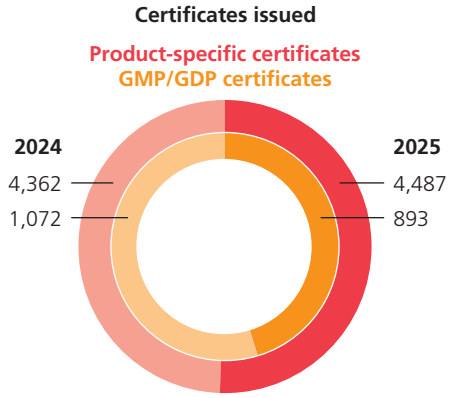
Swissmedic issued 1,314 (1,242) individual import licences for immunological medicinal products, blood and blood products.

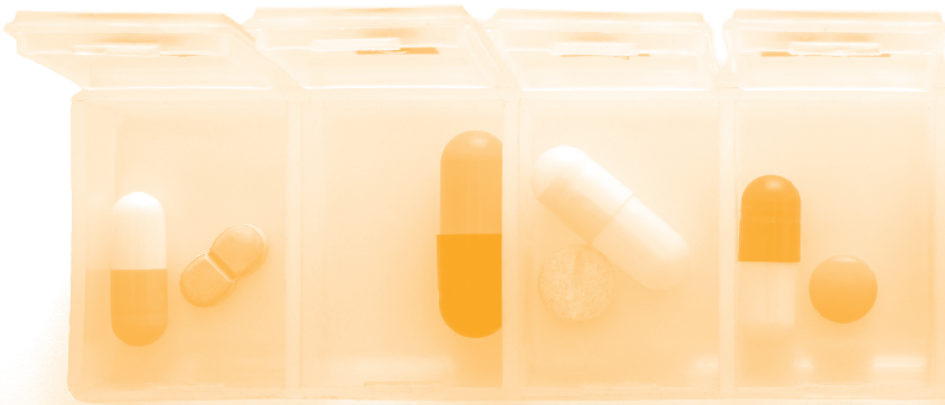
Certificates for medicinal products and ATMPs

Companies with establishment licences may request copies of their licences (certificates) in English. These give foreign customers or authorities confirmation in an internationally standardised format that a valid licence exists. Companies that export medicinal products or ATMPs can apply for confirmation of the current authorisation status in Switzerland in French, English or Spanish.

Activities

Swissmedic issued significantly fewer hard copy certificates in 2025. The European Medicines Agency's EudraGMDP database and, since September 2024, its Swiss counterpart SwissGMDP give market players and authorities a rapid, uncomplicated way to check establishment licence data, including sites, authorised activities, and GMP and GDP status.





Batch assessment and plasma pool tests

Swissmedic's accredited Official Medicines Control Laboratory (OMCL) is responsible for the official batch release of stable blood products, vaccines and other immunological veterinary medicinal products. Batches distributed in Switzerland are released by means of laboratory tests (Official Control Authority Batch Release, OCABR) and/or document review (Official Batch Protocol Review, OBPR) or notification (including presentation of the certificate issued by an OMCL in the EU).

Activities

The number of batch inspections increased again year-on-year. More stable blood products were produced in Switzerland, meaning that the number of batches tested by the OMCL rose accordingly. There was a slight decrease in plasma pool tests and certificate issuing for vaccines.

Blood product batch release

2024 2025

Batch assessments (CH, EU)

882
947

Notifications

369
329

Plasma pool tests

3,112
2,852

Other certificates

613
566

Vaccine batch release

2024 2025

Batch assessments (CH, EU)

91
73

Notifications

168
137

Product analyses as WHO reference laboratory

6
3

Batch release, immunological veterinary medicinal products

2024 2025

Batch assessments

131
126

Notifications

237
248

Laboratory analyses and test method development

The OMCL supports all areas of Swissmedic by carrying out laboratory tests and developing and verifying test methods.

Activities

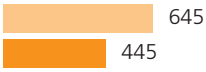
In 2025, the OMCL once again conducted extensive testing of ready-to-use medicinal products. The focus was again on nitrosamines, particularly nitrosamine drug substance-related impurities (NDSRI). Furthermore, the OMCL devoted a lot of time to analysing a large number of illegally imported products.

Laboratory analyses

2024 **2025**

Medicinal products analysed as part of authorisation

Medicinal products analysed as part of market monitoring



Other (pharmacopoeia, ring trials, development, validation, storage)

Inspections

Swissmedic and the four regional inspectorates carry out a variety of inspections, making a significant contribution to ensuring that only perfect-quality and safe medicinal products and ATMPs are manufactured and placed on the market. The inspectors assess compliance with statutory provisions and in particular compliance with the international Good Practice rules that apply to development, the conduct of clinical trials, manufacturing and distribution.

GLP inspections

With the exception of pharmacodynamic testing, non-clinical trials have to be conducted in accordance with Good Laboratory Practice (GLP). Swissmedic carries out monitoring activities (inspections or trial audits) with partners at the Federal Office for the Environment and the Federal Office of Public Health within the framework of the GLP monitoring programme.

Activities

The GLP units for Switzerland were audited by inspector teams from Brazil and Czechia as part of the On-Site Evaluation programme (OSE) of the Organisation for Economic Cooperation and Development (OECD). The evaluation report was discussed and accepted at a meeting of the OECD GLP Working Group in April 2025. The Swiss GLP programme meets all OECD requirements. The next OSE by an OECD team will be performed in around ten years' time.

GLP compliance was inspected at seven (13) assessment facilities in 2025. Swissmedic led six (six) of these. One of the assessment facilities was inspected for the first time.

The authorities responsible for GLP monitoring met once a quarter to share information and provided information on GLP topics to the assessment facilities through a newsletter and at the annual meeting of SPAQA (Swiss Professional Association of Quality Assurance).

GCP and GVP inspections

Swissmedic inspects clinical trials carried out in Switzerland by sponsors in Switzerland or abroad, contract research organisations, other research organisations and trial centres. The inspections assess compliance with the rules of Good Clinical Practice (GCP). They also include the safety and personal rights of trial participants and compliance with scientific quality and integrity criteria. Good Vigilance Practice (GVP) inspections verify compliance with the legally prescribed duty to report adverse drug reactions and the implementation of measures associated with urgent drug risks.

Activities

During 2025, Swissmedic inspected 82 (66) clinical trials involving medicinal products and ATMPs. In addition, it conducted 16 (17) GVP inspections.

GCP and GVP inspections of companies were carried out both via video conferences and on site. Swissmedic also systematically performed desk-based inspections. During these inspections, documentation from the companies was inspected for legal compliance.

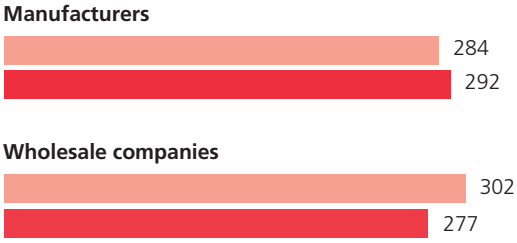
GMP and GDP inspections

Swissmedic and four regional cantonal inspectorates carry out inspections as a prerequisite for issuing or maintaining a pharmaceutical establishment licence. They verify compliance with the quality standards of Good Manufacturing Practice (GMP) on the part of manufacturers of pharmaceutical products or those of Good Distribution Practice (GDP) on the part of wholesale companies.

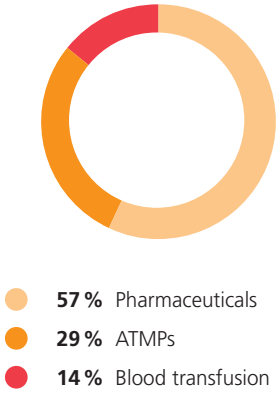
Activities

Swissmedic and the regional inspectorates carried out a total of 569 (586) GMP/GDP inspections of manufacturers and wholesale companies. Reports of major changes to installations, facilities and procedures that impacted GMP/GDP rose slightly to 260 (254). There was also continued significant interest in GMP/GDP-related Scientific Meetings.

GMP/GDP inspections
(Swissmedic and regional inspectorates)



Distribution of GMP/GDP inspections conducted by Swissmedic



Inspections abroad

Swissmedic may inspect manufacturers of medicinal products and ATMPs located abroad at the expense of the importer. Inspections may also be performed at the expense of the sponsor if this is necessary for the review of a clinical trial carried out in Switzerland.

Activities

Swissmedic continued to expand its own foreign inspection programme during 2025.

It performed a GCP inspection in Greece for the first time together with the Greek authorities. In addition, five inspection campaigns – three of which with the European Directorate for the Quality of Medicines and HealthCare (EDQM) – were carried out to verify GMP-compliant manufacturing of a total of 14 active substances at nine difference production sites in India and China. The 14 active substances are used to manufacture 33 preparations authorised in Switzerland.

In accordance with its strategy, the GCP inspectorate participated in a bioequivalence inspection by the MHRA as an observer in 2025. The aim was to determine what steps need to be taken to carry out similar inspections in the future.

Inspections by foreign authorities in Switzerland

Swissmedic and the regional inspectorates operated by the Cantons will, if required, accompany inspections of companies in Switzerland by foreign authorities. For the purposes of these inspections, the Swiss inspectors assume the role of representatives of the relevant Swiss authority.

Activities

The number of inspections of pharmaceutical companies in Switzerland conducted by foreign authorities declined sharply in 2025. 25 (51) inspections of manufacturing facilities were performed, eight of which by the USA, five by Russia, five by Turkey, three by Brazil, two by Mexico and one each by Kazakhstan and Belarus.

The GMP agreement with the USA, which took effect in 2023, brought about a further reduction in inspections by the US Food and Drug Administration (FDA), thus relieving the burden on pharmaceutical companies in Switzerland. The FDA inspections conducted in 2025 were pre-approval inspections.

By contrast, foreign authorities turned increasingly to reliance mechanisms such as sharing inspection reports. A total of 33 GMP inspection reports were requested from Swissmedic, 31 by FDA and two by European authorities.

In addition, foreign authorities performed inspections of Swiss institutions in connection with clinical trials (GCP).

Inspections of microbiological laboratories

Microbiological laboratories must satisfy the requirements defined in the Ordinance on Microbiology Laboratories and comply with Good Laboratory Practice guidelines. Swissmedic monitors compliance with legal provisions and periodically carries out inspections.

Activities

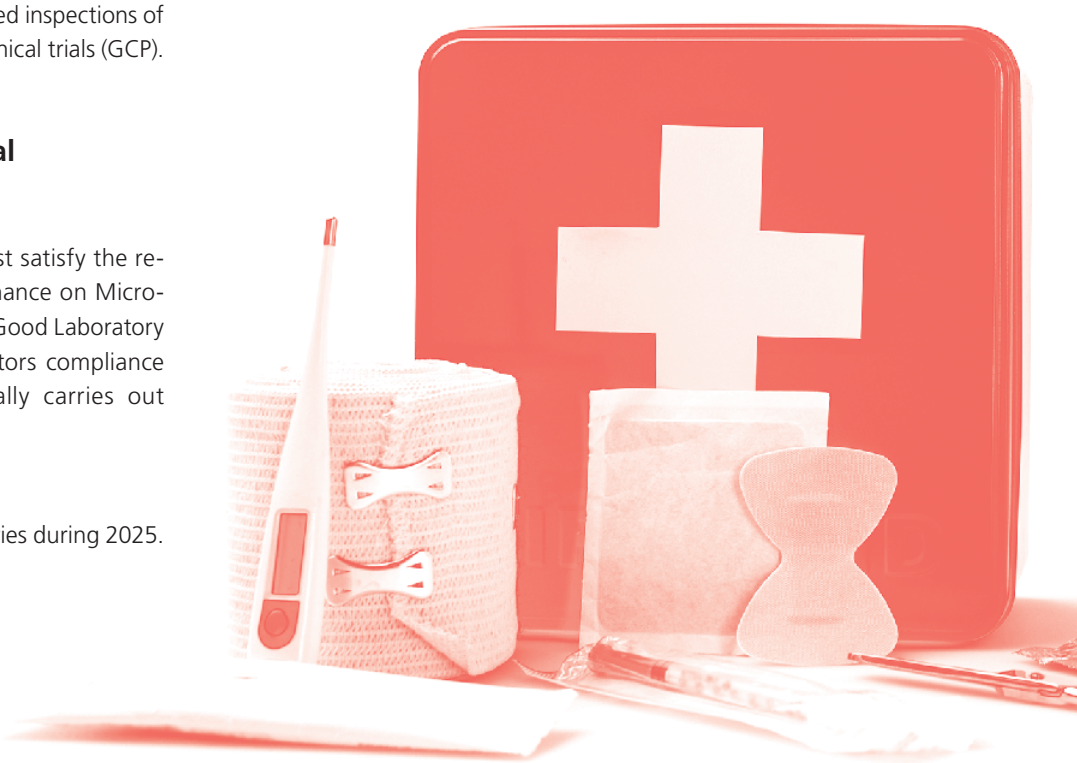
Swissmedic inspected 34 (30) laboratories during 2025.

Inspections for third parties

Swissmedic can provide services for third parties subject to payment of a fee. On behalf of the Federal Office of Public Health (FOPH), Swissmedic carries out inspections and other enforcement tasks related to transplants and genetic tests on humans. Swissmedic also performs certain therapeutic products inspection activities for the Principality of Liechtenstein.

Activities

20 (21) inspections were carried out for the FOPH in 2025.



Other monitoring activities

Monitoring of the blood transfusion service and haemovigilance

Swissmedic monitors blood transfusion activities in Switzerland by means of inspections, licences, market monitoring and standardisation. The blood obtained from donors and the labile blood products manufactured from it are considered to be medicinal products under the terms of the Therapeutic Products Act. A Swissmedic licence is mandatory for the collection of blood and the manufacturing and distribution of labile blood products.

Haemovigilance is the monitoring system employed for blood and labile blood products. It covers the entire transfusion chain from donation through processing and transport to administration to patients. The purpose is to minimise transfusion risks and dangers associated with donated blood and the transfusion of blood and blood products.

Activities

The reporting system was further optimised in 2025, and the reports received on adverse events associated with the collection, manufacture or administration of blood transfusions were assessed on an ongoing basis. Swissmedic published its assessment in the Haemovigilance Annual Report 2025. Dialogue with those under a reporting obligation was maintained and stepped up in 2025, including through holding a course on the basics of haemovigilance, haemovigilance experts accompanying inspections and contributions at external events. In collaboration with national stakeholders and with the involvement of the Federal Office for Public Health, efforts to relieve supply bottlenecks for blood group O, Rhesus-negative erythrocyte concentrates were continued.

In the monitoring of blood transfusion activities, Swissmedic accepted a request by Swiss Transfusion SRC to modify the donor criteria from the start of 2026 with regard to prion diseases, particularly Creutzfeldt-Jakob disease. The first assessment report on the effects of changing the blood donation criteria for MSM (men who have sex with men) has been reviewed and showed no negative development of risks. Both the existing and the newly approved donation criteria are in line with the amendment to the Therapeutic Products Act regarding blood donation that entered into force at the start of 2025. This stipulates, among other things, a ban on payments and non-discrimination.

Monitoring of autologous transplantation

Swissmedic monitors the handling of cells and tissue for autologous transplantation. Relevant activities must be reported. Through inspections, the Agency carries out random checks of compliance with legal quality assurance requirements relating to cells and tissues.

Activities

At the end of 2025, Swissmedic had been notified of 37 (33) institutions that work with cells and tissues for autologous transplantation.

Swissmedic carried out eight (six) inspections.

Appeals procedure

Activities

In 2025, four official decisions issued in connection with licences were contested before the Federal Administrative Court. Two cases are currently pending. Two appeals were dismissed in the year under review. No cases are pending before the Federal Supreme Court.

Establishment licences in facts and figures

Manufacture of medicinal products and ATMPs	**2025**	**2024**
Manufacture of ready-to-use medicinal products and ATMPs	414	422
Manufacture of active pharmaceutical ingredients	187	187
Handling of blood or labile blood products (blood transfusion activities)	86	79

Distribution of medicinal products and ATMPs	**2025**	**2024**
Import of medicinal products and ATMPs	740	739
Wholesale trading in medicinal products and ATMPs	967	1,001
Export of medicinal products and ATMPs	561	565
Trading in medicinal products abroad and ATMPs abroad	410	412
Brokerage or agency activities for medicinal products and ATMPs	20	20

Microbiological laboratories	**2025**	**2024**
Licensed microbiological laboratories under EpidA (patient diagnostics, screening and environmental analysis)	120	121

MEDICINAL PRODUCTS – **MARKET SURVEILLANCE PRODUCT GROUP**

Overview

Number of reports	2025	2024
Adverse reactions, human medicinal products	15,023	13,461
Adverse reactions, veterinary medicinal products	722	658
Quality defects	1,140	992
Illegal imports of medicinal products	6,647	5,668

Monitoring activities	2025	2024
Case opening / signal evaluation, human medicinal products	371	438
Case closure / signal evaluation, human medicinal products	415	441
Risk minimisation measures (updating medicinal product information for human medicinal products)	401	503
Assessment of risk management plans, human medicinal products (including RMP updates)	361	271
Assessment of safety reports, human medicinal products	345	359
Case opening / signal evaluation, veterinary medicinal products	30	14
Assessment of safety reports, veterinary medicinal products	19	20
Batch recalls	39	28
Administrative proceedings connected with illegal imports of medicinal products	6,053	5,056

Vigilance product

Human medicinal products vigilance

Pharmacovigilance

Swissmedic evaluates safety signals associated with medicinal products and vaccines based on, among other things, individual case reports of suspected adverse drug reactions (ADRs) from within Switzerland. If its investigations confirm a new risk, Swissmedic initiates the necessary actions (for example amending the medicinal product information), often after first consulting its international partner authorities. As part of the pharmacovigilance network, all reports from healthcare professionals and patients are entered in the national database and evaluated. Some are also assessed on Swissmedic's behalf at five regional pharmacovigilance centres. Pharmaceutical companies also submit a large number of reports of ADRs from within Switzerland to Swissmedic.

Activities

The number of individual case reports received by Swissmedic increased year-on-year and is at the pre-COVID-19 vaccination campaign level. The number of reports concerning these vaccines again declined significantly.

Pharmacovigilance

2024 **2025**

ADR reports incl. follow-up reports

13,461

15,023

Number of ADR reports involving COVID-19 vaccines

353

131

A technically upgraded individual case report processing database went into service in 2024 to ensure continuing full compliance with increased international requirements (e.g. for data exchange). In the course of 2025, the electronic exchange of reports with numerous pharmaceutical companies was switched to the latest available data format.

Swissmedic has a video for healthcare professionals on its website explaining ADR reporting and answering frequently asked questions.

Reporting adverse reactions

Signals and safety reports

Assessment of risk management plans and safety reports

As part of the procedure for authorising new medicinal products, companies must submit a risk management plan (RMP) in accordance with international guidelines. In the RMP, the authorisation holder must comment on both the known and the potential risks associated with the medicinal product and demonstrate how it intends to prevent them, follow them up and address any gaps in its data. It is obliged to keep the RMP up-to-date and to submit updates for assessment throughout the life cycle of the medicinal product. Swissmedic also assesses Periodic Safety Update Reports (PSURs), as well as evaluating international drug safety data and identifying and evaluating safety signals from national and international sources.

By assessing RMPs, PSURs and signals, Swissmedic evaluates the need for risk mitigation measures.

Activities

In the year under review, Swissmedic assessed a total of 361 (previous year: 271) RMPs and 345 (359) PSURs on human medicinal products.

Risk management plans and safety reports, human medicinal products

2024 **2025**

Number of RMPs, incl. RMP updates

Number of PSURs

Risk mitigation measures

Marketing authorisation holders are obliged to apply for a change to the product information of a medicinal product if new findings concerning its safety come to light. Swissmedic also initiates action ex officio when it becomes aware of new risks. It gives instructions for circular letters on important safety issues (Direct Healthcare Professional Communication, DHPCs) to be sent to professionals. DHPCs and Healthcare Professional Communications (HPCs) – information on medicinal product risks issued by Swissmedic – are also published on the Swissmedic website, in the Swiss medical journal Schweizerische Ärztezeitung and in pharmaJournal.

Activities

The number of signal evaluations completed by Swissmedic increased again in 2025. Swissmedic regularly discussed safety signals with authorities in other countries and in multinational specialist organisations. Risk minimisation measures were implemented promptly. 415 (441) signal procedures were completed. On the basis of the results of these, Swissmedic ordered risk minimising modifications to the medicinal product information of 401 (503) medicinal products.

DHPCs and HPCs were used to inform professional and public audiences about ten (11) safety-relevant issues.

Monitoring activities

2024 **2025**

Number of completed signal procedures

Number of risk minimisation measures
(modified medicinal product information)

Introduction of Safety Update – Updates to Information for healthcare professionals

Since November 2025, people who have subscribed to the Safety of Medicines newsletter receive a monthly overview of safety-relevant updates to the Information for healthcare professionals (findings of signal and PSUR evaluations). As a result, healthcare professionals gain timely access to current safety-related findings.

Introduction of mandatory identification of safety-relevant information

From 1 July 2025, Swissmedic introduced mandatory identification of DHPCs with the "red safety information" symbol.

Important safety information
in consultation with swissmedic

Communications that are not issued by authorities may not show this symbol. The introduction of identification contributes significantly to the target readership recognising DHPCs as important, officially ordered safety-relevant information, thereby further improving medicinal product and patient safety.

Mandatory identification of officially ordered information material with the "blue safety information" symbol was also introduced with effect from the same date.

Officially mandated information material

This symbol may only be used to identify officially ordered information material. In addition to the medicinal product information, this type of information material may be necessary to inform healthcare professionals and patients on the safe use of the medicinal product. The provision of such additional information materials is ordered by Swissmedic.

The blue symbol helps to ensure that the target readership will be reached more reliably in the future. The identification should also help to distinguish clearly between officially ordered information and promotional materials from pharmaceutical companies.

Vigilance for veterinary medicinal products

Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich to collect and assess reports of adverse reactions (ADRs) to veterinary medicinal products.

Activities

The total of 722 reports of ADRs submitted in 2025 primarily involved dogs (424) and cats (160), followed by cattle/calves (65) and horses (25). 12 reports of users experiencing reactions were also submitted.

Tox Info Suisse reported 156 (133) cases of humans being exposed to veterinary medicinal products. Mix-ups, consumption by children and accidental contact with the veterinary medicinal product in question each account for about one third of these reports.

Vigilance for veterinary medicinal products

2024 2025

Number of ADR reports

Signals opened

Number of PSURs

Market monitoring of medicinal products product

Quality defects and batch recalls

Swissmedic records reports on quality defects in authorised medicinal products and preparations undergoing clinical testing and issues instructions for the necessary corrective action. When reports of quality defects are received from abroad, Swissmedic verifies whether the reports also affect products in Switzerland. While incoming reports are being processed, annual monitoring focal points are defined and targeted laboratory testing and inspection activities are set in motion. Where defects in medicinal products constitute a potentially major health risk, batch recalls are initiated or information is sent to professionals and the public.

Activities

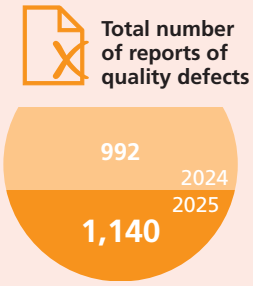
The number of quality defects rose again in 2025, reaching the new record level of 1,140.

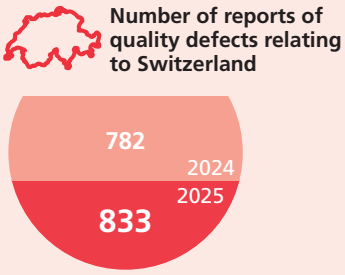
39 batch recalls were conducted in the year under review, 32 of which concerned human medicinal products and seven veterinary medicinal products. Eight recalls extended to patient or end-consumer level. In 16 cases, the preparations were for oral administration, while 14 were for injection or infusion. Particles such as plastic or splinters of glass (nine cases) and stability problems (six cases) are constantly recurring causes of recalls. Four batch recalls were carried out as a result of serious violations of GMP guidelines identified at foreign manufacturers (inspections by other health authorities).

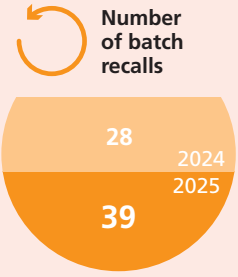
In addition, 17 Direct Healthcare Professional Communications (DHPC) were initiated due to quality problems.

Batch recalls human medicines

Batch recalls veterinary medicines







Out-of-stock products

If an essential medicinal product that is authorised in Switzerland is temporarily unavailable owing to delivery bottlenecks (stock-out situation), the marketing authorisation holder can apply to Swissmedic for approval to place the foreign version of the identical product on the Swiss market temporarily. On receipt of applications, a routine needs assessment is conducted in collaboration with the Federal Office for National Economic Supply to prevent market distortion.

Activities

The total number of applications to temporarily distribute a foreign version of a medicinal product rose slightly compared to 2024. A total of 33 applications were fully processed and approved. Four applications were withdrawn during processing and three were rejected by Swissmedic.

The distribution licences issued were for products including cytostatics (in eight cases), mixed solutions (electrolytes and/or carbohydrates; in four cases), antiepileptics and antibiotics. The licences are published on the Swissmedic website.

Approved applications, human medicinal products

Approved applications, veterinary medicinal products

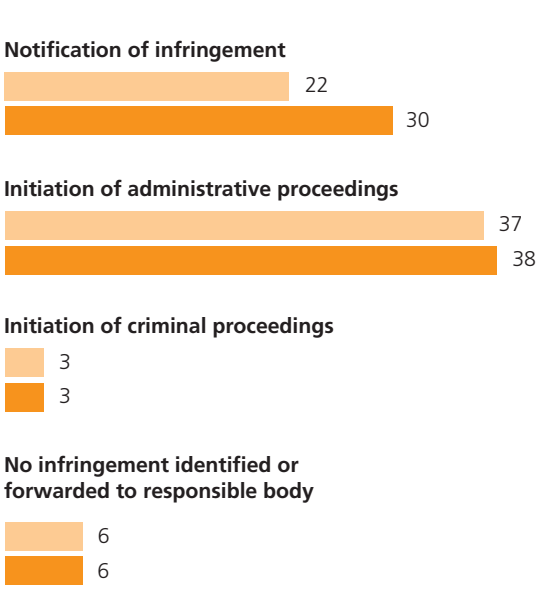
Control of advertising

Swissmedic controls and monitors the advertising of medicinal products and is responsible for the risk-based processing of infringements of advertising rules involving authorised medicinal products that are reported to it or which it identifies by screening advertising destined for the public. This includes checking printed, TV and other electronic advertising destined for the public with the specific aim of identifying and banning misleading advertising that could induce people to take excessive quantities of medicinal products or lead them to believe that medicinal products are safer than they are. Swissmedic responds to infringements that jeopardise patient safety by initiating procedures to enforce corrective actions. Publications, information sheets and presentations are used to inform stakeholders of the current requirements governing medicinal product advertising.

Activities

A total of 77 (68) cases were dealt with as part of post-publication advertising inspection activities in 2025. Depending on the severity of the case, Swissmedic either made authorisation holders aware that they had infringed medicinal product advertising rules or opened administrative proceedings to restore legal compliance. In some cases, Swissmedic initiated criminal proceedings.

Post-publication advertising inspection activities



Swissmedic processed three applications for an advertising permit (pre-publication advertising inspection activities) for a medicinal product that may be dependence-forming or susceptible to abuse during 2025.

Measures against illegal medicinal products

As Switzerland's national single point of contact for Medicrime, Swissmedic works with other authorities and shares information to minimise the risks posed by illegal medicinal products. In the course of this work, Swissmedic nurtures a good national and international network and sensitises the public to the risks to which they are exposing themselves if they use illegal medicinal products. The single point of contact receives reports of falsified medicinal products, illegal distribution and other illegal activities, examines them and initiates corrective action where necessary or forwards them to another responsible body. In close collaboration with the Federal Office for Customs and Border Security (FOCBS), Swissmedic checked medicine imports and ordered the destruction of illegal consignments.

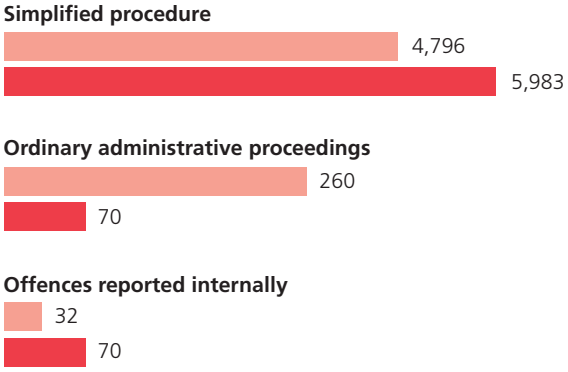
Activities concerning illegal imports

The Medicrime single point of contact received 1,391 lists with suspicious medicinal product consignments from the FOCBS and decided on whether to impound them. 6,398 illegal imports of medicinal products were impounded, of which 93.5 percent or 5,983 consignments were dealt with under the simplified procedure and destroyed. Erectile stimulants, hair loss products, sedatives and antiparasitics in particular were seized to protect the health of the people who ordered them. Furthermore, Swissmedic undertook 70 ordinary administrative proceedings for which a fee is charged and filed internal criminal proceedings with Swissmedic's Penal Division in 70 import cases on the grounds of repeated importation or the large quantities involved. In one case, the single point of contact collated 22 medicinal product imports to the same private individual in a single criminal charge.

Regarding imports of medicinal products with unclear composition or those containing narcotics, which are punishable at cantonal level, the Medicrime single point of contact acted as a triage centre in almost 200 cases.

Measures connected with illegal imports

2024 2025



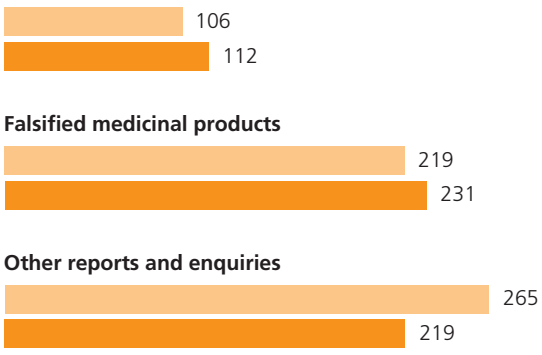
In a focus campaign together with the FOCBS, Swiss Sport Integrity (SSI) and representatives of the Principality of Liechtenstein, 2,117 consignments were checked, of which 27 percent were confiscated. This campaign found that suspicious consignments are increasingly coming from the EU (40 percent); of these, more than 500 consignments had to be released although they came from illegal sources. Half of all consignments from the EU were shipments containing Indian erectile dysfunction products sent from criminal intermediaries in the EU. These intermediaries often divided up the quantities of erectile dysfunction products ordered. During the campaign, more than 200 such partial shipments in small quantities that would have been freely imported during normal routine processes were detected, collated and seized.

Activities concerning suspicion reports

The single point of contact received 562 reports of potential illegal activities concerning medicinal products. The number of reports therefore remained at a similarly high level to the previous year. The reports fell into the following main categories:

Number of suspicion reports

2024 2025



The Medicrime national single point of contract triages suspected cases and thereby also tracks trends, resulting in focused measures. What particularly stood out in the range of illegal offers of medicinal products was that many unwitting Swiss website operators had been the victims of hackers and that e.g. erectile stimulants were for sale on subpages. Swissmedic informed domain owners in 64 cases so that they could restore their hacked website to a state of legal compliance themselves.

Medicrime meeting 2025 – Working together to combat therapeutic product trafficking

As the national point of contact, Swissmedic again planned and held the Medicrime meeting last year. More than 60 representatives of various federal and cantonal authorities and other organisations with legally enshrined duties came together to step up collaboration on combatting illegal therapeutic products, discuss coordinated and effective measures and thereby improve protection for public health.

The focus was on:

- promoting collaboration between authorities with different legal responsibilities
- sharing proven approaches and findings
- information on medicinal product groups that are currently in demand

Appeals procedure

Activities

During 2025, appeals were submitted to the Federal Administrative Court against four official decisions in connection with the market surveillance of medicinal products. 11 cases are currently still pending before the Court. One case was appealed before the Federal Supreme Court in 2025. Three appeals are currently pending before the Federal Supreme Court.

MEDICINAL PRODUCTS – **PENAL LAW PRODUCT GROUP**

Penal Law product

Criminal prosecution

The Therapeutic Products Act empowers Swissmedic to carry out criminal investigations, impose fines and financial penalties, and enforce measures such as confiscations. The Agency represents the prosecution or exercises the rights of a private claimant in cantonal court proceedings.

Activities

One-third more offences were reported in 2025 than in the previous year. Once again, a large proportion of these involved members of the public illegally importing medicinal products. Many of these cases were dealt with using the abridged procedure or were forwarded to the cantonal public prosecutors for a decision, as they are responsible for illegal imports of medicinal products containing narcotics.

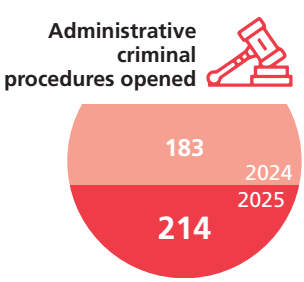
In addition to cases in which medicinal products were illegally imported, the administrative criminal proceedings opened and conducted in 2025 concerned the illegal export, placing on the market and manufacture of medicinal products, contraventions of advertising regulations and unlicensed trading in transplant products.

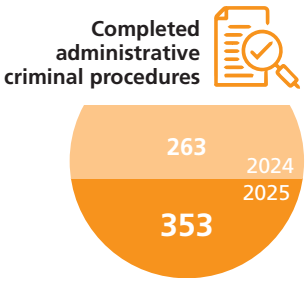
The Swiss Medicrime meeting took place again in 2025 and was attended by criminal prosecution and supervisory agencies responsible for therapeutic products at federal and cantonal level.

At international level, the first monitoring report by contracting states to the Medicrime Convention on the topic of the protection of public health through the Medicrime Convention in times of pandemics was approved. Switzerland was given a positive evaluation and its prosecutors specialising in therapeutic products legislation were commended. Swissmedic represented Switzerland at plenary meetings as a Party to the Convention and in the Committee of Parties as a re-elected member of the Medicrime Bureau.

Once again, Swissmedic exercised the rights of a private claimant in several cantonal prosecutions to enable it to contribute its legal expertise. In one case, Swissmedic launched an appeal against a cantonal order for withdrawal of prosecution, which had been wrongly issued under the Therapeutic Products Act rather than the Narcotics Act. The Zurich Cantonal Supreme Court rejected the appeal, and Swissmedic therefore took the case to the Federal Supreme Court. In a leading decision, the Court fully upheld the appeal in criminal matters and defined the criteria by which the distinction should be drawn between application of the Therapeutic Products Act and the Narcotics Act for medicinal products containing narcotics.

There continued to be a growing number of cantonal cases of cosmetics studios illegally injecting medicinal products which had also been unlawfully imported. Swissmedic also exercised the rights of a private claimant in these cases.





Investigative measures

The Federal Act on Administrative Criminal Law gives Swissmedic's investigators-in-charge powers that are comparable to those of a cantonal or federal prosecutor. For example, they can conduct examination hearings, carry out coercive measures such as seizures and house searches, demand the handover of documents and request the arrest of suspects.

Activities

No house searches were conducted in 2025 as it was possible to obtain the evidence required through less stringent investigative measures.

However, there were 13 examination hearings and 52 administrative criminal proceedings were unified with cantonal criminal proceedings; Swissmedic handled four of these cases.

Swissmedic's application to the Federal Criminal Court to have forensic IT data unsealed and secured was approved in one case. The Lower Appeals Chamber of the Federal Criminal Court rejected appeals in this case filed against Swissmedic for coercive measures (officially mandated blocks on accounts, restriction on recording in the Land Register and a house search conducted in 2024).

As in 2024, a number of proceedings were conducted against pharmacists who had circumvented the exemption provisions that apply to their profession to procure and sell cheap medicinal products from neighbouring countries. These were unauthorised and therefore illegal imports.

A number of cases were also brought for unauthorised trading of transplant products. A judicial assessment was requested in one case, and in another, the accused party submitted an appeal of the first-instance judgement to the Cantonal Supreme Court; both cases are still pending.

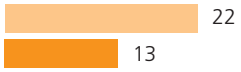
Swissmedic requested international legal assistance from neighbouring European countries in five cases and dealt with six requests itself. Five of these were from nearby countries. An appeal was filed with the Federal Criminal Court against the final ruling on a request for mutual legal assistance in criminal matters from a Central Asian country.

Investigative measures

2024 **2025**

House searches

Examination hearings



Unification with cantonal proceedings

Decisions / verdicts by Swissmedic and the courts

Once the investigation phase has been completed, a penalty decision (penalty order – or if the penalty order is appealed, a penalty ruling) is issued or the case may be abandoned. The penalty ruling and possibly also the penalty order can be appealed before a court of first instance. In these cases, Swissmedic acts for the prosecution.

Activities

94 (previous year: 56) penalty decisions were issued in 2025. 51 decisions, most of which involved illegal imports of medicinal products by the general public, were dealt with under the abridged procedure. In nine cases, criminal proceedings against members of the public for illegally importing medicinal products were abandoned because suspicions could not be sufficiently substantiated (four cases), the limitation period had expired (two cases), the level of culpability and consequences of the offence were negligible (one case), there was a mistake of law (one case) or the culprit was unknown (one case). In a further two cases, Swissmedic asked the cantonal court to replace an unpaid fine issued under an administrative criminal proceeding with a prison sentence.

The public prosecutor's office imposed a summary penalty order in one older case opened by Swissmedic in 2019 and then assigned to the competent canton. This case involved the storage and export of transplants and transplant products without the necessary licences. The accused party was given a suspended custodial sentence and fined for breaching the Transplantation Act. An appeal was filed against the summary penalty order.

One case from 2018, in which the accused had requested a judicial assessment, was also completed in 2025. The accused had purchased medicinal products from a pharmacy abroad through his wholesale company and in the role of Responsible Person for medicinal products, even though the pharmacy did not have the necessary licence. The court supported Swissmedic's position, according to which the accused's clarifications were insufficient, and thereby confirmed the importance of correct supplier validation and the key responsibility entrusted to the Responsible Person. The accused accepted the verdict of the court of first instance, which thereby became final.

MEDICAL DEVICES – **STANDARDS PRODUCT GROUP**

Legal Framework product
Technical Standards product

Legislative work to implement Motion 20.3211 (recognition of non-European regulatory systems)

At its meeting on 30 April 2025, the Federal Council noted the ongoing efforts to implement Motion 20.3211. This aims to open up the possibility for medical devices from non-European regulatory systems, particularly the US FDA, to be placed on the Swiss market. To ensure adequate supplies of medical devices and to guarantee patient safety, the Federal Council defined guidelines and will assign responsibility for controls to private bodies.

A working group has been established to prepare implementation, comprising representatives of the Federal Office of Public Health (FOPH), Swissmedic, the State Secretariat for Economic Affairs (SECO) and the Europe Division of the State Secretariat of the Federal Department of Foreign Affairs (FDHA). The working group has identified differences between the regulatory systems in Switzerland and the US, which need to be taken into account. It proposed to the Federal Council requirements and conditions for the placement on the Swiss market of medical devices authorised by the FDA. In particular, these involve compliance with Swiss legal requirements concerning data protection and the introduction of a quality management system. Definition of a post-marketing surveillance plan and the possibility of requiring clinical evidence are also envisaged. The legislative work will continue in 2026.

swissdamed database

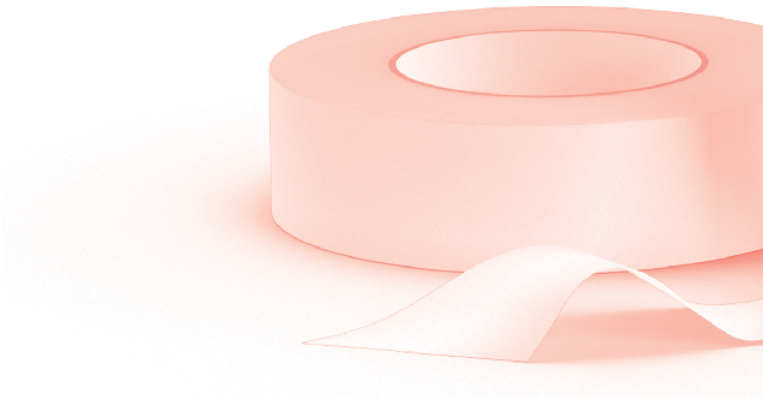
The obligation to register medical devices and in vitro diagnostic medical devices in a central database (swissdamed) that is already enshrined in the ordinances will become mandatory on 1 July 2026 by a Federal Council decision from November 2024.

Swissmedic also updated the information on applicable implementing acts and delegated acts on its website in 2025 to ensure better understanding.

Standards and common specifications

Swissmedic is responsible for registering technical standards and common specifications that are useful for fleshing out the underlying requirements applicable to medical devices. In doing so, wherever possible, the Agency uses internationally harmonised standards and specifications. The list of all newly registered technical standards and common specifications is updated regularly in the Federal Gazette and on the Swissmedic website.

Standards and common specifications



MEDICAL DEVICES – **INFORMATION PRODUCT GROUP**

Informing the General Public product
Informing the Therapeutic Products Sector product

Informing the general public

Swissmedic provides information to the public through various channels (website, social media and its Visible magazine). In February 2025, Swissmedic provided information on the results of inspections of the use of fillers (medical devices for anti-wrinkle injections) carried out together with the cantons and the health risks found.

Press relations

Around 55 (previous year: 125) media enquiries referring specifically to medical devices were received in 2025. Enquiries focused on questions such as how digital health applications are regulated as well as recalls and product risks. Towards the end of the year, there were enquiries in connection with a recall of blood glucose monitors extending to patient level.

Enquiries

Swissmedic answered more than 3,000 enquiries concerning medical devices. The topics of the questions from the general public ranged from plasters and antiseptics to laser hair removal devices to medical devices when travelling. Professionals primarily asked questions on guidance documents, imports, labelling of medical devices, the role of Swiss authorised representatives and the swissdamed medical device database.

Transparency/FoIA

The number of requests for access to official documents (FoIA requests) related to medical devices decreased in 2025.

No appeals are currently pending before the Federal Administrative Court or Federal Supreme Court regarding freedom of information requests. One arbitration procedure is currently pending with the Federal Data Protection and Information Commissioner (FDPIC).

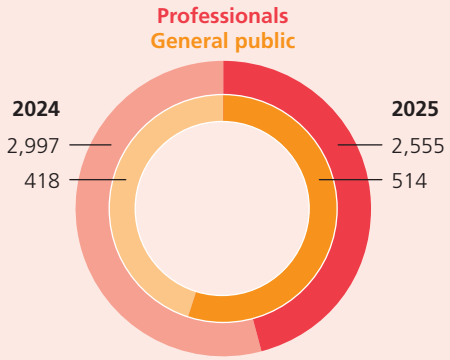
Parliamentary proposals

The topics at political level (parliamentary proposals and other political business items) concerning medical devices varied widely; no recurring pattern was evident.

Information and publications for professionals

Publications on the Swissmedic website, e-mails to contacts in hospitals and the Roundtable on Medical Technology are important resources for providing information to professionals. Furthermore, Swissmedic draws attention to relevant publications through the newsletter that it publishes regularly. Swissmedic is raising awareness among medical device users of the importance of reporting serious incidents (materiovigilance)

Enquiries about medical devices



Requests under FoIA

2024 2025

No. of applications

14
9

Time requirement for processing requests in hours

296
154

Political business items involving medical devices

2024 2025

Parliamentary proposals

13
4

Other political business items in which Swissmedic was involved

28
34

through a new video. In August 2025, the second module of swissdamed, the national database for registering responsible economic operators and medical devices, went live. Swissmedic explained in detail device registration, which is initially voluntary, and provided information on swissdamed and the UDI devices module at the Swiss Medtech National Regulatory Conference in October. Findings from the hospital inspections performed in the previous year were again published in a report, which now also includes causal analysis and specific recommendations for action to improve quality assurance. Swissmedic experts presented information at universities and specialist conferences on the findings of the hospital inspections and the recognised action required. The available guidelines and, in particular, the Good Practice for the Reprocessing of Flexible, Thermolabile Endoscopes published in September 2025 were also presented. These explain the specific requirements in the inspected areas.

Swissmedic updated information sheets and enforcement aids and published answers to FAQs associated with the regulation of medical devices. Information was also provided on combined clinical trials and the EU legislative acts applicable in Switzerland.

In spring 2025, Swissmedic reported on its acceptance as a member of the Management Committee of the International Medical Device Regulators Forum (IMDRF) and its collaboration in numerous working groups to improve international harmonisation of medical device regulation.

As part of its monitoring activities, Swissmedic conducts focus campaigns and inspections. It evaluates the results and publishes them to increase awareness among market players. In 2025, Swissmedic reviewed the documentation from monitoring of medical devices in higher risk classes by the manufacturer. The review found various non-conformities in the majority of cases. Swissmedic required all manufacturers to establish appropriate monitoring processes after placement on the market. These are key for early detection of risks and the introduction of safety measures.

MEDICAL DEVICES – **MARKET ACCESS PRODUCT GROUP**

Licensing product

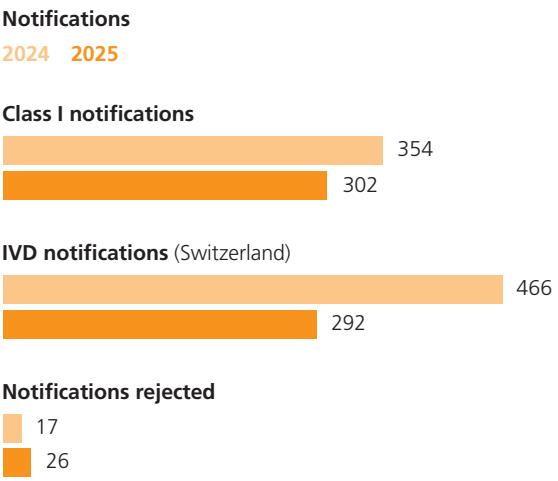
Placing on the market

Manufacturers of medical devices that entail an elevated level of risk must consult an officially accredited notified body. Notification is mandatory for certain classes of medical devices. These notifications are sent to Swissmedic, which carries out random checks (e.g. of classification) as part of market surveillance and issues instructions to make corrections as necessary.

Activities

The number of notifications concerning Class I (e.g. reusable surgical instruments or rolling walkers), custom-made classic or active implantable medical devices and systems and procedure packs fell to 302 (354).

Notifications concerning in vitro diagnostic medical devices (IVDs) also declined to 292 (466).



Three notifications were received for classic and active implantable medical devices produced using or containing devitalised human tissue. In addition, 27 change notifications concerning devitalised human tissue were processed.

Swissmedic initiated administrative proceedings in 26 cases on the grounds of categorisation or classification errors, or returned the notification because it was unclear who was responsible.

Swissmedic can issue exemptions under which non-conforming medical devices can be placed on the market if such devices are necessary for medical provision in Switzerland. 14 applications were submitted and reviewed during 2025. Five applications from among the procedures that were completed were approved.

Clinical trials

Swissmedic approves and monitors clinical trials of medical devices in humans if the devices or intended applications do not meet conformity requirements (category C clinical trials). While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious adverse events and device deficiencies, and reports on participant safety.

Activities

Swissmedic processed 48 first-time applications for new clinical trials of medical devices, of which 39 were approved during the year. 11 of the approved trials were combined trials with medicinal products or advanced therapy medicinal products. There were nine simplified reviews in response to applications for this type of procedure.

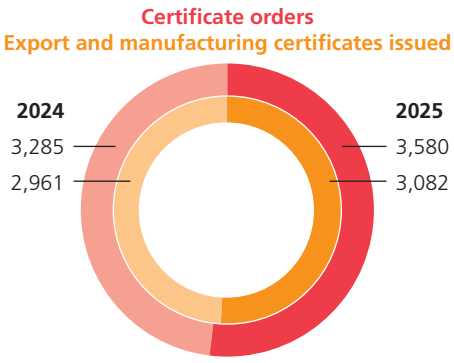
Swissmedic approved 120 major amendments during the course of clinical trials. 40 of the approved amendments were combined trials with medicinal products. As part of its monitoring activities for clinical trials in progress, Swissmedic reviewed 186 amendments, 125 annual reports on the safety of participants and general trial progress, and 45 safety reports from Switzerland. Swissmedic also inspected six ongoing trials at trial centres and at sponsors' premises.

Export certificates

On request, Swissmedic issues export and manufacturing certificates for Swiss companies, confirming that the products in question can be lawfully placed on the market in Switzerland. Foreign authorities may require the export certificates as a precondition for importing devices into their country.

Activities

Swissmedic received 3,580 orders and issued 3,082 export and manufacturing certificates in 2025. 98 percent of applications were completed within 30 days. In addition, 244 orders could not be completed as they either had to be rejected or a decision to dismiss was taken.



swissdamed – medical device database

Swissmedic develops and operates swissdamed, the national medical device database, which comprises two modules and a search function. Through the publicly accessible database, Swissmedic increases transparency in the Swiss medical device market and contributes to medical care.

Actors module

Economic operators must register in the Actors module and are issued a Swiss single registration number (CHRN). A CHRN is a unique Swiss registration number that can be used to unambiguously identify Swiss-domiciled manufacturers, authorised representatives and importers. Foreign manufacturers are recorded in swissdamed via the authorised representatives in the form of mandates. After the data transfer to swissdamed, economic operators were requested to validate their details. To implement this validation, an objection was raised in 411 cases and 120 actors were deactivated due to lack of cooperation.

UDI Devices module

Since August 2025, economic operators have been able to register their medical devices placed on the market in Switzerland in the UDI Devices module. They will be legally required to do this from mid-2026. The individual devices are registered by the economic operators using the UDI-DI (unique device identifier).

Medical devices: facts and figures

Number of authorisations	**2025**	**2024**
Notifications, Class I medical devices	302	354
Notifications, in vitro diagnostic medical devices	292	466
Exemption authorisations	5	10
Licences for new clinical trials	38	39
Export and manufacturing certificates	3,082	2,961

Number of reports	**2025**	**2024**
Serious incidents	7,134	6,317
Suspicion reports	309	321

Monitoring activities	**2025**	**2024**
FSCA implementation	551	659
Safety reports published	574	672
Market monitoring inspections	55	46
Hospital inspections	28	23
Monitoring of amendments to clinical trials in progress	192	146
Monitoring of annual reports	127	105

swissdamed – Actors module – registered economic operators	**2025**	**2024**
Manufacturers	705	705
Authorised representatives	1,166	1,187
Importers	1,971	2,050
Manufacturers of systems and procedure packs	61	53

swissdamed – UDI Devices module – number of registered UDI-DIs	**2025**	**2024***
MD – Class I	1,251	NA
MD – Class IIa	223	NA
MD – Class IIb	94	NA
MD – Class III	6	NA
IVD – Class A	8	NA
IVD – Class B	22	NA
IVD – Class C	0	NA
IVD – Class D	0	NA

* Device registration (voluntary) only possible from 2025

MEDICAL DEVICES – **MARKET SURVEILLANCE PRODUCT GROUP**

Vigilance product

Materiovigilance

Manufacturers and users of medical devices are legally required to report serious incidents that occur in Switzerland or Liechtenstein to Swissmedic. Furthermore, companies also have to report the safety measures they have taken, such as device recalls or software corrections (Field Safety Corrective Action, FSCA). Swissmedic monitors these measures on an ongoing basis.

Activities

The number of reports from Switzerland of serious incidents involving medical devices rose by 13 percent year-on-year. A total of 7,134 incidents were reported.

There were 551 cases in which implementation of safety measures in Switzerland was monitored, a fall of 16 percent versus 2024.

Safety reports were published to inform users in 574 cases.

Swissmedic participated regularly in international meetings on serious incidents in 2025. These medical device safety meetings – which are attended by supervisory authorities from the USA, Australia and Canada, among others – take place each month and facilitate recognition at an early stage of safety problems involving medical devices in worldwide use.

Materiovigilance

2024 **2025**

Total number of reports

Number of reports from Switzerland on serious incidents

Monitoring of FSCA implementation

Safety reports published by Swissmedic

Market Monitoring product

Independent monitoring

Switzerland has adopted the provisions of the European MDR and IVDR unilaterally in Swiss law. Based on this, Swissmedic monitors the Swiss medical devices market independently and continues to expand activities to ensure that protection levels remain equivalent to the EU. The measures implemented as part of market surveillance are partly to replace close integration in the European monitoring system and the associated loss of simplified administrative assistance, participation in joint market monitoring activities and lack of authority-level access to the EU's new EUDAMED database.

Market monitoring procedures

Efficient state-organised controls are essential in guaranteeing a high level of patient safety. Distributors of medical devices in Switzerland must guarantee their conformity. Swissmedic systematically plans annual market monitoring activities, carries out random inspections and receives suspicion reports. It initiates the necessary corrective measures and monitors their implementation. This is an area where the Agency works closely with other national and cantonal authorities.

Activities

The number of suspicions reported in connection with potentially non-compliant medical devices was slightly lower than in 2024. Swissmedic also had to impose corrective actions in fewer cases. These fluctuations are within normal limits and reflect the variable scope and complexity of the procedures.

In addition to processing suspicion reports, Swissmedic monitors the medical devices market closely via random check programmes. Certain focal areas are determined annually, ranging from device conformity to the obligations of economic operators. These focal area reviews, which are also a response to the stricter requirements of the new medical device regulation, are intended to increase market operators' awareness of regulatory requirements.

Swissmedic conducted two focus campaigns in 2025:

The injection of fillers by unqualified individuals and incorrect storage of material pose a risk to customers. The 2024 focus campaign found a high number of infringements. Together with the cantonal therapeutic products authorities, clinics, healthcare institutions and cosmetic studios were therefore investigated again, particularly regarding their use of fillers.

In April 2025, Swissmedic announced targeted inspections of Swiss importers to investigate compliance with their obligations. Importers play a key role in supplying and checking medical devices from abroad that are imported into Switzerland. It is important for patient and user safety that importers are aware of their responsibilities. It is their duty to know and comply with the regulations for medical devices.

Swissmedic carries out inspections of Swiss economic operators as part of market monitoring of medical devices. These inspections may be either announced or unannounced, and performed either randomly or on specific suspicion. Swissmedic stepped up its inspection activities considerably year-on-year as part of focus campaigns and market monitoring procedures.

The number of inspections by foreign authorities of market operators in Switzerland increased.

Notified bodies and inspections

Swissmedic monitors the notified bodies in Switzerland, designates and inspects them, collects their reports on certificates issued, and records these.

Activities

Swissmedic withdrew the designation of the single active notified body as a conformity assessment body for medical devices in 2025 due to discontinuation of business.

Hospital inspections

While the Cantons are responsible for inspecting the reprocessing of medical devices such as surgical instruments and endoscopes, and for ensuring that medical equipment such as X-ray machines and blood test apparatus is maintained correctly in doctors' practices, outpatient clinics and other healthcare institutions, Swissmedic conducts the relevant inspections in hospitals throughout Switzerland. Swissmedic's medical devices monitoring activities also extend to inspecting hospitals' vigilance systems for reporting serious incidents and ensuring hospitals correctly implement Field Safety Corrective Actions (FSCAs).

Activities

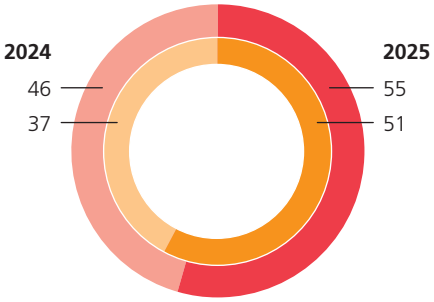
Swissmedic evaluated the hospital inspections conducted in 2024 and published the findings and areas where action is required to improve quality management in healthcare institutions. There were follow-up and monitoring activities for the corrective actions implemented by hospitals from previous inspections. A further focal point was preparing additional enforcement aids (good practices) in conjunction with external specialists. Two key guidelines were published in 2025: Good practice for the maintenance of medical devices and Good practice for the reprocessing of endoscopes.

28 hospitals (a total of 51 areas) were inspected in 2025. The inspections covered medical device reprocessing in central reprocessing units and departments that perform endoscopies (e.g. gastroenterology or urology), maintenance or vigilance reporting systems.

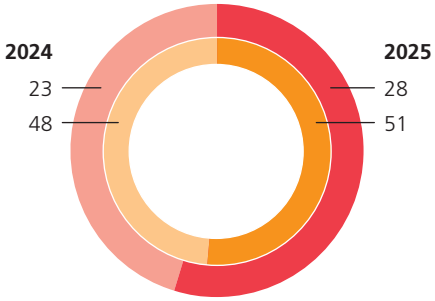
Appeals procedure

During 2025, appeals were submitted to the Federal Administrative Court against six official decisions in connection with the market surveillance of medical devices. 15 cases are currently still pending before the Court. The Federal Administrative Court ruled on five appeals during 2025, three of which were rejected and two of which were dismissed as being without merit.

Market monitoring inspections
Inspections by foreign authorities
(co-ordination with SECO, including accompanying inspectors on site if needed)



No. of hospitals inspected
No. of areas inspected
(reprocessing, maintenance, materiovigilance)



MEDICAL DEVICES – **PENAL LAW PRODUCT GROUP**

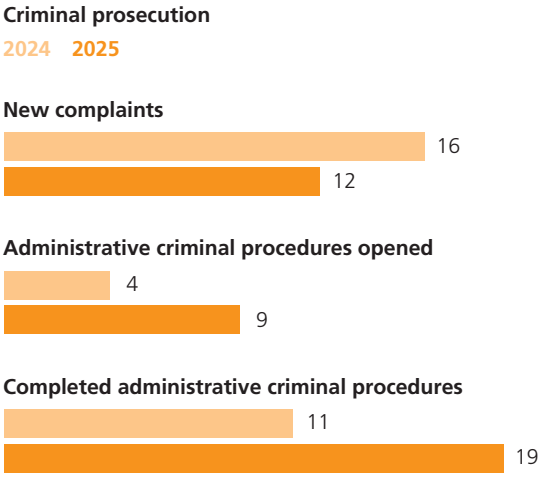
Penal Law product

Criminal prosecution

Activities

Criminal prosecutions in the medical devices sector are often largely dependent on market surveillance reports. There were targeted inspections of Swiss medical device importers in 2025.

The number of offences reported fell by a quarter compared to 2024. In 2025, half of reports came from internal and half from external sources (the public, whistleblowers, business competitors or authorities). Most involved the placing on the market of non-conforming medical devices (lack of Swiss authorised representative CH-REP) and failure to comply with reporting obligations and duty of cooperation.



Investigative measures

Activities

As in 2024, two examination hearings were conducted; however, there were no house searches.

Decisions / verdicts by Swissmedic and the courts

Activities

Several criminal proceedings were conducted against economic operators who had placed medical devices on the market despite no Swiss authorised representative being appointed; this was discovered, for example, through the supervisory audit of importers obligations.

One economic operator did not accept the decision and lost the case in court. They were also obligated to pay illegal income of several tens of thousands of Swiss francs in damages. Proceedings before the court of first instance are still pending in another – similar – case. Two cases of failure to comply with the reporting obligation were concluded with a conviction.

19 cases were concluded from a criminal law perspective in 2025. These included six penalty orders and two penalty rulings issued by Swissmedic. Fines were imposed on natural and legal persons (corporate fines) and financial penalties issued, and payment of damages was ordered.

BALANCE SHEET

(in KCHF)	Annex	31.12.25	31.12.24
Cash and cash equivalents	1	11,490	3,300
Receivables from sales and services	2	51,745	60,732
Uninvoiced procedural fees		5,943	6,427
Prepaid expenses		954	782
Financial assets (debenture bonds)	3	0	20,145
Current assets		**70,132**	**91,386**
Fixed assets	4	2,352	2,765
Real estate	5	56,472	58,629
Intangible assets	6	16,070	14,589
Right of use	7	2,736	2,189
Capital assets		**77,630**	**78,172**
TOTAL ASSETS		**147,762**	**169,558**
Commitments on sales and services		8,388	9,944
Other commitments	8	822	1,936
Deferred income	9	8,040	4,615
Other current provisions	10	5,160	0
Short-term commitments		**22,410**	**16,495**
Lease liabilities	7+8	2,703	2,061
Liability for loyalty bonuses		3,611	3,330
Pension obligations (net)	11	12,254	43,618
Long-term commitments		**18,568**	**49,009**
Annual gain (+) / loss (–)		–31,711	–23,401
Reserves		91,172	114,573
Endowment capital		14,500	14,500
Accumulated actuarial gains (+) / losses (–)		32,823	–1,618
Own capital		**106,784**	**104,054**
TOTAL LIABILITIES		**147,762**	**169,558**

INCOME STATEMENT

(in KCHF)	Annex	2025	2024
Procedural fees and income pursuant to Art. 69 TPA (net)	12	41,535	37,312
Change in work in progress		–484	0
Supervisory levies		60,939	57,750
Other income		314	382
Federal contribution		19,543	19,722
Other operating income		73	75
Net income		**121,920**	**115,241**
Services for third parties		–1,810	–1,963
Personnel	13	–104,160	–96,786
Rental, maintenance, energy, transport and insurance		–2,631	–2,845
Administration		–6,080	–5,848
IT	14	–28,618	–26,937
Other expenses		–333	–320
Amortisation	4–7	–6,556	–4,795
Total operating expenditure		**–150,188**	**–139,494**
Operating income		**–28,268**	**–24,253**
Financial income	15	119	1,166
Financial expense	16	–205	–314
Financial result		**–86**	**852**
Annual gain (+) / loss (–) before actuarial effects		**–28,354**	**–23,401**
Actuarial effects		–3,357	0
Annual gain (+) / loss (–) after actuarial effects		**–31,711**	**–23,401**

STATEMENT OF COMPREHENSIVE INCOME

(in KCHF)	Annex	2025	2024
Annual gain (+) / loss (–)		–31,711	–23,401
Actuarial balance-sheet gains (+) / losses (–)	11	34,440	–20,676
Total		**2,729**	**–44,077**

The income statement does not include any actuarial gains and losses (other income).

CASH FLOW STATEMENT

(in KCHF)	Annex	2025	2024
Income/(expenditure) from business activities			
Annual gain (+) / loss (–)		–31,711	–23,401
Depreciation of tangible fixed assets	4	603	577
Writedowns on real estate	5	2,157	2,590
Amortisation of intangible assets	6	2,588	1,451
Writedowns on right of use	7	249	177
Losses on disposal of assets		958	0
Reversal (–) / recognition (+) of liability for loyalty bonuses		281	146
Reversal (–) / recognition (+) of pension obligations, excl. actuarial (losses) gains	11	3,076	–758
Interest expense (+) / interest income (–)		–324	–858
Cash flow before change in net current assets		**–22,123**	**–20,076**
Increase (–) / decrease (+) in receivables from sales and services	2	8,987	–900
Increase (–) / decrease (+) in uninvoiced procedural fees		484	–878
Increase (–) / decrease (+) in prepaid expenses		–172	114
Increase (+) / decrease (–) in commitments on sales and services		–1,555	1,616
Increase (+) / decrease (–) in other short-term, non-interest-bearing commitments	8	–1,113	618
Increase (+) / decrease (–) in deferred income	9	3,425	175
Increase (+) / decrease (–) in other current provisions	10	5,160	0
Cash flow from business activities		**–6,907**	**–19,331**

(in KCHF)	Annex	2025	2024
Income / (expenditure) from investing activities			
Disposals of financial assets	3	20,145	19,853
Investments in tangible fixed assets	4	–226	–722
Investments in real estate	5	0	–22
Investments in intangible assets	6	–4,991	–9,608
Interest received		375	946
Cash flow from investing activities		**15,302**	**10,447**
Income / (expenditure) from financing activities			
Interest paid		–51	–88
Repayment of lease liabilities	7	–154	–160
Cash flow from financing activities		**–205**	**–248**
Net increase / (decrease) in cash and cash equivalents		**8,190**	**–9,132**
Cash and cash equivalents at start of year	1	3,300	12,432
Cash and cash equivalents at year-end	1	11,490	3,300

STATEMENT OF CHANGES IN EQUITY

(in KCHF)	Annual gain (+) / loss (–)	Reserves	Endowment capital	Accum. actuarial gains (+) / losses (–))	Total equity
Opening balance on 1 Jan 2024	**1,708**	**112,865**	**14,500**	**19,057**	**148,130**
Annual gain (+) / loss (–)	–23,401	0	0	0	–23,401
Other income	0	0	0	–20,676	–20,676
Total	**–23,401**	**0**	**0**	**–20,676**	**–44,077**
Appropriation of gain	**–1,708**	**1,708**	**0**	**0**	**0**
Closing balance on 31 Dec 2025	**–23,401**	**114,573**	**14,500**	**–1,618**	**104,054**
Opening balance on 1 Jan 2025	**–23,401**	**114,573**	**14,500**	**–1,618**	**104,054**
Annual gain (+) / loss (–)	–31,711	0	0	0	–31,711
Other income	0	0	0	34,440	34,440
Total	**–31,711**	**0**	**0**	**34,440**	**2,729**
Appropriation of gain	**23,401**	**–23,401**			**0**
Closing balance on 31 Dec 2025	**–31,711**	**91,172**	**14,500**	**32,823**	**106,784**

ANNEX

Operating activities

Swissmedic is the central Swiss supervisory authority for therapeutic products (medicinal products and medical devices). It operates primarily on the basis of the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act) and the associated implementing ordinances. Based in Bern, Switzerland, Swissmedic is a public institution of the Swiss Confederation and a legal entity in its own right. It is independently organised and managed, has its own budget, and manages its own accounts. Swissmedic is financed through fees, supervisory levies and payments from the federal government as well as through services rendered to third parties. The services it provides in a sovereign capacity are exempt from tax. To ensure efficient controlling, Swissmedic is run according to business management principles.

Summary of the main accounting principles

Introduction

These annual accounts have been prepared in accordance with legal requirements and IFRS Accounting Standards. With the exception of new and revised standards, the accounting principles described have been applied consistently to all years reported here.

As a decentralised administrative unit within the Federal Administration with its own accounts, Swissmedic is fully incorporated into the Federal Administration's consolidated accounts in accordance with Article 55 of the Financial Budget Act.

These financial statements are separate accounts covering the reporting period from 1 January 2025 to 31 December 2025. The balance sheet date is 31 December 2025. The functional and reporting currency is the Swiss franc (CHF). Unless otherwise stated, all amounts are in thousands of Swiss francs (KCHF). Assets and liabilities are stated at acquisition cost unless specified otherwise. Expenses and income are recognised in the period in which they were incurred or received.

These accounts were approved by the Agency Council on 17 April 2026.

Application of new and revised standards

Changes to accounting and valuation principles resulting from the first-time application of new or amended standards and interpretations are applied retroactively unless prospective application is specifically prescribed. Swissmedic applied the following new or revised standards with effect from 1 January 2025:

– Amendments to IAS 21 – Exchange Rates: Lack of Exchangeability (1 January 2025))

Standards that have been implemented, but were not applicable as at 1 January 2025:

– New standard, IFRS 18 – Presentation and Disclosure in Financial Statements (1 January 2027)
– New standard, IFRS 19 – Subsidiaries without Public Accountability: Disclosures (1 January 2027)
– Amendments to IFRS 9 and IFRS 7 – Amendments to the Classification and Measurement of Financial Instruments (1 January 2026)
– Amendments to IFRS 9 and IFRS 7 – Contracts Referencing Nature-dependent Electricity (1 January 2026)
– Amendment to IFRS 21 – Translation to a Hyperinflationary Presentation Currency (1 January 2027)
– Amendments to IAS 28 and IFRS 10 – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (not yet known)
– Annual Improvements to IFRS Accounting Standards – Volume 11 (1 January 2026)

Cash and cash equivalents

Cash and cash equivalents comprise free assets (current accounts for payments) and short-term (max. 90 days) money market investments with financial institutions (cash management). Sight deposits and short-term money market investments with banks (cash management) are stated at nominal value. Any value adjustment on receivables from financial institutions is carried out using the ECL (expected credit losses) model and is based on the rating classifications issued by recognised ratings agencies. The expenditure and income from cash and cash equivalents are debited from or credited to the income statement in the period in which they occurred.

Receivables from sales and services

Receivables from sales and services are short-term in nature and do not involve any financing. They are valued at transaction price when first recognised, then stated at updated acquisition cost less value adjustments. Swissmedic applies the simplified approach for expected credit losses (ECL model), reporting them for their entire duration. These comprise flat-rate adjustments based on historic defaults and adjusted for future expectations as well as individual value adjustments. However, the latter are generally only used for receivables obtained by legally enforced collection. The same procedure is applied to procedural fees that have not been invoiced. All receivables are in Swiss francs.

Financial assets

Swissmedic can invest part of its liquid resources in debenture bonds and state-guaranteed money market investments. Cash flows consist solely of payments of principal and interest on the outstanding capital. Swissmedic has no intention of selling these bonds before they mature. All acquisition costs (fair value of the bond and the transaction costs associated with the purchase, i.e. stamp duty and brokerage) are capitalised on first recognition. The bonds are revalued at updated acquisition cost, applying the effective interest method. Any value adjustment on the financial assets is made using the ECL model and is based on the rating classifications issued by recognised ratings agencies.

Fixed assets / real estate

Fixed assets are stated at acquisition cost less cumulated depreciation. Acquisition cost also includes all costs incurred in transporting the asset to its destination and preparing it to the state of operational readiness intended by management. Costs are depreciated on a straight-line basis over the expected useful life of the asset and are recognised in the income statement under depreciation on fixed assets. The estimated useful life per asset class for the current period and years used for comparison is as follows:

No.	Asset class	Useful life
15000	Laboratory equipment	10 years
15100	Office equipment and furnishings	5 years
15110	Archive furnishings	10 years
15200	Hardware	3 years
16000	Properties, building shell	50 years
16000	Properties, interior fit-out	20 years
16020	Construction and investment costs for properties	10 years
16100	Land	Unlimited

The residual value, useful life and amortisation method of each asset are reviewed at the end of each reporting period and adjusted as necessary. If the carrying amount of an asset exceeds the estimated achievable amount, the asset is devalued by the resulting difference. The carrying value of a particular fixed asset is eliminated from the accounts when it is sold or at the time at which no further benefit is expected to accrue from continued use or sale. Any proceeds or losses from disposal are recorded as a gain or loss on the disposal of property, plant and equipment.

Intangible assets

Intangible assets are stated at acquisition or manufacturing cost. Only the costs incurred during the design and realisation phase can be capitalised, provided the following criteria are fulfilled:
– The acquisition or manufacturing costs can be reliably determined.
– The intangible asset is identifiable, i.e. the asset is separable or based on contractual or legal rights.
– Power and authorisation to dispose of the intangible asset must be held.
– It is likely that Swissmedic will derive future economic benefit from the intangible asset.

Intangible assets are amortised on a straight-line basis over their expected useful life starting from the time they go into service.

No.	Asset class	Useful life
17910	Software	3–10 years

The residual value, useful life and amortisation method of each intangible asset is reviewed at the end of each reporting period and adjusted as necessary. If the carrying amount of an asset exceeds the estimated achievable amount, the asset is devalued by the resulting difference.

Right of use

The value of right of use is the valuation of the lease liability when first recognised. Right of use is valued at acquisition cost less cumulative ordinary amortisation and (extraordinary) impairments, and factors in any re-evaluations of the lease liability. Costs are amortised on a straight-line basis over the expected useful life of the right of use or the agreed term of the contract, whichever is shorter, and are recognised in the income statement under depreciation on fixed assets.

Lease liabilities

First-time valuation of lease liabilities is based on the present value of the minimum lease payments over the expected term. Lease liability valuations contain both fixed and variable lease payments where such payments are index-linked (e.g. to the consumer price index). Expected payments arising from the exercise prices of call options and penalty payments on termination are also factored into calculations of lease liabilities.

Lease payments are discounted using the interest rate underlying the lease. This is the interest rate at which the present value of lease payments matches the fair value of the underlying asset and the initial direct costs of the lessor. If this rate is not known, the incremental borrowing rate is applied. This represents the interest rate for loans with a similar term and collateral that would be needed to finance the asset in a comparable economic situation. Each lease payment is divided into an amortisation and an interest expense component. The amortisation component is deducted from the stated lease liability.

Commitments on sales and services

Commitments on sales and services are as yet unpaid suppliers' invoices that generally become due within 30 days and are paid. Valuation is at updated acquisition cost, which is equivalent to nominal value.

Pension obligations

Swissmedic pays pension benefits to employees after they have ceased working. Pension obligations are covered by the Swiss Federal Pension Fund PUBLICA on a defined contribution basis. Swissmedic may have a legal or de facto obligation to pay additional contributions if the pension fund does not hold sufficient assets to pay the pension entitlements of all employees. This makes it a defined benefit plan under IFRS.

The present value of defined benefit obligations is determined annually by an independent actuary applying the projected unit credit method. The calculations are based on actuarial assumptions. These are geared to the expectations for the period during which the obligations have to be fulfilled as those expectations stand on the closing date. The plan assets are recognised at fair value. Actuarial gains and losses derive from changes in the assumptions made, discrepancies between the actual and anticipated yield from plan assets, and the difference between actual benefit entitlements and entitlements based on actuarial assumptions. These are stated under other income. However, the costs of the defined benefit pension plan are reported in the income statement.

Liabilities for future entitlements from loyalty bonuses

Swissmedic rewards employees' loyalty by awarding additional holiday, the first award taking place after five years' service. At the end of the reporting year, accumulated entitlements to loyalty bonuses as at the cut-off date of 31 December are determined, and the amount is discounted as of the cut-off date. The liability for loyalty bonuses is then adapted to this amount and recognised accordingly. As with provisions for pension fund obligations, this calculation is currently performed annually by an independent actuary.

Capital management

Any reserves that are set aside are used in accordance with Article 79 of the Therapeutic Products Act to finance future investments and cover potential losses.

Income

Swissmedic's income mainly comprises earnings from fees, supervisory levies, payments from the federal government and various other small earnings items. Revenue from contracts with customers primarily consists of procedural fees and supervisory levies.

Income from contracts with customers
Procedural fees and income pursuant to Article 69 Therapeutic Products Act (net)
In accordance with Article 65 paragraph 1 of the Therapeutic Products Act, Swissmedic charges fees for authorising human and veterinary medicinal products, issuing establishment licences for the manufacture of and wholesale trading in medicines, and approving clinical trials of therapeutic products. Swissmedic provides services in a sovereign capacity for a large number of customers. Service provision takes place at a specific point in time and is completed when the decision or official decision is issued.

On any balance sheet date there are applications in progress, the revenue from which is reported in accordance with the progress made in processing them. This progress is quantified by assessing the accumulated direct staffing costs for all ongoing applications from the system at the end of the year. The resulting deferred revenue is reported in the balance sheet as uninvoiced procedural fees. Billing (particularly transaction price) is based on the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products. The procedures are standardised to the extent that the key transaction criteria (requirements, service to be provided and price) are predefined and do not have to be negotiated with each customer on a case-by-case basis. The majority of fees are flat-rate fees. However, the Fees Ordinance stipulates various circumstances under which fees may be reduced.

Income pursuant to Article 69 of the Therapeutic Products Act comprises speakers' fees for presentations given by employees, income from events, sales of legislative documents and publications, and earnings from third-party assignments (particularly service agreements with the Federal Office of Public Health).

Supervisory levies
In accordance with Article 65 paragraphs 2 and 3 of the Therapeutic Products Act, Swissmedic charges a supervisory levy that is based on the ex-factory price of authorised medicinal products, vaccines, veterinary medicinal products and transplant products sold in Switzerland. The details are set out in the Ordinance on supervisory levies payable to the Swiss Agency for Therapeutic Products. A uniform rate of 0.65 percent is charged. Assessment is based on total turnover from medicinal and transplant products sold at ex-factory prices as determined from the self-declaration submitted by marketing authorisation holders. Service provision takes place at a specific point in time and is payable for one calendar year in each case. At the time the financial statements are prepared, the self-declarations have been submitted and it is no longer necessary to estimate the deferred revenue.

Federal contribution
In accordance with Article 77 paragraph 2 of the Therapeutic Products Act, the contribution provided by the Confederation is used to fund services that are not covered by fees and levies. Paragraph 2bis specifies that legislative work, enforcement of criminal law and medical devices surveillance are funded in their entirety from the federal contribution.

The federal contribution is defined annually as part of the federal budget. It is currently not sufficient to finance the tasks set out in Article 77 paragraph 2bis of the Therapeutic Products Act in full. The shortfall amounts to CHF 16.7 million.

Financial result

The individual items in the financial result are reported in accordance with the prohibition on netting, i.e. gains and losses are not offset against each other. Swissmedic does not hold any derivative financial instruments and does not undertake any hedging transactions.

Financial expense
Financial expense includes negative interest from Swissmedic's bankers, lease liabilities and exchange rate losses (difference between the book rate and the rate actually paid).

Financial income
Financial income includes income from interest on bank accounts, debenture bonds and short-term money market investments as well as exchange rate gains (difference between the book rate and the rate actually paid).

Risk assessment and risk management

Risk assessment

Interest rate risk

Swissmedic does not have any interest-bearing commitments. There is thus no risk from changes in interest rates.

Credit risk

Fees and levies account for the majority of sales income. Although these do not become due until the service in question has been provided, the risk of default and associated losses is marginal. The same is true of the state-guaranteed debenture bonds. Accordingly, there is no material credit risk.

Liquidity risk

Liquidity planning takes place on a monthly basis. To bridge liquidity bottlenecks for cash management purposes, Swissmedic has a current account credit facility with its bankers.

Contractual cash flows from financial commitments (in KCHF)	Due in 3 mths	Due in 3–12 mths	Due in 12–60 mths	Due in more than 60 mths	Total
Commitments on sales and services towards third parties	6,525	0	0	0	6,525
Commitments on sales and services towards related parties (over CHF 1 mn)	3,340	0	0	0	3,340
Other commitments on sales and services towards related parties	79	0	0	0	79
Lease obligations towards third parties	51	152	812	1,421	2,436
Total contractual cash flows from financial commitments 31.12.2024	**9,995**	**152**	**812**	**1,421**	**12,380**
Commitments on sales and services towards third parties	5,696	0	0	0	5,696
Commitments on sales and services towards related parties (over CHF 1 mn)	2,328	0	0	0	2,328
Other commitments on sales and services towards related parties	364	0	0	0	364
Lease obligations towards third parties	51	153	1,128	1,691	3,023
Total contractual cash flows from financial commitments 31.12.2025	**8,439**	**153**	**1,128**	**1,691**	**11,411**

Risk management and ICS

Swissmedic's internal control system (ICS) is part of its comprehensive risk management system. It identifies the operational risks associated with finance-related business processes, describes and quantifies them, and specifies regulatory, organisational and technical control measures to mitigate them. Internal control measures are integrated into operational procedures, being performed either simultaneously with or immediately before or after the activities in question. Internal controls are an integral part of processes. The auditors verify the existence of the ICS annually and the Agency Council discusses it with the Management Board at each of its March meetings.

Valuation uncertainties

The key forward-looking assumptions are listed in the Annex, along with details of other material sources of uncertainty affecting estimates as at the cut-off date that may give rise to a significant risk of recognised assets and liabilities having to be adjusted within the next financial year.

For the purpose of assessing pension obligations, actuarial assumptions (discount rate, salary and pension trends) that cannot be reliably verified are made in consultation with the actuary.

Notes on the balance sheet

1 Cash and cash equivalents

(in KCHF)	31.12.25	31.12.24
Current accounts at banks	11,490	3,300
Money market investments	0	0
Total cash and cash equivalents	**11,490**	**3,300**

2 Receivables from sales and services

Trade receivables from third parties

(in KCHF)	31.12.25	31.12.24
Not overdue	51,474	60,438
1–30 days overdue	128	54
More than 30 days overdue	264	285
Total receivables from sales and services (gross)	51,866	60,777
Individual value adjustments	–117	–39
Flat-rate value adjustment	–4	–6
Total receivables from sales and services (net)	**51,745**	**60,732**

Receivables from supervisory levies are recognised as at 31 December because service provision took place in the financial year just ended. However, they do not become due until the following year. They are then, invoiced on the basis of the self-declarations that have to be submitted by the end of January of the new year. For this reason, receivables from sales and services are always high at the year end, but not due.

Value adjustments on receivables

(in KCHF)	31.12.25	31.12.24
Total value adjustments on receivables as at 1 January	–45	–55
Recognition	–76	0
Reversal	0	10
Use	0	0
Total value adjustments on receivables as at 31 December (total of individual and flat-rate adjustments)	**–121**	**–45**

3 Financial assets

Carrying amounts (in KCHF)	31.12.25	31.12.24
– CHF 5 mn Basler Kantonalbank, matured 29 Mar. 2025, interest rate 1.875%	0	5,030
– CHF 10 mn Swiss Confederation, matured 24 July 2025, interest rate 1.5%	0	10,073
– CHF 5 mn Mortgage Bond Bank, matured 15 July 2025, interest rate 1.75%	0	5,042
Total debenture bonds	**0**	**20,145**
of which short-term	0	20,145
of which long-term	0	0

Fair values (in KCHF)	31.12.25	31.12.24
– CHF 5 mn Basler Kantonalbank, matured 29 Mar. 2025, interest rate 1.875%	0	5,013
– CHF 10 mn Swiss Confederation, matured 24 July 2025, interest rate 1.5%	0	10,071
– CHF 5 mn Mortgage Bond Bank, matured 15 July 2025, interest rate 1.75%	0	5,035
Total debenture bonds	**0**	**20,119**
of which short-term	0	20,119
of which long-term	0	0

Swissmedic held no financial assets as at the balance sheet date.

4 Fixed assets

Statement of changes (in KCHF)	Furnishing	Archive equipment	Laboratory equipment	Computer systems	Total fixed assets
Acquisition cost					
1 January 2024	**2,986**	**1,929**	**6,855**	**289**	**12,059**
Additions	86	0	683	36	805
Disposals	0	–103	–692	–39	–834
31 December 2024	**3,072**	**1,826**	**6,846**	**286**	**12,030**
1 January 2025	**3,072**	**1,826**	**6,846**	**286**	**12,030**
Additions	0	0	226	0	226
Disposals	–49	0	–187	0	–236
31 December 2025	**3,023**	**1,826**	**6,885**	**286**	**12,020**
Accumulated depreciation					
1 January 2024	**–2,819**	**–1,929**	**–4,568**	**–123**	**–9,439**
Additions	–68	0	–432	–77	–577
Disposals	0	103	609	39	751
31 December 2024	**–2,887**	**–1,826**	**–4,391**	**–161**	**–9,265**
Net carrying amounts as at 31 December 2024	**185**	**0**	**2,455**	**125**	**2,765**
1 January 2025	**–2,887**	**–1,826**	**–4,391**	**–161**	**–9,265**
Additions	–60	0	–467	–76	–603
Disposals	49	0	151	0	200
31 December 2025	**–2,898**	**–1,826**	**–4,707**	**–237**	**–9,668**
Net carrying amounts as at 31 December 2025	**125**	**0**	**2,178**	**49**	**2,352**

As at the balance sheet date, there were no indications of any unanticipated impairments.

5 Real estate

Statement of changes (in KCHF)	Renovation account	Property	Land	Total real estate
Acquisition cost				
1 January 2024	**491**	**85,746**	**11,730**	**97,967**
Additions	0	22	0	22
Reclassifications	–491	491	0	0
31 December 2024	**0**	**86,259**	**11,730**	**97,989**
1 January 2025	**0**	**86,259**	**11,730**	**97,989**
Additions	0	0	0	0
Reclassifications	0	0	0	0
Disposals	0	0	0	0
31 December 2025	**0**	**86,259**	**11,730**	**97,989**
Accumulated depreciation				
1 January 2024	**0**	**–36,770**	**0**	**–36,770**
Additions	0	–2,590	0	–2,590
31 December 2024	**0**	**–39,360**	**0**	**–39,360**
Net carrying amounts as at 31 December 2024	**0**	**46,899**	**11,730**	**58,629**
1 January 2025	**0**	**–39,360**	**0**	**–39,360**
Additions	0	–2,157	0	–2,157
31 December 2025	**0**	**–41,517**	**0**	**–41,517**
Net carrying amounts as at 31 December 2025	**0**	**44,742**	**11,730**	**56,472**

Swissmedic's real estate includes the three properties at Hallerstrasse 7, Erlachstrasse 8 and Freiburgstrasse 139 in Bern. All properties are used solely for Swissmedic's business purposes. No investments were made in the year under review. As at the balance sheet date, there were no indications of any unanticipated impairments. The property at Freiburgstrasse 139 is under liens amounting to CHF 10 million.

6 Intangible assets

Statement of changes (in KCHF)	Software in development	Software developed by Swissmedic	Total intangible assets
Acquisition cost			
1 January 2024	**5,591**	**17,346**	**22,937**
Additions	9,500	147	9,647
Disposals	0	–1,142	–1,142
Reclassifications	–7,153	7,115	–38
31 December 2024	**7,938**	**23,466**	**31,404**
1 January 2025	**7,938**	**23,466**	**31,404**
Additions	1,327	3,664	4,991
Disposals	0	–923	–923
Reclassifications	–7,539	7,539	0
31 December 2025	**1,726**	**33,746**	**35,472**
Accumulated depreciation			
1 January 2024	**0**	**–16,506**	**–16,506**
Additions	0	–1,451	–1,451
Disposals	0	1,142	1,142
31 December 2024	**0**	**–16,815**	**–16,815**
Net carrying amounts as at 31 December 2024	**7,938**	**6,651**	**14,589**
1 January 2025	**0**	**–16,815**	**–16,815**
Additions		–2,588	–2,588
Disposals			0
31 December 2025	**0**	**–19,403**	**–19,403**
Net carrying amounts as at 31 December 2025	**1,726**	**14,343**	**16,070**

In 2025, the productive applications of swissdamed and the first modules of the customer portal as well as the expanded version of the Public Cloud Foundation were capitalised as intangible assets. As at the balance sheet date, there were no indications of any unanticipated impairments.

7 Right of use

Statement of changes (in KCHF)	Right of use	Total right of use
Acquisition cost		
1 January 2024	**3,257**	**3,257**
Additions / disposals	0	0
31 December 2024	**3,257**	**3,257**
1 January 2025	**3,257**	**3,257**
Additions / disposals	796	796
31 December 2025	**4,053**	**4,053**
Accumulated depreciation		
1 January 2024	**–891**	**–891**
Additions / disposals	–177	–177
31 December 2024	**–1,068**	**–1,068**
Net carrying amounts as at 31 December 2024	**2,189**	**2,189**
1 January 2025	**–1,068**	**–1,068**
Additions / disposals	–249	–249
31 December 2025	**–1,317**	**–1,317**
Net carrying amounts as at 31 December 2025	**2,736**	**2,736**

Right of use applies to the ten-year rental agreement with the option of extension by further increments of ten years for Swissmedic's long-term archive. The extension option is factored into capitalisation of lease liabilities. The rental agreement runs until the end of 2036. As at the balance sheet date, there were no indications of any unanticipated impairments.

Lease liabilities

(in KCHF)	31.12.25	31.12.24
Starting balance as at 1 January	**2,264**	**2,421**
Contract extension	796	0
Redemption	–204	–203
Accrued interest	51	46
Final balance as at 31 December	**2,907**	**2,264**
of which short-term	204	203
of which long-term	2,703	2,061

8 Other commitments

(in KCHF)	31.12.25	31.12.24
Short-term lease liabilities	204	203
Other short-term commitments towards third parties	618	1,733
Total other short-term commitments	**822**	**1,936**

Other commitments comprise the short-term component of lease liabilities, obligations towards the Compensation Office, withholding tax due as at the balance sheet date and assets confiscated by Swissmedic.

9 Deferred income

(in KCHF)	31.12.25	31.12.24
Deferred income	3,593	179
Amount deferred for leave and flexitime	4,447	4,436
Total deferred income	**8,040**	**4,615**

10 Other current provisions

Other current provisions were set aside in the year under review to finance the agreed reorganisation scheduled for the following year.

11 Pension provision

Description of pension plans and pension institution

Under Article 76 of the Therapeutic Products Act, Swissmedic employees are insured against the economic consequences of age, disability and death with the Swiss federal pension fund PUBLICA. PUBLICA is an autonomous public institution of the Swiss Confederation. Swissmedic has its own pension fund that is attached to the PUBLICA collective pension fund. The pension plan provides disability, death, old-age and departure benefits that exceed the minimum required by law. Insured members can choose from different savings contribution plans. Their choice of plan does not affect the amount of the employer contributions.

Responsibilities of the joint committee and fund commission

The organisation and responsibilities are set out in the Federal Act on the Federal Pension Fund (PUBLICA Act). Each pension fund has its own joint committee. Among other things, these committees contribute to the conclusion of the affiliation agreement and make decisions on the use of any surpluses. The joint committee comprises two employer representatives and two employee representatives. The supreme governing body of PUBLICA is the fund commission, which, like the joint committee, comprises equal numbers of employee and employer representatives. It supervises and controls the management of PUBLICA.

Special situations

The pension fund regulations do not specify any minimum financing requirement (provided the pension fund has a statutory surplus); however, they do prescribe minimum requirements for contributions, as explained below. Under local legislation, the options available to members of the joint committee to distribute benefits from available funds to beneficiaries in the event of a surplus are limited. Should the pension fund show a deficit, however, members and the employer have to pay additional restructuring contributions until the fund returns to equilibrium.

Financing agreements on future contributions

Legislation governing occupational old age, survivors and disability benefits provides for minimum benefits on retirement and minimum annual contributions. However, employers can also pay higher contributions. These are defined in the pension fund regulations. In addition, employers can also pay one-off contributions or advances into the pension fund (employer contribution reserve). These contributions are then tied up and may not be paid back to the employer. By law, minimum annual contributions still have to be paid even if a surplus exists. Both employer and employee contributions are paid for active members. The employer contribution must be at least the same as the employee contribution.

Pension fund status is calculated as follows:

(in KCHF)	2025	2024
Change in commitments and assets		
Dynamic present value of benefit obligations at start of year	**–429,202**	**–370,674**
Actuarial pension benefit expenses	–13,173	–10,522
Employee contributions	–5,884	–5,616
Past benefit expenses	0	0
Interest expense	–4,291	–5,558
Benefits paid	7,656	887
Actuarial gain (+) / loss (–) on commitments	16,000	–37,719
Dynamic present value of benefit obligations at year-end	**–428,894**	**–429,202**
Plan assets at market value at start of year	**385,584**	**346,974**
Interest income	3,855	5,202
Employer contributions	10,683	11,775
Employee contributions	5,884	5,616
Benefits paid	–7,656	–887
Administrative expenses	–150	–139
Actuarial gain (+) / loss (–) on assets	18,440	17,043
Plan assets at market value at year-end	**416,640**	**385,584**
Balance sheet	**31.12.25**	**31.12.24**
Plan assets at market value	416,640	385,584
Dynamic present value of benefit obligations (DBO)	–428,894	–429,202
Assets (+) / liabilities (–) in the balance sheet	**–12,254**	**–43,618**
Duration	16.30	16.80

Income statement (in KCHF)	2025	2024
Actuarial pension benefit expenses	–13,173	–10,522
Interest expense	–4,291	–5,558
Interest income	3,855	5,202
Past service cost	0	0
Administrative expenses	–150	–139
Net expenses for benefit obligations	**–13,759**	**–11,017**
Change in the balance sheet	**31.12.25**	**31.12.24**
Liabilities on the balance sheet at start of year	**–43,618**	**–23,700**
Net benefit expenses (employer)	–13,759	–11,017
Employer contributions	10,683	11,775
Actuarial gains (+) / losses (–)	34,440	–20,676
Liabilities on the balance sheet at year-end	**–12,254**	**–43,618**
Anticipated employer contribution payment in following year	10,496	10,458
Effective return on plan assets	22,295	22,245
Key actuarial assumptions as at balance sheet date	**31.12.25**	**31.12.24**
Discount rate	1.3 %	1.00 %
Future payroll increases	1.50 %	1.50 %
Future pension increases	0.00 %	0.00 %
Projected interest rate	2.00 %	2.00 %
Actuarial bases	OPA 2020 GT	OPA 2020 GT
Probable rate of turnover	High	High
Retirement age	63.5	63.5
Life expectancy at retirement age	24.67/26.43	24.55/26.32
Asset allocation	**31.12.25**	**31.12.24**
Cash and cash equivalents	5.00 %	2.90 %
Bonds	36.60 %	38.70 %
Equities	34.30 %	34.40 %
Real estate	19.50 %	20.20 %
Other	4.60 %	3.80 %
Total	**100.00 %**	**100.00 %**
Of which stock exchange-traded	79.30 %	78.30 %

Defined benefit pension plans	31.12.25	31.12.24
Revaluation of actuarial gain (+) / loss (–) from obligations	**16,000**	**–37,719**
Owing to changes in holdings	–5,710	–6,455
Owing to demographic assumptions	0	0
Owing to financial assumptions	21,710	–31,264
Revaluation of actuarial gain / loss from investments	**18,440**	**17,043**
Total amount recognised in equity	**34,440**	**–20,676**

Sensitivities – impact on DBO (in KCHF)	2025	2024
Discount rate +0.25%	–16,845	–17,439
Discount rate –0.25%	17,972	18,628
Payroll increase +0.25%	1,376	1,428
Payroll increase –0.25%	–1,343	–1,394
Pension increase +0.25%	11,948	12,377
Pension increase –0.25% (not lower than 0%)	0	0
1-year increase in life expectancy	16,797	16,897

The sensitivity analysis is based on a change in one assumption while the other assumptions remain unchanged (ceteris paribus). The sole exception is a change in technical interest rate accompanied by a simultaneous change in the projected interest rate for savings capital. The sensitivity of benefit obligations was assessed using the projected unit credit method – the same method that was used to assess obligations in the annual accounts.

Notes on the income statement

12 Procedural fees and income pursuant to Article 69 Therapeutic Products Act

(in KCHF)	2025	2024
Authorisation (with no fee rebates)	29,655	27,690
Licensing	14,237	12,683
Therapeutic products information	3	2
Informing the general public	0	1
Market monitoring	4,220	3,810
Penal law	83	12
Fee surcharges	810	505
Earnings from conferences (Art. 69 TPA)	39	245
Earnings from publications (Art. 69 TPA)	0	0
Earnings from services for third parties (Art. 69 TPA)	189	188
Fee reductions	–7,701	–7,824
Total procedural fees and income pursuant to Art. 69 TPA	**41,535**	**37,312**

Income from procedural fees increased year-on-year, by CHF 4.2 million (previous year CHF -1.5 million).

13 Personnel

(in KCHF)	2025	2024
Wages and salaries	–79,900	–76,519
Net expenses for benefit obligations	–10,684	–11,017
Social security	–6,867	–6,939
Change in other current provisions	–5,160	0
Other personnel expenses	–1,468	–1,957
Work by third parties	–81	–353
Total personnel expenses	**–104,160**	**–96,785**

Wage and salary expenses rose by CHF 7.2 million year-on-year. CHF 5.2 million of this is attributable to the provision for the scheduled reorganisation in the following year. Operational personnel costs increased by CHF 2.0 million (2.1%) in the year under review.

14 IT

(in KCHF)	2025	2024
Operating services	–11,212	–11,122
Hardware	–250	–534
Software licences	–2,639	–1,663
Development and project management services	–14,263	–11,982
Maintenance and support services	–254	–1,636
Total IT	**–28,618**	**–26,937**

IT expenses rose by CHF 1.7 million in 2025. Operating costs remained stable year-on-year. The additional expenditure was largely attributable to a one-time effect from a change of service provider.

15 Financial income

(in KCHF)	2025	2024
Interest income from receivables and debenture bonds, net	102	1,155
Unrealised exchange rate gains from foreign currencies	17	11
Total financial income	**119**	**1,166**

16 Financial expense

(in KCHF)	2025	2024
Interest expense, banks	0	0
Interest expense, leases	–51	–45
Unrealised exchange rate losses from debenture bonds	–145	–257
Unrealised exchange rate losses from foreign currencies	–9	–12
Total financial expense	**–205**	**–314**

Other notes

Contingent liabilities and contingent assets

Pending proceedings
Pending administrative appeals proceedings: The litigation risk associated with pending appeals is generally limited to the possibility of having to pay the other party's costs and of sustaining a minor loss of procedural fees. Given the consistently high percentage of procedures that have been decided in Swissmedic's favour, the maximum contingent liability for upheld appeals is not expected to exceed CHF 20,000 annually.

Pending administrative proceedings: Swissmedic's prosecution activities always involve a certain likelihood of acquittals and of Swissmedic consequently having to pay compensation (particularly for defence costs). Although it is difficult to assess the amount of this contingent liability, the average is unlikely to exceed CHF 100,000 per year.

Transactions with related parties

Related parties are companies and individuals that could either exert influence on Swissmedic or have influence exerted on them by Swissmedic. Swissmedic regards the following as related parties:

- General Secretariat of the Federal Department of Home Affairs (GS FDHA)
- Federal Pension Fund PUBLICA
- Federal Compensation Office (CFC)
- Federal Office of Information Technology, Systems and Telecommunication (FOITT)
- Members of the Agency Council
- Members of the Management Board

All transactions with related parties are conducted on the basis of customary customer or supplier relationships and on the same terms as transactions with unrelated third parties. Transactions worth CHF 1 million or more are reported.

Transactions with related parties

All transactions with related parties take place at arm's length, i.e. at market value. Only material transactions (i.e. those exceeding CHF 1 million) with the Confederation and organisations related to the Confederation are disclosed separately in the notes to the financial statements. The following transactions were conducted with related parties:

(in KCHF)	31.12.25	31.12.24
PUBLICA, social insurance contributions	1,410	1,371
FOITT, IT expenses	918	1,969
CFC, social insurance contributions	0	0
Total commitments towards related parties	**2,328**	**3,340**

(in KCHF)	2025	2024
GS FDHA, federal contribution	19,543	19,722
Total net income involving related parties	**19,543**	**19,722**
PUBLICA, social insurance contributions	16,585	17,401
FOITT, IT expenses	7,463	7,280
CFC, social insurance contributions	10,977	9,495
Total operating expenses involving related parties	**35,025**	**34,176**

Remuneration of individuals in key positions

The following fees and salaries were paid:

(in KCHF)	2025	2024
Short-term benefits due to the Management Board	2,401	2,198
Benefits following termination of employment contract	413	369
Total remuneration of individuals in key positions	**2,814**	**2,567**

The Management Board consisted of the Executive Director and seven members. The remuneration is subject to the Ordinance on the Personnel of the Swiss Agency for Therapeutic Products.

Events after the balance sheet date

No events that might have an impact on the information presented in these financial statements have occurred since the balance sheet date.

Report of the statutory auditors

Shape the future with confidence

Ernst & Young Ltd
Schanzenstrasse 4a
P.O. Box
CH-3001 Berne

Phone: +41 58 286 61 11
www.ey.com/en_ch

To the Federal Council regarding the financial statements of Swissmedic, Swiss Agency for Therapeutic Products, Berne

Berne, 30 April 2026

Report of the statutory auditor

Report on the audit of the financial statements

Opinion
We have audited the financial statements of Swissmedic, Swiss Agency for Therapeutic Products (the Agency), which comprise the balance sheet as at 31 December 2025, the income statement, the statement of comprehensive income, the cash flow statement and the statement of changes in equity for the year then ended, and notes to the financial statements, including material accounting policy information.

In our opinion, the accompanying financial statements give a true and fair view of the financial position of the Agency as at 31 December 2025 and of its financial performance and its cash flows for the year then ended in accordance with IFRS Accounting Standards and comply with Swiss law.

Basis for opinion
We conducted our audit in accordance with Swiss law, International Standards on Auditing (ISA) and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the “Auditor's responsibilities for the audit of the financial statements” section of our report. We are independent of the Group in accordance with the provisions of Swiss law, together with the requirements of the Swiss audit profession, as well as those of the International Ethics Standards Board for Accountants’ *International Code of Ethics for Professional Accountants (including International Independence Standards)* (IESBA Code). We have also fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other information
The Agency Council is responsible for the other information. The other information comprises the information included in the annual report, but does not include the financial statements, the stand-alone financial statements and our auditor’s reports thereon.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

Shape the future with confidence

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibility of the Agency Council for the financial statements
The Agency Council is responsible for the preparation of the financial statements, which give a true and fair view in accordance with IFRS Accounting Standards and the provisions of Swiss law, and for such internal control as the Agency Council determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Agency Council is responsible for assessing the Agency's ability to continue as a going concern, disclosing, as applicable, matters related to going concern, and using the going concern basis of accounting unless the Agency Council either intends to liquidate the Agency or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements
Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Swiss law, ISA and SA-CH will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on EXPERTsuisse's website at: https://www.expertsuisse.ch/en/audit-report. This description forms an integral part of our report.

Shape the future with confidence

Report on other legal and regulatory requirements

In accordance with Art. 728a para. 1 item 3 CO and PS-CH 890, we confirm that an internal control system exists, which has been designed for the preparation of the financial statements according to the instructions of the Agency Council.

We recommend that the financial statements submitted to you be approved.

Ernst & Young Ltd

Stefan Schmid
(Qualified Signature)
Licensed audit expert
(Auditor in charge)

Cédric Meyer
(Qualified Signature)
Licensed audit expert

Enclosure

- financial statements (balance sheet, income statement, statement of comprehensive income, cash flow statement, statement of changes in equity and notes)

swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7
3012 Bern
Tel. +41 58 462 02 11
www.swissmedic.ch