swissmedic

ANNUAL REPORT 2023

Mission

Our competence – for therapeutic products you can trust.

Guiding principles of Swissmedic

CONTENTS

FOREWORDS

Innovating for more efficient and effective authorisation and surveillance

Lukas Bruhin, President of the Agency Council

We have successfully completed the first year in the new 2023–2026 strategy period. In December 2022, the Federal Council approved our new strategic goals, which cover efficient, independent supervision, expansion of national and international cooperation and trust-driven communication with the public. Supporting innovation and promoting digitalisation is one focus area.

New technologies are increasing the efficacy and efficiency of market surveillance for medicinal products and medical devices. Swissmedic is more actively supporting the development of innovative therapeutic products to enable rapid access to new therapies. Our Innovation Office is an important component in our strategy of innovation. This office plays a major role in promoting and supporting innovative approaches to medicinal product development by providing scientific and regulatory advice. It acts as the interface between Swissmedic and the people actively involved in medicinal product development with the aim of speeding up access to new promising treatments while still guaranteeing regulatory safety and efficacy standards.

One milestone this year was the groundwork on the creation of a new Medical Devices Surveillance Sector. This organisational unit, which came into being on 1 January 2024, reflects the increased significance of medical devices activities as well as demonstrating our ability to adapt to the rapidly changing demands of the healthcare sector.

National and international cooperation and communication with the public remain extremely important, and Swissmedic is heavily engaged internationally as the audit by the Swiss Federal Audit Office (SFAO) has shown. The SFAO conducted a detailed analysis of our authorisation processes and monitoring systems during 2023 and found them to be very competitive compared with other countries. Despite this positive outcome, we will continue to improve our processes and performance during 2024.

I would particularly like to thank our employees, without whose commitment and expertise Swissmedic would not be a leading regulatory authority. Their willingness to work together in a multidisciplinary setting, encourage innovation and support the digital transformation we are undergoing is exemplary.

The years ahead will be dominated by the continuing development of digitalisation, the transformation of Swissmedic's platforms, the focus on personalised medicine and reachieving compliance with timelines. Swissmedic is willing to take up these challenges and to continue to serve the interests of public health.

Swissmedic sets the course for the future

Raimund Bruhin, Executive Director

2023 was the first year in Swissmedic's new strategy period. It is only the second four-year strategy period under the new governance system, which was enshrined in law as part of the bottom-up revision of the Therapeutic Products Act that has been in force since 2019. Last year was also the year in which managing the coronavirus pandemic ceased to be a dominant issue. Nevertheless, 2023 brought several challenges of its own, fast-paced operational business and a number of highlights.

The 2023–2026 strategy has been aligned with the Confederation's masterplan to strengthen biomedical research and technology. Certain elements of this masterplan were added to Swissmedic's strategic objectives and transferred to the operational environment. The continuing development of Swissmedic, the process of digital transformation at the Agency and regulatory innovations were addressed and international cooperation was further expanded.

One momentous milestone for Swissmedic was becoming a WHO-Listed Authority. We are one of the first three therapeutic products agencies in the world to fulfil the stringent international regulatory benchmark of the World Health Organization (WHO), having first undergone and achieved top ratings in a comprehensive assessment of all areas of our business. This achievement also earned us major international acclaim.

A further highlight was being granted Official Observer status at Management Committee meetings of the International Medical Device Regulators Forum. This strategic partnership enables us to help set standards for medical devices and in vitro diagnostic medical devices at global level, which in turn simplifies market surveillance and enforcement in Switzerland. At the same time, by creating our own Medical Devices Surveillance Sector at the beginning of 2024, we are giving this strategic business area the necessary weight both inside and outside the organisation, which will enable us to address on an equal footing with national and international stakeholders a spectrum of tasks that will only become broader and more challenging.

Digital transformation is a key factor in successful regulatory innovation, both within the organisation itself and in terms of its external impact in dealings with stakeholders, specifically international partner authorities and the domestic and global therapeutic products industry. This is an area where a systematic approach enabled us to lay the organisational and conceptual foundation at operational level. It also included the roll-out of an information security management system, which makes us one of the first administrative units to comply with the relevant IT security aspects in accordance with ISO/IEC 27001.

Swissmedic achieved its operational annual targets in a dynamic environment, positioned itself as an enabler of regulatory innovation by stepping up stakeholder dialogue and set its course for the future.

SWISSMEDIC AT A GLANCE

Core tasks of Swissmedic

Swissmedic is the Swiss Agency for Therapeutic Products. It is a scientifically independent, politically neutral authority with economic and safety-related supervisory tasks whose primary role in accordance with the legal basis is to ensure that only high-quality, safe and effective medicinal products and medical devices (therapeutic products) are placed on the market in Switzerland.

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. For the purposes of enforcing therapeutic products legislation, Swissmedic can impose administrative measures and initiate administrative proceedings. It also has a duty to provide public information about therapeutic products.

The key achievements and figures for 2023 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. The vast majority of its income is derived from fees and supervisory levies, with only a small part coming from taxes (payments from the federal government). The federal contribution is used to finance legislative and criminal prosecution activities and monitoring activities for medical devices. Swissmedic is an expert organisation. Accordingly, personnel expenses account for approximately 75 percent of operating costs.

The 2023 financial statements with accompanying commentary start on page 66.

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

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

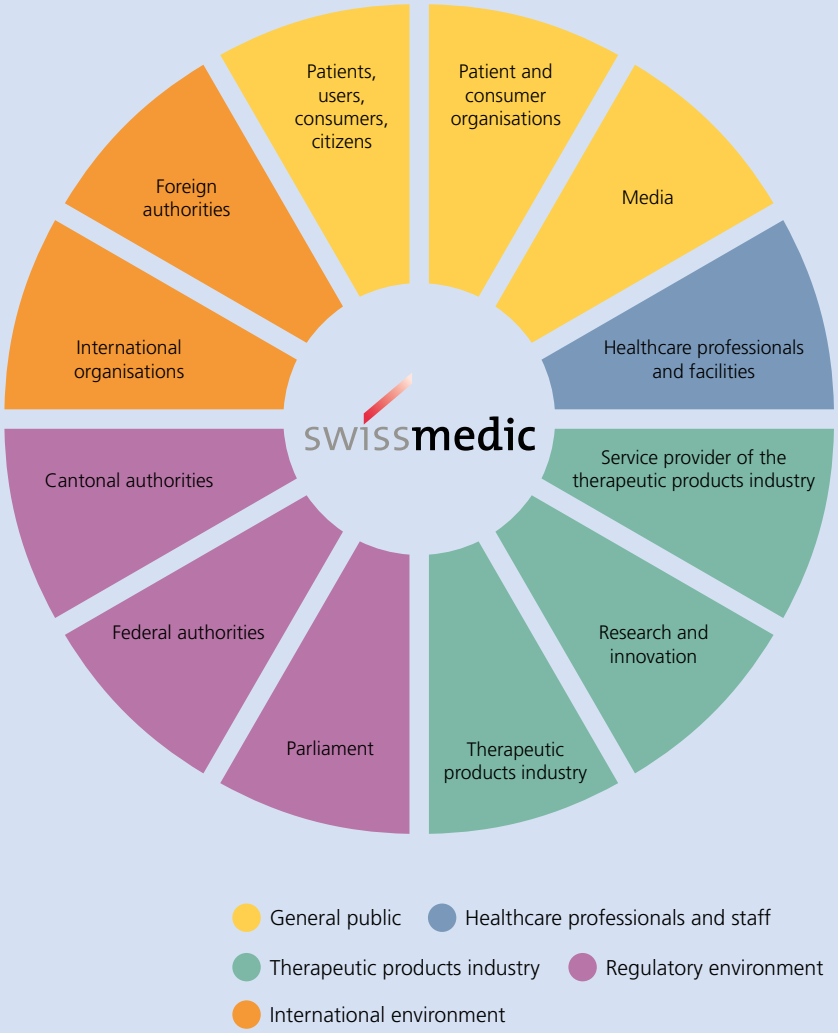
Information PG
- Informing the General Public (P)
- Informing the Therapeutic Products Sector (P)

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

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

Penal Law PG
- Penal Law (P)

Our stakeholders



Swissmedic fulfils its mandate in a broad-ranging environment characterised by varying needs and expectations. Its stakeholder map comprises:

- The public (citizens, users, patient and consumer organisations) and the media
- Healthcare and medical professionals and healthcare institutions (e.g. hospitals)
- The therapeutic products industry and its service providers, as well as research and innovation (start-ups, incubators and innovators)
- The regulatory environment, consisting of parliament and federal and cantonal authorities
- The international environment, consisting of international organisations and other countries' authorities

Swissmedic engages in regular national-level dialogue with its different stakeholder groups. The coordination meetings with representatives of the Association of Cantonal Pharmacists, the cross-agency Expert Panel for Delimitation Questions (with representatives of the FOPH, FSVO, the Cantons and Swissmedic), the patient and consumer organisations working group and the round table meetings with the therapeutic products industry and industry associations are well established.

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 and 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 Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)
- 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)

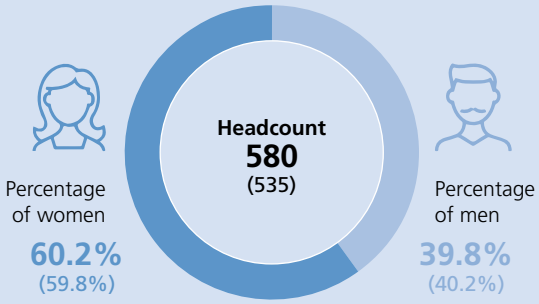
People, culture and values

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 impressive skills and commitment to ensure that only high-quality, safe and effective therapeutic products are placed on the market to protect the health of humans and animals.

Headcount rose by around 50 full-time positions (target figure) during 2023, firstly to keep pace with the strategic objectives of more intensive monitoring of the therapeutic products market, assisting the development of innovative treatments or digital transformation, and secondly to deal with new legal responsibilities, such as in data protection and information security. The human resources functional strategy for 2023 to 2026 sets out the activities and measures that human resources management will use to contribute to the implementation of the strategic objectives and ensures that Swissmedic will continue to have enough proficient and motivated people to enable it to efficiently perform the tasks assigned to it in a suitable organisation.

A competent and independent control of therapeutic products guarantees the safety of patients and is important for Switzerland as a location for pharmaceuticals and medical technology. Subject to the legal requirements, Swissmedic performs its tasks efficiently, transparently and independently. In fulfilling its official regulatory remit, Swissmedic consistently adheres to the principle of proportionality and follows international standards. Its supervisory remit involves a risk-based, international approach. Integrity, quality, transparency, commitment and respect are core values that define the way Swissmedic employees conduct themselves.

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



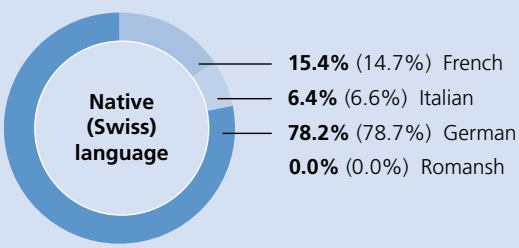
493 Full-time equivalents (current) (451)

Percentage of women in executive positions (40.6%) **42.5%**

47.1 Average age (46.8)

Part-time working (up to 89% FTE) (50.7%) **49.5%**

3.1% Fluctuation rate (5.1%)



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 current period of office ends on 31 December 2024. The rules put in place to guarantee the experts' neutrality are published on Swissmedic's website, as is a list of members and their vested interests.

The HMEC, chaired by Prof. Dr. Stephan Krähenbühl, met 12 times and issued 49 (previous year: 46) recommendations. The majority concerned new authorisations or additional indications for medicinal products. In addition, HMEC members carried out 21 (previous year: 26) assessments of parts of dossiers and 33 (previous year: 24) individual expert opinions were obtained.

The VMEC, chaired by Dr. Barbara Knutti, met twice and issued seven (previous year: eight) recommendations on applications for new authorisations of veterinary medicinal products, additional indications and new target animal species for authorised veterinary medicinal products. VMEC members also delivered 13 (previous year: 14) individual expert opinions.

Members of the HMEC/VMEC and their vested interests

Expert Commission for Radiopharmaceuticals

The Expert Commission for Radiopharmaceuticals employed by the Federal Council is made up of external experts from universities and hospitals across Switzerland. It works jointly with Swissmedic and the Federal Office of Public Health to assess applications for the authorisation and approval of radiopharmaceuticals that are subject to both therapeutic products and radiological protection legislation.

Pharmacopoeia experts

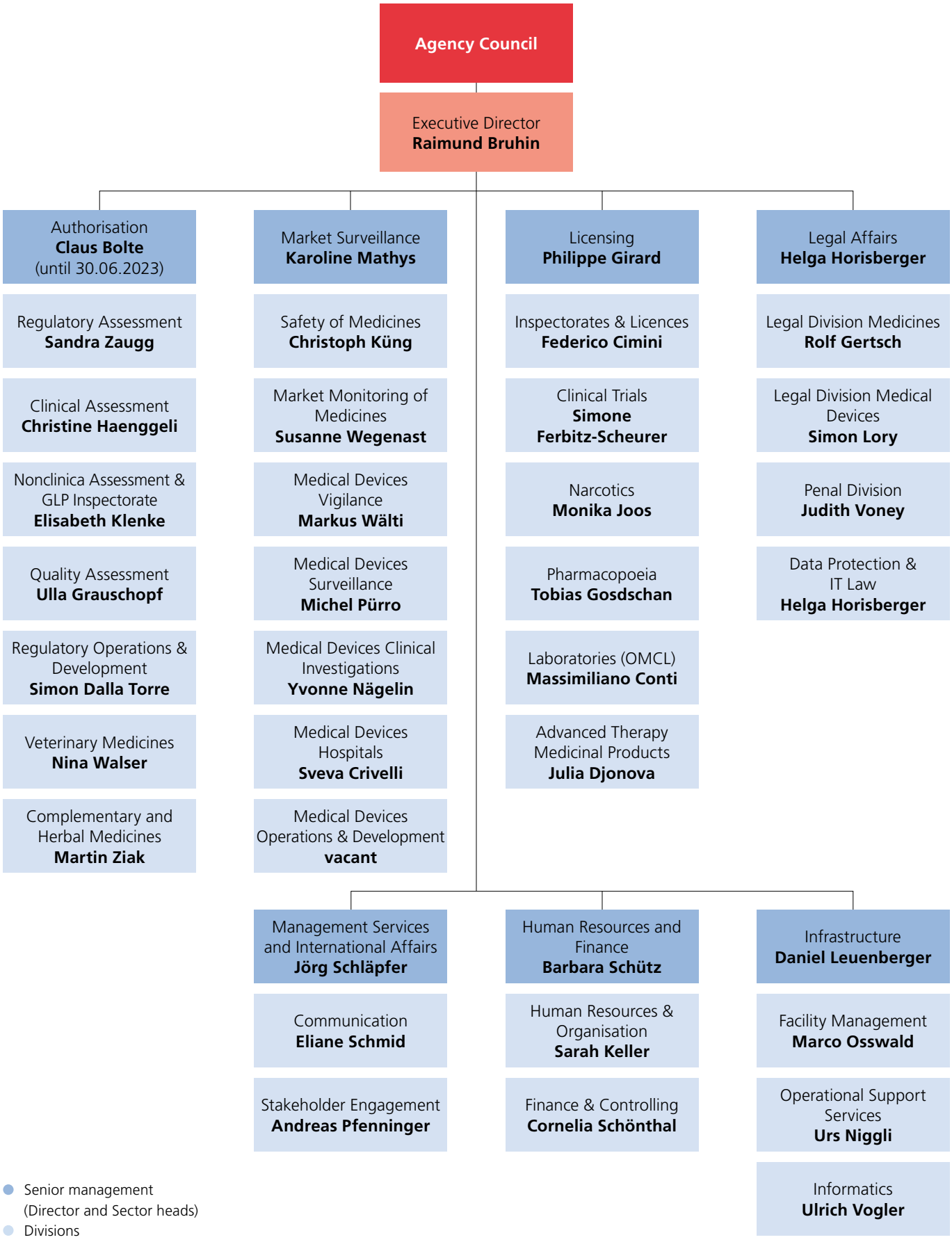
Around 130 Swiss specialists from industry, the universities, community and hospital pharmacies, druggists and authorities contribute to the preparation of the Pharmacopoeia. The experts work firstly in the Swiss pharmacopoeia expert groups convened by Swissmedic and secondly in the specialist committees 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 76 (previous year: 74) mandates are currently held across all Swiss pharmacopoeia committees.

Swiss experts currently hold 104 (previous year: 98) of the approximately 900 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 expert groups

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 the strategic objectives, submits them to the Federal Council for approval and reports annually on the fulfilment of objectives.

On 9 December 2022, the Federal Council approved the strategic objectives for 2023–2026, with their focus areas of:

- 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 medical professionals
- Being known to the public as a trustworthy authority
- Using state-of-the-art digital technologies and transforming into an agile and data-focused authority

Strategic objectives

The following milestones were achieved during 2023:

- New "Swissmedic surveillance and enforcement" concept implemented
- Additional inspection capacity and expertise created and more inspections (of clinical trials or players in the medical device sector, for example) conducted
- Innovation Office with a regular on-the-ground presence at various locations in Switzerland (Lausanne, Geneva, Zurich and Basel) set up and initial contact with over 30 start-ups, incubators and research groups established
- Official Observer status obtained at Management Committee meetings of the International Medical Device Regulators Forum
- Links established with the various cantonal representatives, particularly the single points of contact (SPOCs)
- Foundations laid for the roll-out of new technologies and sourcing of cloud services
- Data strategy approved
- Agile work organisation and digital transformation resources put in place

Sustainable development

The 2030 Agenda for Sustainable Development defines 17 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 Bill and Melinda 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. By doing so the Agency is also actively addressing one of Switzerland's health foreign policy goals. Work in this area during 2023 focused on dialogue and training courses for regulatory authorities from these countries. The two week-long regulatory training courses that took place at Swissmedic premises attracted a total of 46 participants from 16 countries. A further four people were trained to conduct GMP (Good Manufacturing Practice) inspections.

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

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

In 2023, Swissmedic launched its Innovation Office pilot project to support the development of novel therapeutic products. The office runs various campaigns to promote the development of advanced therapy medicinal products (ATMPs). The Innovation Office provides knowledge and advises university researchers and start-ups on the manufacturing conditions under which a product can be authorised or what conditions need to be met for a clinical trial or authorisation application to be approved. By taking a proactive approach to dialogue, Swissmedic learns what stakeholders' needs are and helps them fulfil regulatory and scientific requirements during the early stages. This happens both through Scientific Advice Meetings and the informal sharing of information during an ongoing project. Thanks to the close cooperation and the constant mutual sharing of knowledge, Swissmedic is able to process and approve the corresponding application for a promising treatment 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 has been promoting equal opportunities for many years by offering attractive employment conditions and part-time working. The proportion of women in executive positions rose from 40 to 44 percent during 2023. There will be equal numbers of women and men on the Management Board from January 2024.

(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)

Swissmedic has been using renewable energy at its three buildings for many years, and the Agency is constantly expanding its renewable sources. An additional photovoltaic installation with an output of just under 113 kWp came on stream at Swissmedic's headquarters and office building at Hallerstrasse 7 in October 2023. The existing system on the flat roof of the office building at Erlachstrasse 8 was upgraded by the addition of extra panels, which increased total output from 19.5 kWp to 23 kWp. These systems, together with the system at the laboratory and office building at Freiburgstrasse 139, generated a total of approximately 149,000 kWh of electricity in 2023.

By generating its own heat from photovoltaic and geothermal sources, Swissmedic has been able to substantially reduce the amount it sources from the district heating network in recent years. Adopting a variety of measures such as the systematic conversion of the lighting to LED technology also reduced Swissmedic's total energy consumption by approximately 10 percent year-on-year from 1,405 MWh to 1,277 MWh.

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

SUSTAINABLE DEVELOPMENT GOALS

Internationally networked and recognised

In October 2023, Swissmedic was one of the first three therapeutic products agencies in the world to be listed by the World Health Organization (WHO) as a WHO-Listed Authority (WLA). Thus the Agency has been recognised as a regulatory authority that complies with international standards and practices following an assessment using the WHO's global benchmarking tool. Listing provides confirmation that Swissmedic has achieved maximum maturity in all areas of its operational business. The WLA framework was initiated based on the World Health Assembly Resolution on strengthening regulatory systems for medical products and the WHO Roadmap for access to medicines, vaccines and health products 2019–2023. The WLA-framework provides a transparent and evidence-based pathway for regulatory authorities to be globally recognised as meeting WHO and other internationally accepted standards and practices. Having a list of trusted WLAs in place will facilitate reliance among regulatory authorities and enhance international cooperation with the aim of promoting better access to safe, effective, high-quality medicinal products.

Standardisation and harmonisation of medicinal product regulatory requirements has been ongoing for many years. Swissmedic contributes to and takes leadership roles in international organisations such as the International Council for Harmonisation (ICH), where the Agency once again held the vice chairship of the ICH Assembly in 2023. The task of driving forward international convergence and harmonisation for medical devices regulations lies with the International Medical Device Regulators Forum (IMDRF). Such harmonisation provides an important basis for reducing regulatory effort for both authorities and companies and for exploiting synergies through regulatory cooperation. After Swissmedic had become an established member of five out of eight international working groups within a short time, the IMDRF granted it Official Observer status at Management Committee meetings. This new status is an important interim step towards Swissmedic's strategic objective of being admitted as a member of the Management Committee.

Swissmedic partners with other authorities to review authorisation applications for medicinal products and also works with them on market surveillance. The Access consortium (therapeutic products authorities of Australia, Canada, Singapore, the United Kingdom and Switzerland) reviews applications using a work-sharing arrangement, while Project Orbis, an initiative by the Oncology Center of Excellence of the US Food and Drug Administration (FDA) to speed up authorisation processes for new cancer treatments at global level, operates under a parallel assessment approach.

International cooperation is also important in market surveillance, particularly in connection with emerging risks. For example, the Nitrosamine Specialist Group coordinates interaction with international partner authorities and represents Swissmedic in international committees to ensure a harmonised approach to requirements for dealing with potentially genotoxic impurities in medicinal products.

Swissmedic also holds regular international dialogue on approaches to digital transformation and the real-world implementation of the cloud strategies pursued by therapeutic products authorities, particularly with the European Medicines Agency, the member organisations of the Access Consortium and the FDA. The Swissmedic4.0 innovation lab's cooperation with the FDA, authorities in the Netherlands, the Paul Ehrlich Institute, the Brazilian Health Regulatory Agency and Israeli authorities on large language models (LLMs) played a significant role during 2023. The LLM Task Force developed an application called AskYourDocuments that enables the authorities to work with confidential files in a secure environment. Swissmedic also made a key contribution to a position paper on the secure use of LLMs from a regulatory science perspective. Finally, Swissmedic is involved in the Global Coalition for Regulatory Science Research and will co-chair the organisation's 2024 summit.

WHO-Listed Authority (WLA)

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 from 2020 to 2023.

Swissmedic is divided into the following seven Sectors: Authorisation, Market Surveillance, Licensing, Legal Affairs, Management Services and International Affairs, Human Resources and Finance, and Infrastructure. The Sector heads are members of the Management Board and report directly to the Executive Director.

Work commenced on the creation of a dedicated Medical Devices Sector during 2023. The organisational project was completed on schedule. By the end of the year, all necessary regulatory, organisational, staffing and administrative work had been completed, and the new organisational structure comprising the core Sectors of "Medicinal Product Authorisation and Vigilance", "Medicinal Product Licences and Surveillance" and "Medical Devices Surveillance" was implemented on schedule on 1 January 2024.

The Transformation of Swissmedic Platforms (TSP) Division of the Infrastructure Sector was dissolved after the initialisation phase had been completed in mid-2023. The development of new digital enterprise solutions and coordination of the technical, organisational and transformational activities needed to replace the existing applications will now be managed by the TSP programme, which can be adapted to the relevant requirements and needs with greater agility.

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 President. 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,** President; attorney-at-law; partner in Arioli Law, owner and general manager of Layout Consulting GmbH
- **Giovan Maria Zanini,** Vice President; 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 Ruegg Bless,** regional governor (Statthalter) and Chair 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

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-a-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.

Lukas Bruhin, President (since 1 August 2020)

Giovan Maria Zanini, Vice President (since 1 January 2015)

Daniel Betticher, Prof. Dr. med. (since 1 January 2020)

Lukas Engelberger, Dr. iur. (since 1 April 2017)

Olivier Guillod, Prof. Dr. iur. (since 1 January 2015)

Monika Rüegg Bless (since 1 January 2022)

Marie-Denise Schaller, Prof. Dr. med. (since 1 January 2018)

Agency Council

The Agency Council appoints a strategy committee, a finance and controlling committee, an appointments and remuneration committee, and a government committees committee from among its ranks. The committees deal with matters falling within their area of responsibility and submit them to the full Agency Council.

Key issues during 2023 were political and regulatory developments in medical devices, digital transformation and the appointment of the new Head of Authorisation and Vigilance. One of the tasks the Agency Council addresses each year is the disclosure of Council members' vested interests and Management Board members' occupations and public offices held. The Agency Council members also attended various training events and conferences (for example boardroom best practice, healthcare sector trends, law and innovation).

Remuneration for the Agency Council in 2023 totalled CHF 194,000 (previous year: CHF 202,000) including expenses, of which CHF 54,000 (previous year: CHF 58,000) was paid to the President.

Management Board

Raimund Bruhin, Dr. med.; Executive Director

Claus Bolte, Dr. med.; Deputy Executive Director (until 30 June 2023)

Philippe Girard, Dr.; Vice Director

Helga Horisberger

Daniel Leuenberger

Karoline Mathys Badertscher, Dr. pharm.

Jörg Schläpfer, Dr. med. vet., PhD

Barbara Schütz Baumgartner

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. Of the eight members, three – or 37.5 percent – are women.

- **Raimund Bruhin,** Dr. med.; Executive Director
- **Claus Bolte,** Dr. med.; Deputy Executive Director, Head of Authorisation Sector (until mid-2023)
- **Philippe Girard,** Dr.; Vice Director, Head of Licensing Sector
- **Helga Horisberger,** Head of Legal Affairs Sector
- **Daniel Leuenberger,** Head of Infrastructure Sector
- **Karoline Mathys Badertscher,** Dr. pharm.; Head of Market Surveillance Sector
- **Jorg Schlapfer,** Dr. med. vet., PhD; Head of Management Services and International Affairs Sector
- **Barbara Schütz Baumgartner,** Head of Human Resources and Finance Sector

At the end of 2022, Dr. Claus Bolte decided to step down from his post with effect from 30 June 2023. His deputy, Dr. Elisabeth Klenke, led the Authorisation Sector on an interim basis until year end. Dr. Eveline Trachsel joined the Management Board as the new Sector Head on 1 January 2024.

The Management Board confirms compliance with the Swissmedic Code of Conduct annually and publishes 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 Ordinance on the Personnel of the Swiss Agency for Therapeutic Products. The total amount paid to the Management Board in remuneration was CHF 1,980,906 (previous year: CHF 2,059,811), of which CHF 333,268 was paid to the Executive Director (previous year: CHF 322,690).

Management Board

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 classified the new EU pharmaceutical regulation as a strategic risk during 2023. 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 2023 and reported that the level of documentation was appropriate for Swissmedic's size and complexity.

During 2023, the process of initially setting up the information security management system (ISMS) that complies with ISO/IEC 27001 begun in 2022 was completed and the ISMS went into operational service. This makes Swissmedic one of the first administrative units to have an institutionalised ISMS and gives the Agency a valuable tool for structured management of information security risks and measures.

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.

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. The Federal Council opened the consultation procedure on 8 December 2023, and it continued until the end of March 2024. The revision addresses three specific issues: digitalisation of therapeutic products prescribing, dispensing and use; advanced therapy medicinal products (ATMPs); and extensive alignment of the rules for veterinary medicinal products with the modified EU legislation.

Revision of Agency ordinances

The Ordinance on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO) was revised during 2023. This revision was prompted by Parliament's decision in September 2022 to simplify the rules for parallel imports of medicinal products as part of the cost containment package. The new provisions in the Ordinance reduce the cost of parallel imports to marketing authorisation holders without compromising patient safety. The changes took effect on 1 January 2024.

Furthermore, the various Annexes to the Ordinances issued by the Agency Council were reviewed in light of the current state of the art in science and amended as necessary. The Annexes to the Ordinance on the Simplified Licensing and Notification Procedure for Complementary and Phytotherapeutic Products (KPTPO) were revised during 2023. Work on revising the Annexes to the Ordinance on the Licensing Requirements for Therapeutic Products (TPLRO) was started, as was the revision of TPLO.

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.

34 substances and one new group of substances were added to the Narcotics Lists Ordinance during 2023. These included tramadol, various designer drugs, hexahydrocannabinol and a further cannabinoids substance group.

New ordinances and revision of existing ordinances

The following ordinances are currently being revised or created:

- Ordinance on clinical trials of medicinal products
- Ordinance for devitalised cells and tissue

Mutual Recognition Agreement

In January 2023, Switzerland and the United States signed a Mutual Recognition Agreement (MRA) covering Good Manufacturing Practice (GMP) inspections for medicinal products. The Agreement came into force on 27 July 2023 after the two partner authorities – Swissmedic and the US Food and Drug Administration (FDA) – had scrutinised each other's processes for monitoring medicinal product manufacturers in their respective countries and found them to be comparable. The Agreement strengthens Switzerland as a centre of pharmaceutical activity and puts it on an equal footing with the European Union (EU) and United Kingdom in terms of the US market.

Memorandum of Understanding

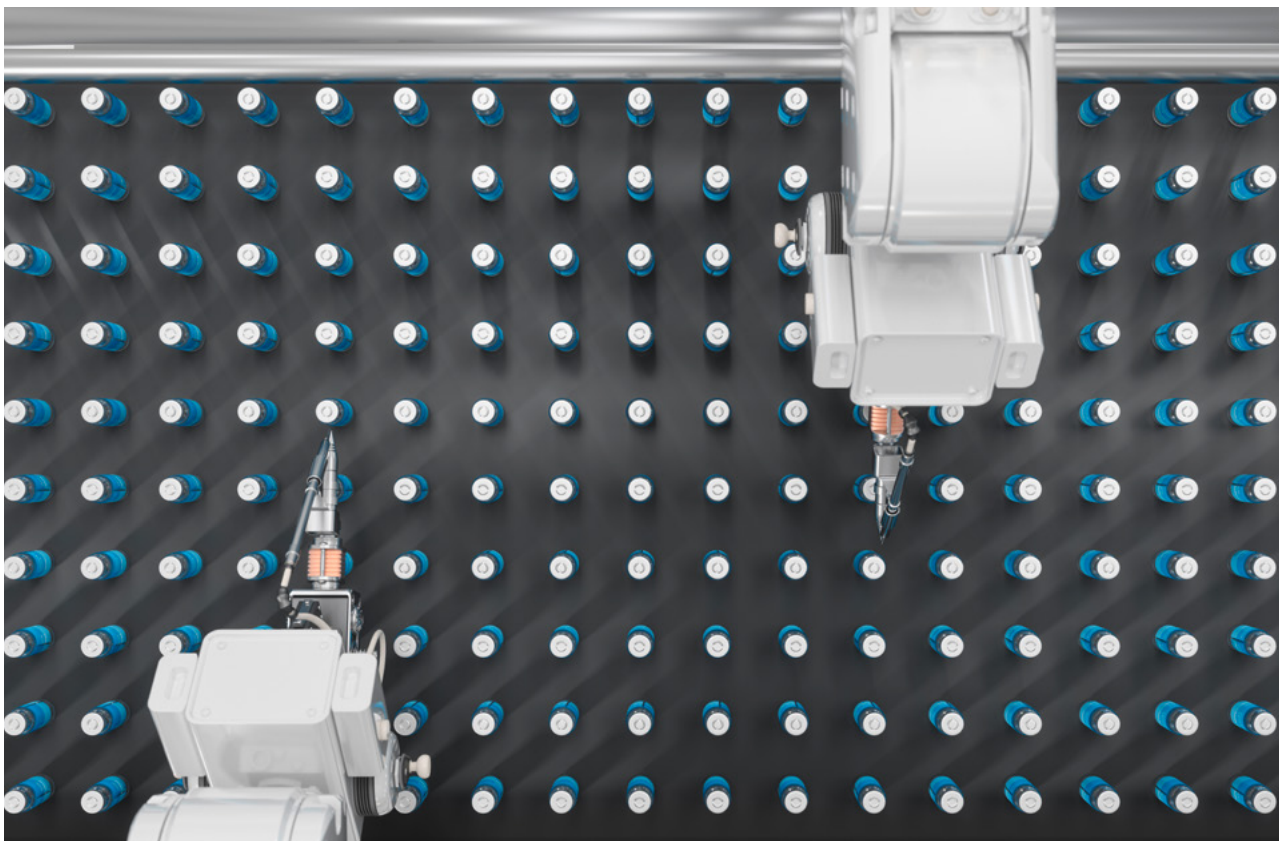
On 26 January 2023, Swissmedic signed a Memorandum of Understanding (MoU) with the United Kingdom's Veterinary Medicines Directorate (VMD). The signing of the Memorandum of Understanding is the result of the excellent bilateral collaboration with the VMD. The aim of the collaboration is to promote understanding of regulatory frameworks and sharing of information. The focus here is on increased collaboration in the review of authorisation applications for veterinary medicinal products.

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 reflect the current state of science and technology and are legally binding.

The 11th edition of Ph. Eur., including Supplements 11.1 and 11.2, and the 12th edition of Ph. Helv. came into effect during 2023. The latter had been published in October 2022 to allow users to implement it on time.

In September 2023, Swissmedic hosted the editorial conference for the German edition of Ph. Eur. The conference comprises representatives from Germany, Austria and Switzerland who make a contribution to medicinal product safety in German-speaking countries by translating the Ph. Eur.



MEDICINAL PRODUCTS – **INFORMATION 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 aims to build public confidence in the Agency by providing balanced, objective and audience-appropriate information. In addition to its website and various newsletters, its primary mass-audience publication is "Visible" magazine. "Visible" is published twice a year in printed form and as an online version with added video content. The magazine gives an in-depth insight into Swissmedic's work.

As part of celebrations to mark the 175th anniversary of the Federal Constitution, Swissmedic took part in the Federal Administration's open day event, hosting a stand and a quiz show and talking to visitors from across Switzerland.

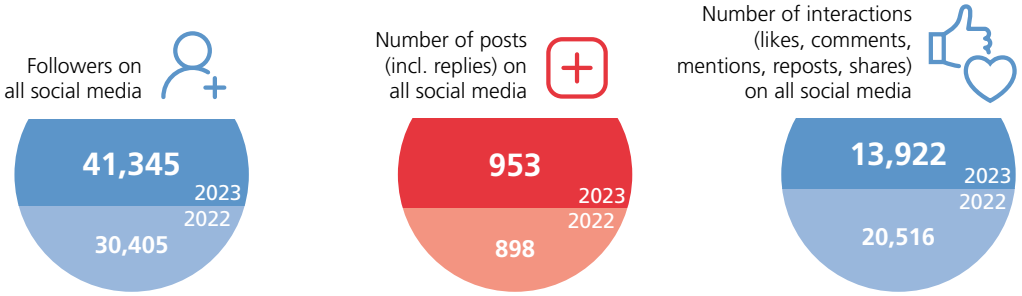
Social media

Information was regularly posted on LinkedIn, Facebook, X (formerly Twitter) and Instagram. Posts included warnings against illegally importing medicinal products as well as information on international campaigns such as MedSafetyWeek. At the end of 2023, Swissmedic had over 41,300 followers across all channels. Although Swissmedic actively posted slightly more than in 2022, there were substantially fewer reactions. Swissmedic employs rapid, transparent and demands-driven community management to promote confidence in its activities.

Press relations

Swissmedic recorded 1,125 contacts with media representatives during 2023. Just under 1,000 of these concerned medicinal products and business policy. The number was thus around 50 percent higher than before the pandemic. As in 2022, Swissmedic specialists gave 20 interviews and background briefings.

Issues such as illegal imports of medicinal products, the ban on designer drugs and the blood donation criteria for men who have sex with men approved by Swissmedic generated broad interest. However, the spotlight shifted from the key issue of preceding years – the COVID-19 pandemic and the authorisation of vaccines, including indication extensions and undesirable effects.



Enquiries

Each year, Swissmedic answers questions from lay-people, medical professionals, other specialists and stakeholders. Just under 6,000 enquiries were received during 2023, with COVID-related questions declining significantly compared to 2022 and 2021. The main issues of public concern were the general rules applicable to medicines needed when travelling, importing medicines for personal use and cannabis for medical purposes. Specialist questions primarily concerned establishment licences and the role of Responsible Persons.

Transparency / FoIA

The Federal Act on Freedom of Information in the Administration (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.

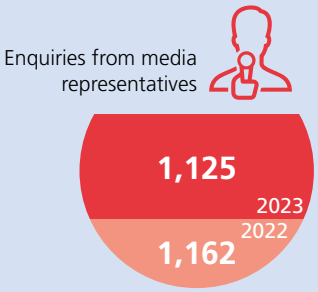
The number of freedom of information requests submitted increased year-on-year. Full or partial access was granted in most cases, but completely refused in three.

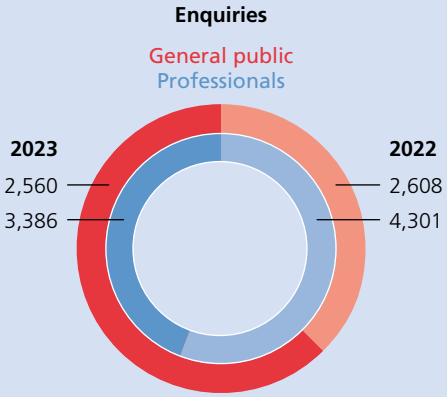
No appeals are currently pending before the Federal Administrative Court or Federal Supreme Court regarding freedom of information requests.

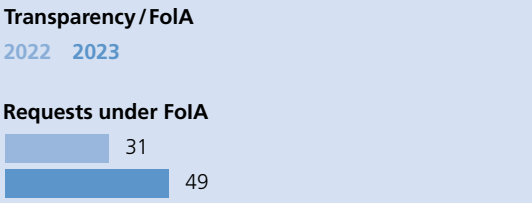
Parliamentary proposals and expert evidence to parliamentary committees

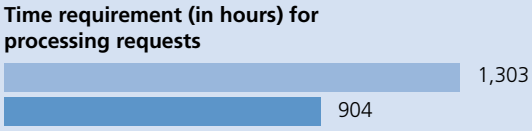
Swissmedic acted as lead agency on three (previous year: 12) parliamentary proposals. One is connected with the digitalisation of healthcare and sets out to establish whether all pharmaceutical forms that are used solely by medical professionals can be omitted from package leaflets if there is a QR code on the packaging. The National Council rejected one postulate demanding Swissmedic's association with the European Medicines Agency (EMA).

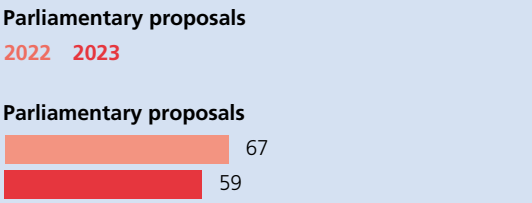
Swissmedic representatives attended the meetings of various parliamentary committees throughout the year, providing information on matters such as approaches to innovation in the medicinal products sector.











Publications and events for professionals

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

The round table meetings are an important forum for dialogue with the therapeutic products industry and industry associations. Round table meetings with stakeholders from the regulatory affairs, electronic Common Technical Dossier (eCTD), veterinary medicinal products and Good Manufacturing and Distribution Practice (GMP/GDP) areas were held during 2023. Discussions included the Access Consortium's new work-sharing procedure for priority submissions (Promise Pilot Pathway), optimising accelerated application hearings and the performance of inspections in other countries.

A round table meeting on innovation was held with representatives of academia, industry and the EMA. The topic was regulatory implementation of the 3Rs (replace, reduce, refine) and the use of new methods to replace animal testing in medicinal product safety.

Other events were also held, such as the clinical trials symposium, the inspectors' training course, which attracted GMP and GDP inspectors from all corners of the globe, the EDQM Borderline Products Network meeting and the Medicrime meeting, a forum in which national and cantonal enforcement agencies and public prosecutors can share information on the fight against therapeutic products crime.

MEDICINAL PRODUCTS – **MARKET ACCESS PRODUCT GROUP**

Authorisation product

Overview

In 2023, 12,342 (previous year: 12,530) authorisation applications and applications for variations were submitted for human and veterinary medicinal products, and 12,022 (previous year: 11,720) were completed. The target values for compliance with the time limits for first authorisations, extensions and major variations were not achieved. Of the 41 human medicines with new active substances authorised, Swissmedic processed 35 (85 percent) within the prescribed time limits. The median delay for the remaining six was 16 calendar days. 106 (previous year: 77) company meetings were held before or during the authorisation process. At the end of 2023, 4,036 (previous year: 3,961) applications were in progress.

Applications received	2023	2022
First authorisations of innovative medicinal products	114	101
First authorisations of non-innovative medicinal products	245	188
Extensions	59	48
Major variations	1,846	2,213
Minor variations	7,247	7,377
Other applications	2,831	2,603

Applications completed	2023	2022
First authorisations of innovative medicinal products	103	109
First authorisations of non-innovative medicinal products	180	230
Extensions	33	42
Major variations	1,723	1,649
Minor variations	7,184	7,173
Other applications	2,799	2,517

Deadline compliance	2023	2022
First authorisations of innovative medicinal products	83%	97%
First authorisations of non-innovative medicinal products	91%	97%
Extensions	88%	97%
Major variations	75%	97%
Minor variations	100%	95%
Other applications	97%	95%

Authorisation procedure

Various authorisation procedures are available to applicants for new authorisations, extensions and new or modified indications. Swissmedic differentiates between procedures with standard time limits (the standard and reliance procedures) and various fast-track procedures.

Authorisation under Article 13 Therapeutic Products Act

The first reliance procedure is the authorisation procedure under Article 13 TPA. 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 provided that the submitted documents from the foreign procedure are not more than five years old, correspond to the authorisation status in the other country, and that full final assessment reports exist.

Authorisation under Article 14 Therapeutic Products Act

The second reliance procedure is the procedure under Article 14 para. 1 let. a$^{bis\text{-}quater}$ TPA. 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.

Fast-track authorisation procedure

It is possible to request a fast-track authorisation procedure (FTP) 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 use of the medicinal product promises 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 once 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.

Procedure with prior notification

Applicants can request a procedure with prior notification (PPN) 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 reviews authorisation applications under a work-sharing arrangement. In Orbis, applications are reviewed in parallel with the FDA and other regulatory authorities.

Number of applications for new authorisations, extensions and variations processed under reliance procedures

Human medicinal products

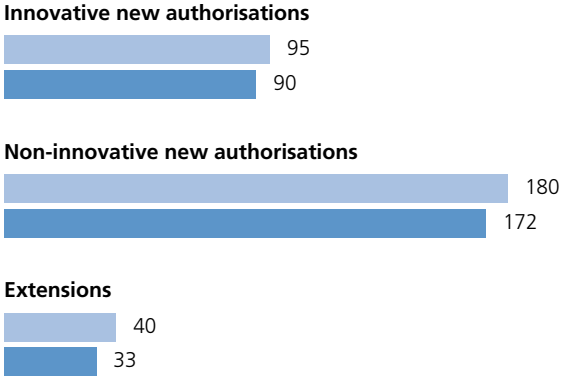
New authorisations and extensions

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 (medicinal products with new active substances or extensions such as new pharmaceutical forms) and non-innovative medicinal products (e.g. medicinal products with known active substances).

Activities:
Completed applications for innovative and non-innovative new authorisations and extensions fell by a good 6 percent year-on-year.

Number of applications completed for

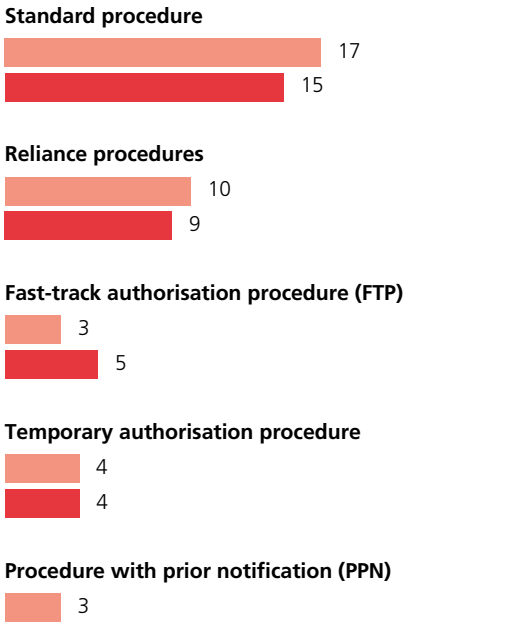
2022 **2023**



41 (previous year: 47) of the 90 innovative new authorisations involved human medicinal products with new active substances. Authorisation was granted under various procedures. Fast-track procedures were used for 17 applications (41 percent). The median lead time (companies' time and Swissmedic's time) was 441 (previous year: 456) calendar days. The resulting lead time for the four Access procedures was 403 (previous year: 340) calendar days, and that for the five Orbis procedures 341 (previous year: 403) days. Participation in Orbis had a positive effect on submission gaps (timing of submissions to the different authorities), which were just 31 days (median) compared with the FDA.

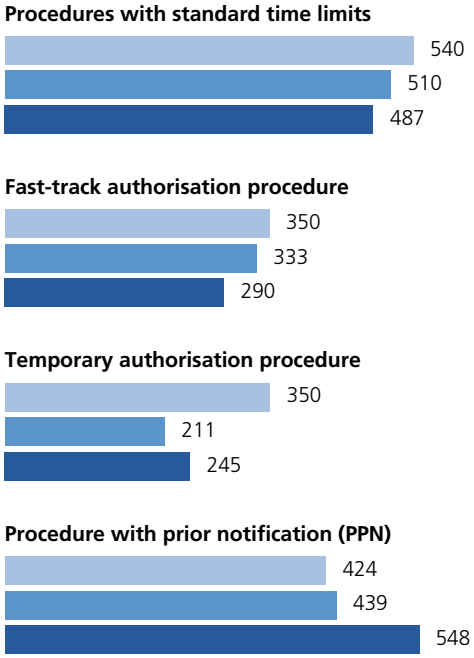
Number of new authorisations of human medicinal products with new active substances by procedure (multiple procedures possible)

2022 **2023**



Median lead time in calendar days for different authorisation procedures for human medicinal products with new active substances

Time limit 2022 **2023**



12 of the 65 approved applications for indication extensions were processed under the fast-track procedure. The median lead time for all new applications was 352 (previous year: 345) calendar days.

Number of authorised indication extensions (multiple procedures possible)

2022 2023

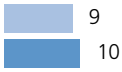
Standard procedure

Reliance procedures

Fast-track authorisation procedure (FTP)

Procedure with prior notification (PPN)

International procedures (Access and Orbis)



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 major variations include such items as additional indications, substantial changes in active substance or finished product manufacturing processes or changes in recommended dosage.

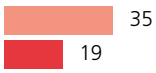
Activities:
Type II variations decreased by 6 percent. A total of 1,560 (previous year: 1,668) were completed.

Number of completed type II variations

2022 2023

Additional indications

Change in recommended dosage



All other type II variations

Minor variations and other applications

Any variation to an authorised medicinal product requires approval by Swissmedic. 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. Of the remaining applications, around 70 percent were for authorisation renewals, quality conditions or discontinuation of authorisation

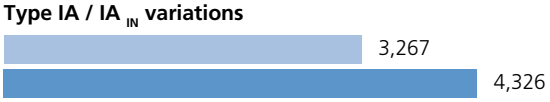
Activities:
Applications in this category increased by around 17 percent, with 9,332 (previous year: 7,953) being completed.

Number of completed variations
Collective applications were counted as one application

2022 2023

Type IB variations

Type IA / IA_{IN} variations



Other applications

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 (previous year: two) ATMPs with new active substances were authorised during 2023: two gene therapy products and one product based on small interfering ribonucleic acid (siRNA).

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 by an agency with comparable medicinal product control (particularly the EMA or FDA).

Activities:
Orphan drug status was recognised in 46 cases (previous year: 40). 27 (previous year: 20) 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. Biosimilars differ from generics in that evidence of clinical efficacy and safety has to be provided.

Activities:
Two (previous year: 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 investigation plans.

Activities:
18 applications for verification of complete fulfilment of PIP conditions were completed, 16 of which were approved. In addition, 22 (previous year: 29) paediatric trials were authorised in 2022.

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:
One (previous year: five) new vaccine was approved in 2023. Moreover, three vaccines were converted from a temporary authorisation to an authorisation with completed documentation.

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 TPA.

Activities:
14 applications for the authorisation of production of non-standardisable medicinal products were being processed in 2023, the same number as in 2022.

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 for a specific indication, a large number of medicinal products with no indication are authorised for individual therapy, generally under a notification procedure, under which, in accordance with legal requirements, proof of efficacy does not have to be provided.

Activities:
Eight (previous year: eight) applications for the new authorisation of complementary medicinal products with indication were completed.

Once again, there was a significant rise in authorisations of single products without indication (homeopathic and anthroposophic medicines, and Chinese medicinal products).

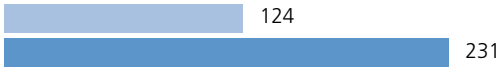
Completed new applications for complementary medicinal products

2022 2023

Medicinal product with indication under simplified procedure

Simplified authorisation with reduced dossier

Single products without indication under notification procedure



Combined products without indication under notification procedure

Herbal medicinal products

Herbal medicinal products are medicinal products with specified indications, whose active substances consist entirely of one or more herbal substances or one or more herbal 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:
Eight (previous year: ten) applications for new authorisation were completed under the simplified authorisation procedure including three co-marketing medicinal products.

Veterinary medicinal products

Since 1 January 2023, Swissmedic has also been responsible for authorising and monitoring the safety, quality and efficacy of immunological veterinary medicinal products such as vaccines. Transferring responsibility for these immunological veterinary medicinal products from the Institute of Virology and Immunology (IVI) to Swissmedic pools responsibilities, increases efficiency and leverages specialist synergies. A total of 119 veterinary medicinal products were transferred from the IVI to Swissmedic.

At the request of Swissmedic and scienceindustries, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) has granted Switzerland Official Observer status. The VICH is a trilateral programme between the EU, USA and Japan which aims to harmonise the technical requirements for the registration of veterinary medicinal products. As an Observer, Swissmedic is entitled to attend Steering Committee meetings, delegate experts to Working Groups and thus to work actively with partner authorities and industry associations in other countries to drive the ongoing development of international requirements for the authorisation of veterinary medicinal products.

New authorisations

New authorisation of veterinary medicinal products is granted following a comprehensive review of the safety, efficacy and quality documentation submitted by the applicant. The authorisation procedure distinguishes between innovative medicinal products (medicinal products with new active substances) and non-innovative medicinal products (medicinal products with 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 when the product in question has been administered to animals.

Activities:
21 (previous year: 15) applications for new authorisations were completed, five of which involved immunological veterinary medicinal products.

Number of new applications completed

2022 2023

Innovative new authorisations

Non-innovative new authorisations

Seven (previous year: three) of the 13 innovative new authorisations involved veterinary medicinal products with new active substances. The median lead time (companies' time and Swissmedic's time) for these applications was 440 calendar days. Three applications were authorised under Article 13 of the Therapeutic Products Act.

Variations

Activities:
A total of 569 (previous year: 559) applications for variations were processed and completed.

Number of applications completed for

2022 2023

Additional indications

All other type II variations assessed as "major"

Type IB variations assessed as "minor"

Variations without assessment

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:
Two (previous year: five) official decisions connected with product authorisation were contested before the Federal Administrative Court in 2023. Five cases are currently still pending before the Federal Administrative Court, while four appeals are pending before the Federal Supreme Court.

First authorisations of human medicinal products with a new active substance

	Medicinal product	Active substance(s)	Indication
Oncology and haematological malignancies	Jaypirca	Pirtobrutinib	Mantle cell lymphoma (MCL)
	Ayvakyt	Avapritinib	Gastrointestinal stromal tumours (GIST)
	Lunsumio	Mosunetuzumab	Follicular lymphoma
	Elrexfio	Elranatamab	Multiple myeloma
	Talvey	Talquetamab	Multiple myeloma
	Imjudo	Tremelimumab	Hepatocellular carcinoma
	Columvi	Glofitamab	Diffuse large B-cell lymphoma (DLBCL)
	Elzonris	Tagraxofusp	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
	Zepzelca	Lurbinectedin	Small cell lung cancer (SCLC)
	Kimmtrak	Tebentafusp	Uveal melanoma
Haematology and haemostaseology	Alhemo	Concizumab	Factor IX deficiency
	Hemgenix	Etranacogene dezaparvovec	Factor IX deficiency
	Aspaveli	Pegcetacoplan	Paroxysmal nocturnal haemoglobinuria (PNH)
	Enjaymo	Sutimlimab	Cold agglutinin disease
Infectiology and vaccines	Livtencity	Maribavir	Cytomegalovirus (CMV) infection/illness following stem cell/organ transplants
	Sunlenca	Lenacapavir	HIV-1 infection
	Beyfortus	Nirsevimab	Prevention of respiratory syncytial virus (RSV) infection
	Vaxneuvance	Pneumococcal polysaccharide conjugate vaccine	Active immunisation for the prevention of *Streptococcus pneumoniae* infection
Endocrinology and metabolism	milgamma	Benfotiamine	Vitamin B1 deficiency
	Elfabrio	Pegunigalsidase alfa	Alpha-galactosidase A deficiency (Fabry disease)
	Libmeldy	Atidarsagene autotemcel	Metachromatic leukodystrophy
	Xenpozyme	Olipudase alfa	Acid sphingomyelinase deficiency (Niemann-Pick disease)
Diagnostics	Verdye	Indocyanine green	Cardiovascular and microcirculation, hepatic function, ocular blood flow
	Elucirem	Gadopiclenol	CNS and other parts of the body
	Locametz	Gozetotide	Prostate cancer
Rheumatology and immunology	Spevigo	Spesolimab	Generalised pustular psoriasis
	Lupkynis	Voclosporin	Lupus nephritis
	Condrosulf Plus	Chondroitin sulfate, glucosamine	Gonarthrosis
Cardiology and nephrology	Vafseo	Vadadustat	Symptomatic anaemia associated with chronic kidney disease
	Camzyos	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy (oHCM)
Gastroenterology	Spaverin	Drotaverine	Functional disorders of the gastrointestinal tract
	Omvoh	Mirikizumab	Ulcerative colitis

	Medicinal product	Active substance(s)	Indication
Neurology and psychiatry	Vydura	Rimegepant	Migraine
	Amvuttra	Vutrisiran	Hereditary transthyretin amyloidosis (hATTR amyloidosis) with polyneuropathy
Radiotherapeutic agents	Pluvicto	Lutetium (177Lu) vipivotide tetraxetan	Prostate cancer (mCRPC)
	Pluvicto CA	Lutetium (177Lu) vipivotide tetraxetan	Prostate cancer (mCRPC)
Dermatology	Letybo	Botulinum toxin type A (CBFC26 strain)	Vertical lines between the eyebrows
	Nuceiva	Botulinum toxin type A (from *Clostridium botulinum* strain KCDC)	Vertical lines between the eyebrows
Gynaecology and obstetrics	Veoza	Fezolinetant	Vasomotor symptoms (VMS) in postmenopausal patients
	Ryeqo	Relugolix, estradiol, norethisterone	Heavy menstrual bleeding associated with uterine fibroids
Ophthalmology	Roclanda	Lantanoprost and netarsudil	Elevated intraocular pressure associated with primary open-angle glaucoma or ocular hypertension

First authorisations of veterinary medicinal products with a new active substance

	Medicinal product	Active substance(s)	Indication
Antidiabetics	Senvelgo 15 mg/ml ad us. vet	Velagliflozin	Treatment of diabetes mellitus in cats
Appetite stimulants	Eluracat 20 mg/ml ad us. vet	Capromorelin	Stimulation of weight gain in cats with poor appetite or unintended weight loss resulting from chronic kidney disease.
Antiparasitics	Felpreva ad us. vet	Tigolaner, praziquantel, emodepside	Treatment of cats with, or at risk of, mixed parasitic infection
Vaccines	CircoMax ad us. vet	Two inactivated recombinant chimeric porcine circovirus 1 expressing the porcine circovirus 2a ORF2 protein and the porcine circovirus 2b ORF2 protein, respectively	Induction of active immunisation of pigs against porcine circovirus type 2 (PCV2)
	Fencovis ad us. vet	Inactivated bovine rotavirus, serotype G6P1, strain TM-91, inactivated bovine coronavirus, strain C-197, inactivated *Escherichia (E.) coli*, expressing F5 (K99) adhesin, strain O8:K35	Active immunisation of pregnant heifers and cows against bovine rotavirus, bovine coronavirus and *E. coli* to stimulate the development of antibodies and to increase the level of passive immunity of calves against neonatal diarrhoea by feeding them colostrum from vaccinated cows
	Equilis West Nile ad us. vet.	Inactivated chimeric flavivirus strain YF-WN	Active immunisation of horses against West Nile virus (WNV)
Diseases of the musculoskeletal system	Daxocox ad us. vet.	Enflicoxib	Relief of pain and inflammation associated with osteoarthritis in dogs

Medicinal products: facts and figures

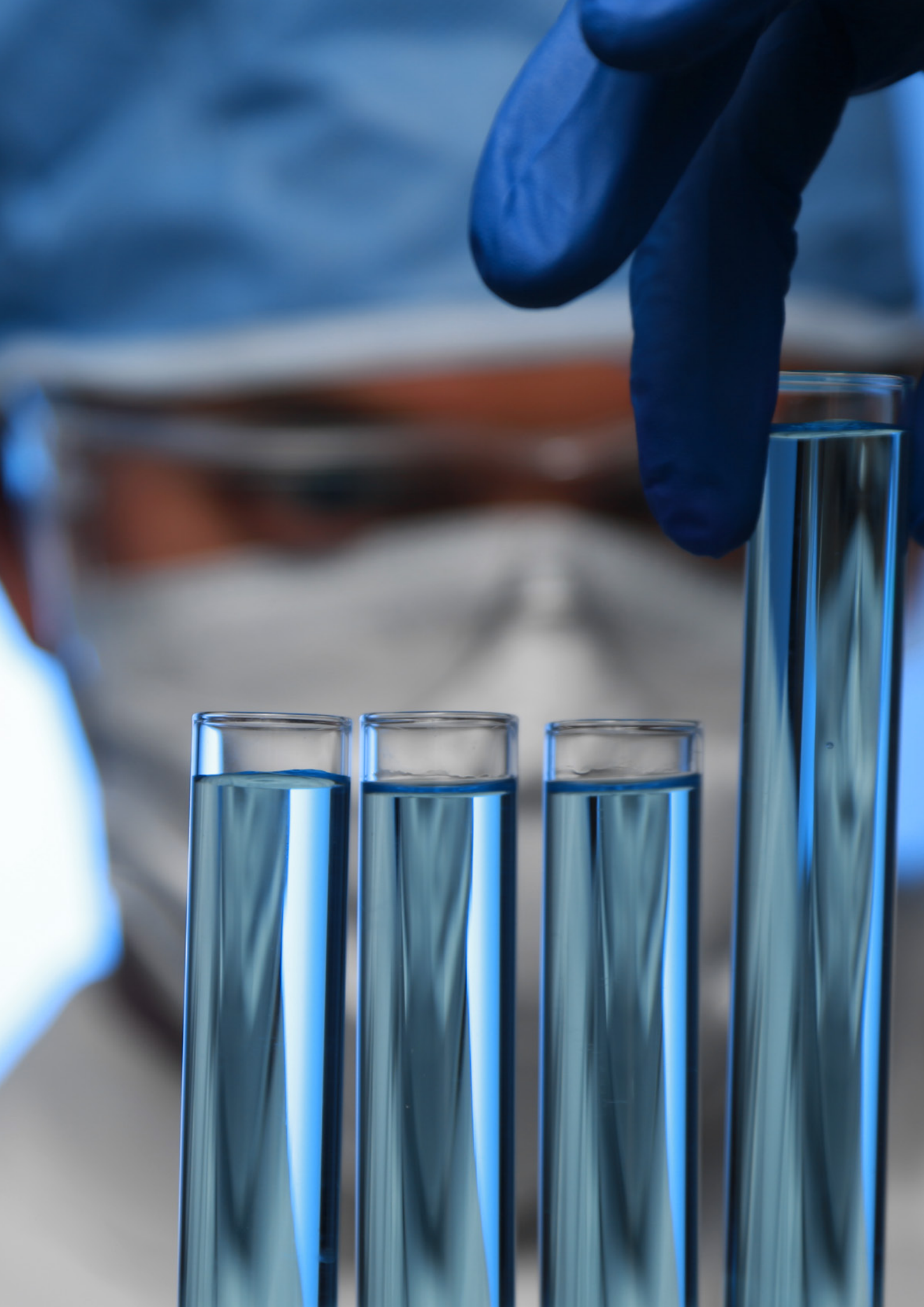
Number of authorisations by type of product

Number of authorisations	2023	2022
Human medicinal products	**5,769**	**5,765**
Synthetics	4,806	4,805
Biotechnologicals	441	429
Vaccines	68	66
Blood products	65	64
Radiopharmaceuticals	53	54
Allergen products	270	285
Bacterial and yeast products	24	22
Antidotes / antivenins	41	40
Transplant products	**19**	**16**
Complementary and herbal medicines	**12,325**	**12,273**
Phytopharmaceuticals	395	413
Homeopathics	587	606
Anthroposophics	342	355
Ayurvedic medicinal products	1	1
Tibetan medicinal products	5	5
Other alternative treatments	5	5
Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication	10,756	10,868
Chinese medicines with no indication	234	20
Lozenges	**34**	**36**
Veterinary medicinal products	**772**	**674**

Number of authorisations by dispensing category

Number of authorisations	2023	2022
A Single dispensing on medical/veterinary prescription	1,649	1,677
B Dispensed on medical/veterinary prescription	4,191	4,018
D Dispensed after expert advice	1,914	1,986
E Dispensed without expert advice	170	179

4 (previous year: 20) medicinal products are 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	2023	2022
Establishment licences TPA / Epidemics Act	1,166	1,126
Licences for handling controlled substances	406	394
Licences for the cultivation of cannabis for medical purposes	25	6
Import / export permits for controlled substances	5,221	5,597
Licences for new clinical trials	175	186
Import licences for vaccines and blood products	1,111	1,236
Batch assessment and plasma pool tests	4,699	4,285

Number of inspections	2023	2022
GLP inspections	5	10
GCP inspections	46	35
GVP inspections	18	13
GMP / GDP inspections	163	141
Microbiological laboratory inspections	34	35
Autologous cell and tissue inspections	10	4
Inspections for third parties	25	19

Time limits	2023	2022
Establishment licences TPA / Epidemics Act	100%	97%
Licences for handling controlled substances	100%	95%
Import / export permits for controlled substances	100%	95%
Licences for new clinical trials	88%	95%
Import licences for vaccines and blood products	100%	97%
Batch assessment and plasma pool tests	100%	98%

Establishment licences

Companies that manufacture or distribute medicinal or transplant products 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 and transplant products

Activities:
787 (previous year: 680) establishment licences were issued, extended, modified or revoked during 2023. As at the end of 2023, all companies now have a licence issued under the revised Therapeutic Products Act that came into force in 2019. The manufacturing licences are registered in the EudraGMDP database operated by the European Medicines Agency in accordance with Switzerland's agreement with the EU on mutual recognition of conformity assessments.

Establishment licences for microbiological laboratories

Activities:
Swissmedic processed 76 (previous year: 80) applications from microbiological laboratories for new establishment licences or changes to or renewal of existing licences.

Licences for handling controlled substances

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. Swissmedic must be notified of deliveries within Switzerland of narcotics in Lists a, b, d and e of the Narcotics Ordinance. 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 accounts, which are then submitted to Swissmedic. The Agency examines these annual accounts and forwards a consolidated report to the International Narcotics Control Board (INCB) at UNO in Vienna in accordance with international agreements.

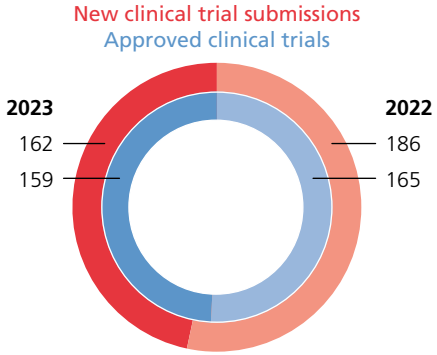
Activities:
Swissmedic processed 224 (previous year: 217) applications for new establishment licences or changes to or renewal of existing licences and examined the annual accounts of 481 company sites for the report to the INCB.

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 test product is guaranteed. Clinical trials may only be carried out in Switzerland if they have been approved by an ethics committee and by Swissmedic.

Activities:
Swissmedic received 162 applications for new clinical trials of medicinal products during 2023. 14 involved first-in-human trials. A total of 159 clinical trials was approved, of which seven were approved in combination with a medical device and one in combination with an advanced therapy medicinal product. The complexity of the application dossiers continued to rise in line with the growth in product complexity.



In addition, Swissmedic processed 2,703 (previous year: 2,698) other requests or notifications relating to clinical trials (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, end-of-trial reports) as well as 150 (previous year: 118) reports of suspected unexpected serious adverse reactions (SUSAR).

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

Documents submitted in support of applications for approval of 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 processed 16 (previous year: 14) applications for new clinical trials with transplant products and 90 (previous year: 63) clinical trial amendments.

The shift in clinical trial focus towards complex-design trials of innovative medications for cancer or genetic diseases continued.

Import licences for vaccines and blood products

Activities:
Swissmedic issued 1,111 (previous year: 1,236) individual import licences for immunological medicinal products, blood and blood products during 2023.

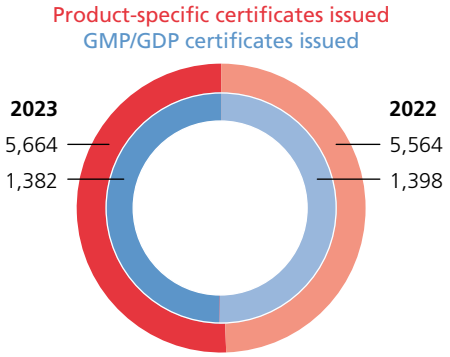
Special licences

Activities:
Since the entry into force of the revised Veterinary Medicinal Products Ordinance on 1 July 2022, the Federal Food Safety and Veterinary Office has been responsible for issuing special licences to import veterinary medicinal products. As a result, no further new special licences were issued by Swissmedic. The number of licences issued during 2022 was 286.

Certificates for medicinal and transplant products

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

Activities:
Following the introduction of the new establishment licence format in early 2019, manufacturers of medicinal products, their trading partners and medicinal product regulatory authorities can search for certificates in EudraGMDP, the database operated by the European Medicines Agency. As a result, the number of certificates issued has declined significantly by around 25 percent since 2019.



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.

Activities:
The number of batch inspections increased by just under 10 percent on the previous year. More stable blood products were produced in Switzerland, meaning that the number of batches tested by the OMCL rose accordingly. By contrast, the demand for COVID vaccines and the associated batch release activities declined.

Since 1 January 2023, the OMCL has also been responsible for the official batch testing of immunological veterinary medicinal products. Batches distributed in Switzerland were released for the Swiss market by means of Official Batch Protocol Review or notification (including presentation of the certificate issued by an OMCL in the EU).

Blood product batch release

2022 2023

Batch assessments (CH, EU)

765
815

Notifications

377
417

Plasma pool tests

2,893
2,897

Vaccine batch release

2022 2023

Batch assessments (CH, EU)

75
67

Notifications

171
149

Product analyses as WHO reference laboratory

4
7

Batch release, immunological veterinary medicinal products

2022 2023

Batch assessments

N/A
102

Notifications

N/A
245

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 2023, the OMCL once again tested active pharmaceutical ingredients and finished products for nitrosamines, after these had been detected in various products worldwide. A further major area of activity involved the investigation of a large number of illegally imported products.

New authorisations and market monitoring

2022 **2023**

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 transplant products 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. Where Swissmedic has evidence of non-compliance with regulatory requirements, the Agency conducts inspections aimed specifically at restoring a legally compliant situation (for-cause inspections).

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 study audits) with the relevant partners at the Federal Office for the Environment and the Federal Office of Public Health within the framework of the GLP monitoring programme.

Activities:
Swissmedic inspected GLP compliance at a total of five (previous year: ten) assessment facilities. The Agency led four of these inspections. Three assessment facilities left the GLP programme.

The three GLP units held quarterly meetings for the purpose of sharing information from important OECD and EU international working groups. The authorities responsible for GLP supervision provide information to the assessment facilities in an annual newsletter.

GCP and GVP inspections

Swissmedic inspects clinical trials carried out in Switzerland by sponsors, contract research organisations, other research organisations and trial centres. The inspections are carried out according to defined risk criteria and 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:
Regular inspections of clinical trials in hospitals resumed following the pandemic.

GCP and GVP inspections of companies were carried out partly on-site and partly using the videoconference-based remote procedure. Swissmedic also systematically performed desk-based inspections. In the course of these inspections, companies were asked to submit specific documents, which were then inspected for legal compliance.

In the year under review, Swissmedic inspected a total of 46 (previous year: 35) clinical trials of medicinal products. In addition, it conducted 18 (previous year: 13) GVP inspections.

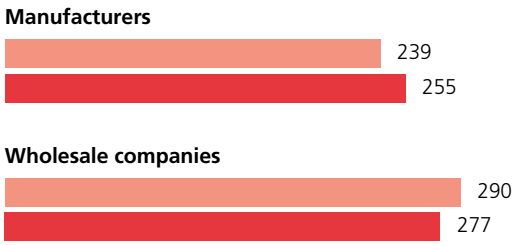
GMP and GDP inspections

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.

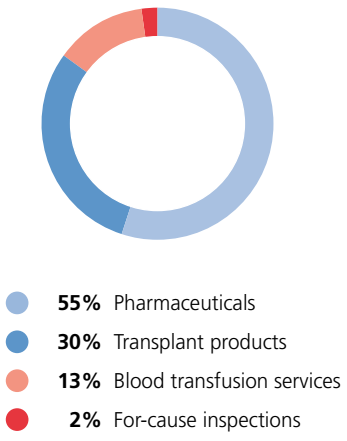
Activities:
Swissmedic and the regional inspectorates carried out a total of 532 (previous year: 529) GMP/GDP inspections of manufacturers and wholesale companies. Reports of major changes to installations, facilities and procedures that impacted GMP / GDP rose to 181, a 9 percent increase on the previous year's figure of 166. Similarly, demand for GMP-related Scientific Advice Meetings rose sharply.

During 2023, Swissmedic's inspectorate successfully extended its scope of accreditation under ISO 17020 to advanced therapy medicinal products, probably making it the first inspectorate in the world to be accredited for such products.

Number of GMP/GDP inspections (Swissmedic and regional inspectorates)



The inspections conducted by Swissmedic covered the following areas:



Inspections abroad

Swissmedic may inspect manufacturers of medicinal and transplant products located abroad at the expense of the importer.

Activities:
Following the lifting of pandemic-related travel restrictions, Swissmedic expanded its own foreign inspections programme in 2023. It did this firstly by resuming participation in the EDQM's programme, under which inspections of two active substance manufacturers in India and two in China were conducted, and secondly by conducting two inspections of its own in India and the USA. The preliminary work for these inspections was enough in itself to persuade many companies not to seek approval for their foreign suppliers. In connection with assessments by partner authorities, Swissmedic also accompanied two inspections in the USA and two in Taiwan.

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 Swiss inspections system.

Activities:
The number of inspections in 2023 by foreign supervisory authorities of pharmaceutical companies in Switzerland returned to pre-pandemic levels. 78 (previous year: 34) inspections were conducted; 37 by the USA, 16 by Russia, the remaining 25 by Turkey, Brazil, Libya, China, Mexico, Armenia, Belarus, Kazakhstan, Colombia and Taiwan.

The agreement with the USA, which came into force in 2023, did not have a major effect because many inspections were conducted or scheduled before the Agreement took effect and were not cancelled.

Swissmedic accompanied two GCP inspections by the European Medicines Agency EMA, two by the US FDA and one by the Japanese medicinal products authority PMDA in Switzerland.

Inspections of microbiological laboratories

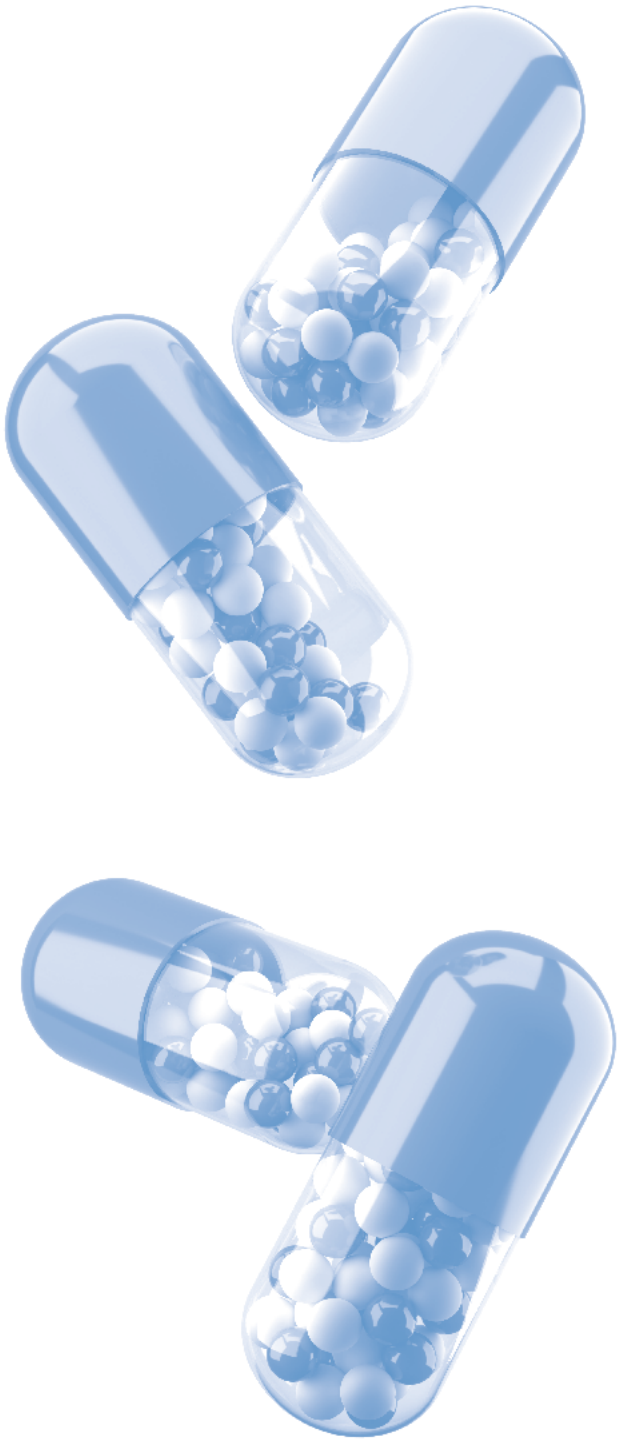
Microbiological laboratories must satisfy the requirements defined in the Ordinance on Microbiological Laboratories and comply with Good Laboratory Practice guidelines. Swissmedic monitors compliance with legal provisions and periodically carries out inspections.

Activities:
Swissmedic again conducted a substantial number of routine laboratory inspections. A total of 34 (previous year: 35) inspections were conducted.

Inspections for third parties

Swissmedic can provide services for third parties subject to payment of a fee. On behalf of the 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:
25 (previous year: 19) inspections were carried out for the FOPH in 2023.



Other monitoring activities

Monitoring of the blood transfusion service

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, the manufacturing of labile blood products and the distribution of labile blood products.

Activities:
During the year under review, Swissmedic approved an application to amend the blood donation criteria for men who have sex with men (MSM).

Monitoring of autologous transplantation

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

Activities:
At the end of 2023, Swissmedic had been notified of 24 (previous year: 22) institutions that work with tissues and cells for autologous transplantation.

Swissmedic conducted ten (previous year: four) inspections.

Appeals procedure

Activities:
No official decision issued in connection with licences was contested in 2023. One case before the Federal Administrative Court was resolved, no further cases are pending. Similarly, no cases are pending before the Federal Supreme Court.

Establishment licences issued under the old and new legislation in facts and figures

Manufacturing of medicinal products (under the old legislation)	2023	2022
Manufacturing of medicinal products (with a licence for distribution)	0	8
Manufacturing of medicinal products (without a licence for distribution)	0	7
Institutions with a Swissmedic licence for handling blood or labile blood products (blood transfusion activities)	0	3

Distribution of medicinal products (under the old legislation)	2023	2022
Import of medicinal products	0	26
Wholesale trading in medicinal products	0	57
Export of medicinal products	0	22
Trading in medicinal products abroad	0	20

Manufacturing of medicinal and transplant products (under the new legislation)	2023	2022
Manufacture of ready-to-use medicinal products and transplant products	431	395
Manufacture of active pharmaceutical ingredients	188	177
Handling of blood or labile blood products (blood transfusion activities)	81	77

Distribution of medicinal and transplant products (under the new legislation)	2023	2022
Import of medicinal products and transplant products	721	672
Wholesale trading in medicinal products and transplant products	1,005	950
Export of medicinal products and transplant products	560	526
Trading in medicinal products abroad and transplant products abroad	414	374
Brokerage or agency activities for medicinal products and transplant products	20	13

Microbiological laboratories	2023	2022
With a Swissmedic licence issued under the old procedure (1 January 2016 to 31 December 2018; activities A, B and / or C)	1	10
With a Swissmedic licence issued under the new procedure (from 1 January 2019; activities SE 1, SE 2 and / or SE 3)	122	117

MEDICINAL PRODUCTS – **MARKET SURVEILLANCE PRODUCT GROUP**

Overview

Number of reports	2023	2022
Adverse reactions, human medicinal products	15,317	21,701
Adverse reactions, veterinary medicinal products	465	422
Adverse events associated with the collection, production or administration of blood transfusions.	4,474	4,868
Quality defects	920	924
Illegal imports of medicinal products (customs interceptions)	6,319	6,475

Monitoring activities	2023	2022
Case opening / signal evaluation	402	260
Case closure / implementation of measures	368	248
Assessment of safety reports	511	480
Assessment of risk management plan updates	271	253
Batch recalls	30	27
Administrative proceedings connected with illegal imports of medicinal products	6,171	6,477

Vigilance product

Human medicinal products vigilance

Pharmacovigilance

Swissmedic evaluates safety signals associated with medicinal products and vaccines on the basis of reports of 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 medical professionals and, in increasing numbers, patients are entered in the national database and evaluated. Some are also assessed on Swissmedic's behalf at five regional pharmacovigilance centres (RPvCs). Pharmaceutical companies also submit a large number of reports of ADRs from within Switzerland to Swissmedic.

Activities:
Once again, there was a substantial fall in the number of ADR reports received following the steep rise in reports in 2021 and 2022 attributable to COVID-19 vaccines.

VigilanceOne Ultimate, the database used to process ADR reports from Switzerland, was upgraded in readiness for data exchange using the more complex E2B(R3) format (ICH guideline: Electronic Transmission of Individual Case Safety Reports).

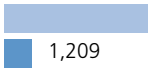
Swissmedic regularly discussed safety signals with authorities in other countries and in multinational specialist organisations. Swissmedic publishes information for medical professionals on clinically relevant side effects drawn from real-life cases on its website. The number of publications was increased in 2023.

Pharmacovigilance

2022 2023

ADR reports incl. follow-up reports

Number of reports involving COVID-19 vaccines



Signals opened

The Swiss Federal Audit Office audited the vigilance system for medicinal products and vaccines in 2023 and published its report.

Audit report

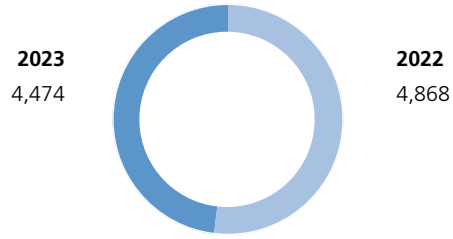
Haemovigilance

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

Activities:
During 2023, Swissmedic revised the reporting process for quality defects involving blood and labile blood products and provided an information sheet and report form. Targeted inspections and presentations were used to raise awareness among those under a reporting obligation.

Furthermore, cooperation with cantonal agencies, experts and external organisations was stepped up, for example as part of the revision of the "Guidelines for quality assurance in transfusion practice".

Number of reports involving blood products



Vigilance for veterinary medicinal products

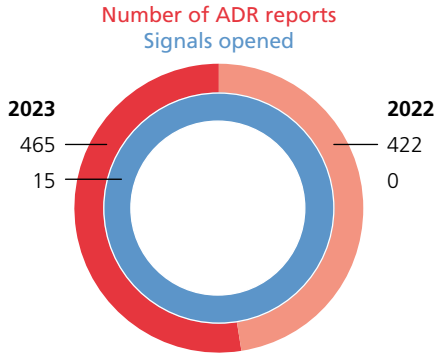
Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich to collect and assess reports of adverse reactions (ADRs) to veterinary medicinal products.

Activities:
Monitoring immunological veterinary medicinal products has been Swissmedic's task since it assumed responsibility for them in January 2023. 111 reports of ADRs involving immunological veterinary medicinal products were received in 2023.

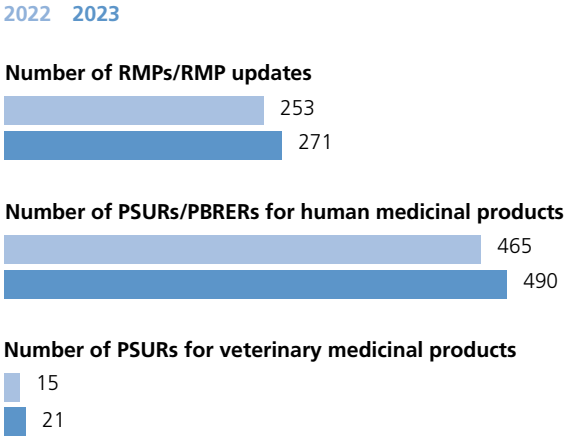
The 465 reports of ADRs primarily involved dogs (216) and cats (92), followed by cattle (37) and horses (5). Four reports of users experiencing reactions were also submitted.

Tox Info Suisse reported 113 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



Risk management plans and safety reports



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 for assessment 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) and Periodic Benefit Risk Evaluation Reports (PBRERs). In addition, it evaluates international drug safety data and identifies and evaluates safety signals from national and international sources.

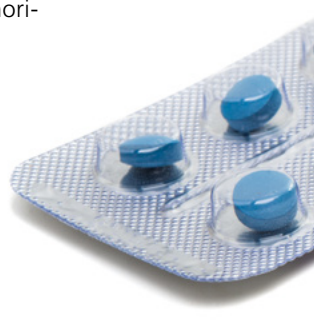
Activities:
In the year under review, Swissmedic assessed a total of 782 (previous year: 733) reports.

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 reviews the circular letters sent to healthcare professionals – Direct Healthcare Professional Communications, DHPCs – and sends them to recipients. 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 signals evaluated by Swissmedic increased sharply in 2023. Risk minimisation measures were implemented promptly. 368 (previous year: 243) signal procedures were completed.

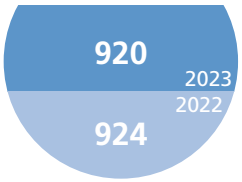
DHPCs and HPCs were used to inform professional and public audiences about nine (previous year: eight) safety-relevant issues. The information concerned medicinal products marketed by 31 (previous year: 17) authorisation holders.



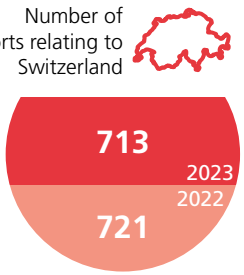
Market monitoring of medicinal products product

Quality defects and batch recalls

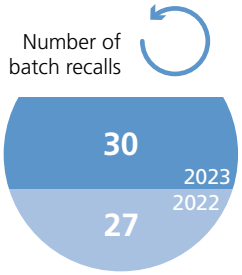
Number of reports of quality defects



Number of reports relating to Switzerland



Number of 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 or the public.

Activities:
Following a continuous rise in recent years, the number of quality defects to be processed remained stable at the previous year's level. The reported quality issues resulted in 27 batches of human medicinal products and three batches of veterinary medicinal products being recalled. Five recalls extended to patient or end-user level. The product groups most heavily affected by recalls were preparations for injection or infusion (12 cases), which, with ophthalmics (four cases), accounted for more than half of withdrawals from the market. Eight recalls involved orally administered products.

Swissmedic's planned market monitoring activities in 2023 focused primarily on testing various medicinal products that are used for an extended period of time (e.g. certain antihypertensives and antidepressants) for nitrosamine contamination. The Agency ordered batch recalls in two cases after the OMCL found nitrosamine concentrations in excess of the safety limit. In addition to the recalls, an international rapid alert was triggered to inform partner authorities in the PIC/S network about the results of testing.

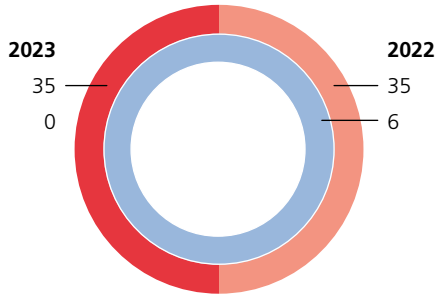
Out-of-stock products

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.

Activities:
30 of the 35 applications to distribute the foreign version of a medicinal product for a restricted period were completed and approved in 2023. One involved a veterinary medicinal product. Four applications were withdrawn while they were being processed, two after they had been approved. Swissmedic rejected one application. No new licences for medicinal products intended specifically to treat COVID-19 patients had to be issued.

By far the majority of licences issued to distribute foreign versions of products involved imports of oncologicals. Other applications concerned clotting factors, antibiotics and vaccines. On receipt of applications, Swissmedic conducts a routine needs assessment in collaboration with the Federal Office for National Economic Supply to prevent market distortion.

Total number of out-of-stock applications
Number of COVID-19-related out-of-stock applications



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 80 (previous year: 50) cases were dealt with as part of post-publication advertising inspection activities in 2023. Administrative proceedings had to be opened in 27 (previous year: 33) cases for the purpose of restoring legal compliance. Criminal proceedings were initiated in five (previous year: three) cases. In 36 cases, the marketing authorisation holders were made aware that they had infringed advertising rules, while in the remaining 12 cases Swissmedic found no infringements of advertising rules or was not responsible for enforcement.

Swissmedic processed three applications for an advertising permit for a medicinal product that may be dependence-forming or susceptible to abuse.

Measures against illegal medicinal products

Swissmedic sensitises the public to the risks associated with using illegal medicinal products. It maintains dialogue with other authorities and promotes effective national and international networking. Swissmedic receives reports of counterfeit medicinal products, illegal distribution and other illegal activities, examines them and initiates corrective action where necessary. Swissmedic works closely with the customs authorities to control medicine imports and orders the destruction of illegal packages.

Activities:
90 percent, or just under 6,000, of the illegally imported medicinal products impounded by customs offices were dealt with under the simplified procedure and destroyed. This has made it possible to seize erectile stimulants, slimming products and psychotropic agents in particular to protect the health of the people who ordered them. Swissmedic also undertook ordinary administrative proceedings in 185 cases and administrative penal proceedings in 41 cases, the costs of which were charged to the intended recipients.

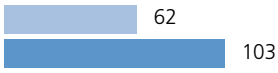
Two warnings were published to highlight the dangers of imported medicinal products of unknown or illegal origin: One erectile stimulant caused side effects serious enough to warrant hospitalisation. Swissmedic analysed the product and found it was overdosed. In the second case, a counterfeit diabetes medicine procured abroad and used in Switzerland to assist with weight loss caused life-threatening side effects.

Illegal medicinal products

2022 **2023**

Administrative proceedings connected with illegal imports

Illegal distribution of medicinal products



Counterfeit medicinal products

Appeals procedure

Activities:
During 2023, appeals were submitted to the Federal Administrative Court against 11 official decisions in connection with the market surveillance of medicinal products. Ten cases are currently still pending before the Court. No cases are still pending before the Federal Supreme Court after one appeal was not admitted during 2023.

MEDICINAL PRODUCTS – **PENAL LAW PRODUCT GROUP**

Penal Law product

Criminal prosecution

The Therapeutic Products Act empowers Swissmedic to carry out penal 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:
The number of reports of offences received in 2023 increased by more than half year-on-year. This is primarily due to the increase in members of the public illegally importing medicinal products. A large number of these cases were dealt with swiftly using the abridged procedure.

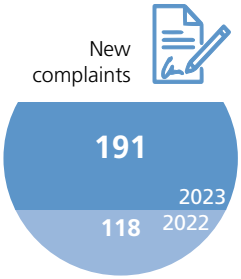
In addition to cases in which medicinal products were illegally imported, the administrative penal proceedings opened and conducted in 2023 concerned the illegal placing on the market and manufacturing of medicinal products, contraventions of advertising regulations, unlicensed trading abroad and counterfeit medicinal products.

The various powers to prosecute therapeutic products crime demand close collaboration between all participating agencies. Once again, a number of information events took place during 2023, including the Swiss Medicrime meeting, which was attended by representatives from federal and cantonal therapeutic products criminal prosecution and supervisory agencies. At international level, the member states of the MEDICRIME Convention continued their first monitoring process and agreed on a three-year strategy. Swissmedic represents Switzerland at plenary meetings as a Party to the Convention and in the Committee of Parties as a member of the Bureau.

Once again, Swissmedic exercised the rights of a private claimant in several prosecutions conducted by the Cantons during 2023 to enable it to contribute its legal expertise in matters concerning therapeutic products. In pursuit of the same aim, Swissmedic launched an appeal against an acquittal; the cantonal court upheld its appeal. The case in question concerned a medical professional who was dispensing medicinal products to patients despite having had their licence to practise withdrawn.

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. In particular, 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.



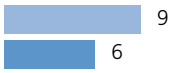
Activities:
Swissmedic conducted six house searches in connection with two major cases involving the illegal importing and trading in substantial quantities of erectile stimulants and unauthorised medicinal products. In addition, 26 examination hearings were conducted and 29 cases were unified with cantonal prosecution authorities. Swissmedic handled three of these cases.

Swissmedic requested international legal assistance from neighbouring and eastern European countries in three cases and dealt with three requests from European countries.

Investigative measures

2022 **2023**

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 and penalty ruling) is issued and the case may be transferred to the competent courts or abandoned. Swissmedic represents the prosecution in cases that are brought to court.

Activities:
53 penalty decisions were issued during 2023. 31 decisions, most of which involved illegal imports of medicines by the general public, were dealt with under the abridged procedure. Criminal proceedings were halted in eight cases. One case, in which Swissmedic prevailed, was brought before a cantonal court. The background to this was the conviction of the Responsible Person of a medicinal products wholesaler for failing to exercise their duty of care in connection with medicinal products. As part of the conviction, the Responsible Person was ordered to pay damages.

One protracted and extensive criminal case was finally concluded in 2023 with the imposition of a penalty order. In addition to a fine, the accused was also ordered to pay substantial six-digit damages.

In one case involving two foreign nationals accused of trading internationally in narcotics and therapeutic products using suspected counterfeit documents, Swissmedic brought proceedings in the competent criminal court, charging the individuals in question with organised commercial criminal action and endangering the health of a large number of people.

2022 **2023**

Penalty orders, penalty rulings and rulings abandoning proceedings

Cantonal judgement

MEDICAL DEVICES – **STANDARDS PRODUCT GROUP**

Legal Framework product Technical Standards product

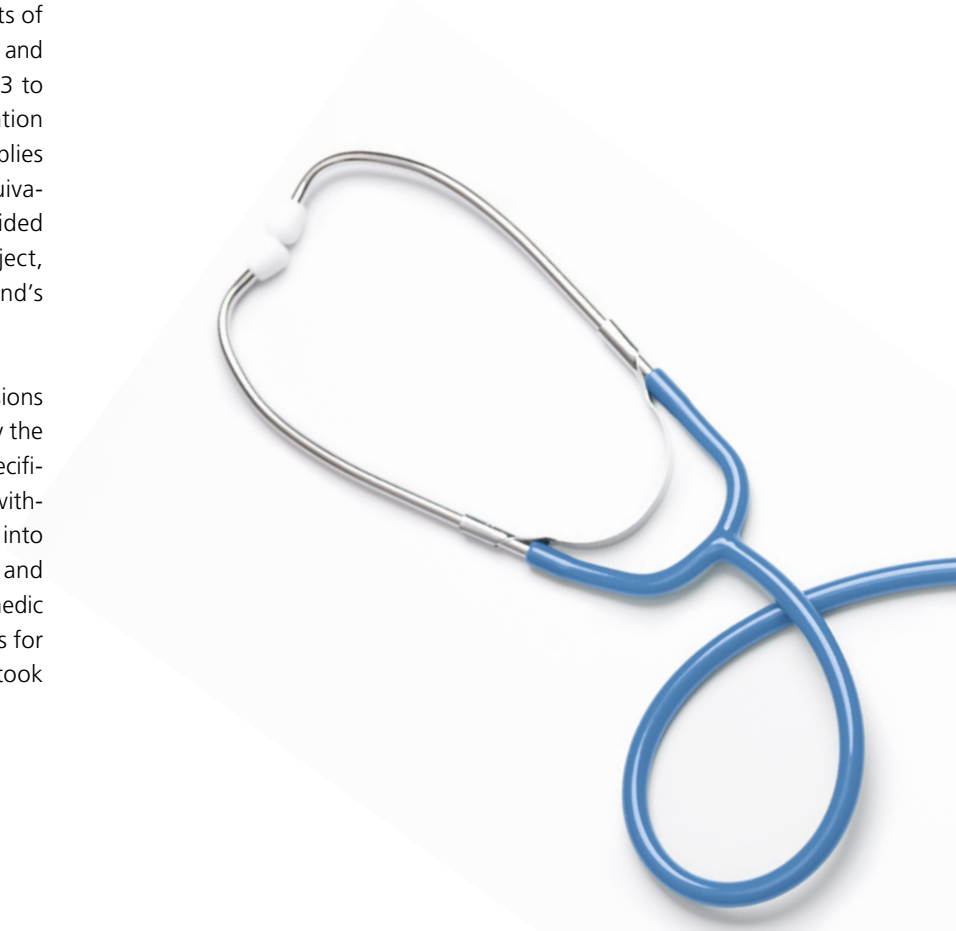
Medical Devices Regulation

The legislative project to implement the new, stricter EU regulations (Medical Devices Regulation, MDR, and In Vitro Diagnostic Medical Devices Regulation, IVDR) has been completed. As a result, Switzerland now has medical devices regulations comparable with those in the EU. A transitional period for implementation lasting until 26 may 2024 had originally been provided. However, the shortage of capacity at the notified bodies responsible for conducting conformity assessments of medical devices resulted in the European Parliament and EU Council issuing a regulation on 15 March 2023 to extend the transitional period for the new regulation subject to certain requirements. To safeguard supplies of medical devices in Switzerland and ensure equivalence with EU legislation, the Federal Council decided on 29 September 2023, as part of a follow-up project, to also extend the transitional periods in Switzerland's Medical Devices Ordinance (MedDO).

The follow-up project also implemented the provisions relating to the Implementing Regulations issued by the European Commission, establishing the common specifications and classification rules for product groups without an intended medical purpose. Following entry into force of the revised MedDO and the designation and publication of the common specifications by Swissmedic in the Federal Gazette, the new legal requirements for products without an intended medical purpose took effect in Switzerland on 1 November 2023.

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. Wherever possible, the Agency registers internationally harmonised standards and common specifications. The list of registered technical standards and common specifications is updated regularly in the Federal Gazette and on the Swissmedic website.



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). The June 2023 edition of "Visible" explained the circumstances under which software is a medical device and a team of inspectors talked about the monitoring and enforcement activities for medical devices. The November issue discussed hospitals' obligations as regards medical devices maintenance, reprocessing and vigilance as well as Swissmedic's findings from hospital inspections.

Press relations

Around 120 (previous year: 50) media enquiries referring specifically to medical devices were received in 2023. While many of them once again concerned various aspects of the new medical devices regulation, specific devices such as blood pressure monitors or implants were also addressed. The results of the hospital inspections conducted in 2021 and 2022 aroused particular interest.

Enquiries

Swissmedic answered some 2,200 enquiries about medical devices. Enquiries from laypeople addressed subjects ranging from sticking plasters and disinfectants or whether health insurers were required to reimburse medical devices (not Swissmedic's responsibility) to real-life issues involving implants. Enquiries from professionals primarily concerned authorised representatives in Switzerland, market access in general and Swissdamed, the Swiss medical devices database.

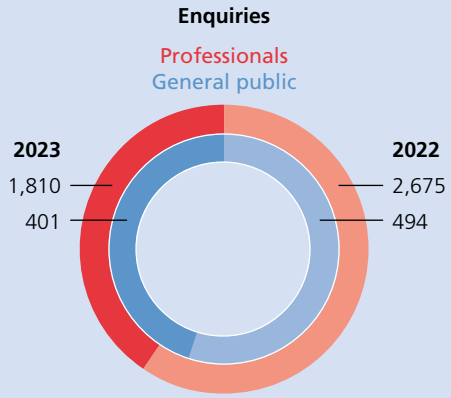
Transparency / FoIA

The number of applications for access to official documents connected with medical devices more than doubled in 2023.

No appeals are currently pending before the Federal Administrative Court or Federal Supreme Court regarding freedom of information requests.

Parliamentary proposals

The main subject at political level (parliamentary proposals and other political business items) was security of the supply of medical devices.



Transparency / FoIA

2022 2023

Requests under FoIA

6
15

Time requirement (in hours) for processing requests

71
349

Parliamentary proposals

2022 2023

Parliamentary proposals

8
9

Other political business items in which Swissmedic was involved

35
28

Information and publications for professionals

Publications on the Swissmedic website and raising awareness among economic operators at medtech round table meetings are an important resource for providing information to professionals. Furthermore, Swissmedic draws attention to relevant publications through the newsletter that it publishes several times a year. During 2023, information activities were dominated by the extended transitional periods for medical devices and the impact of the implementation of the new medical devices regulation on products without an intended medical purpose that are now subject to it. A dedicated information page was set up on the Swissmedic website for consumers of and economic operators in these product groups. In addition, two videos provide information on the devices that are affected by the regulation and what needs to be remembered when using them.

Swissmedic experts gave presentations on aspects of the medical devices regulation and specific requirements arising from it for hospitals at various specialist events in 2023.

Furthermore, Swissmedic published and updated answers to frequently asked questions associated with the new regulation and enforcement aids. Supplementary information on the "in-house" devices manufactured in healthcare institutions was also provided during 2023.

Swissmedic has also stepped up focus campaigns and inspections as part of its monitoring activities. It evaluates the results and publishes them to increase awareness among market players. Furthermore, the findings from the hospital inspections conducted in previous years were compiled in a report and published via various channels.

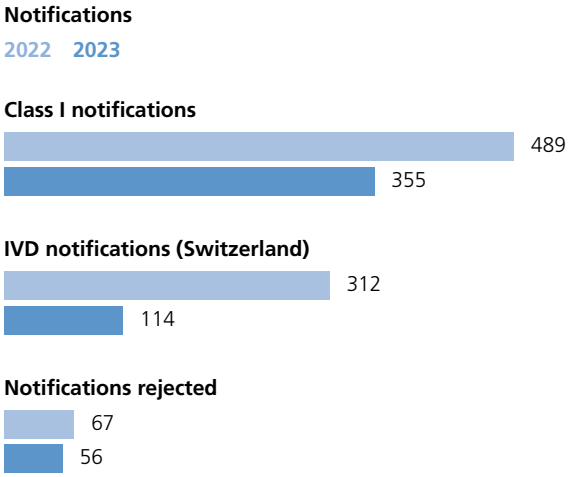
MEDICAL DEVICES – **MARKET ACCESS PRODUCT GROUP**

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 medical devices. Notifications for these devices are sent to Swissmedic, which carries out random checks to ensure devices have been correctly classified and issues instructions to make corrections as necessary.

Activities:
Notifications concerning Class 1 medical devices (e.g. reusable surgical instruments or rolling walkers), custom-made classic or active implantable medical devices and systems and procedure packs fell during 2023. Notifications concerning in vitro diagnostic medical devices (IVDs) also declined significantly once more, following their peak in the previous year.



Five notifications were submitted for classic and active implantable medical devices produced using or containing devitalised human tissue. In addition, 21 change notifications concerning devitalised human tissue were processed.

In 56 cases, Swissmedic rejected the notifications because the products had been incorrectly categorised or classified, or because they did not fall under its responsibility.

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. 20 applications were submitted and reviewed during 2023. 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 are not CE-certified (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.

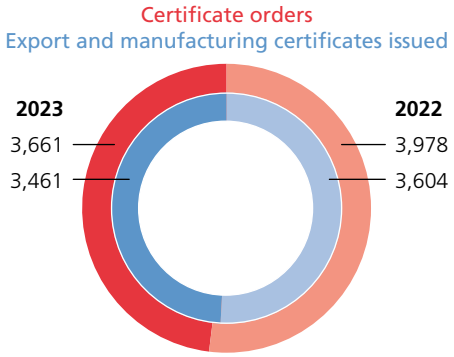
Activities:
Swissmedic processed 47 applications for new clinical trials of medical devices. 36 of these were approved during the year. Eight of the approved trials were combined trials with medicinal products or advanced therapy medicinal products. There were ten simplified reviews in response to applications for this type of procedure.

Swissmedic approved 77 major amendments during the course of clinical trials. 11 of the approved amendments were combined trials with medicinal products. As part of its monitoring activities for ongoing trials, Swissmedic reviewed 126 amendments, 104 Annual Safety Reports and 30 safety reports from Switzerland. Swissmedic also inspected four 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 are lawfully marketed in Switzerland. Foreign authorities may require the export certificates as a precondition for importing devices into their country.

Activities:
Swissmedic received 3,661 orders in 2023 and issued 3,461 export and manufacturing certificates. 99 percent of applications were completed within 30 days.



Unique identification number

Under the revised Medical Devices Ordinance, Swissmedic issues a Swiss Single Registration Number (CHRN) to economic operators who submit the appropriate application. A CHRN is a unique identification number that can be used to unambiguously identify Swiss-domiciled manufacturers, authorised representatives and importers.

Activities:
Swissmedic received 518 applications in 2023 and issued 512 identification numbers. 95 percent of applications were processed within 30 days.

MEDICAL DEVICES – **MARKET ACCESS AND MARKET SURVEILLANCE PRODUCT GROUP**

Medical devices: facts and figures

Number of authorisations	2023	2022
Notifications, Class I medical devices	355	489
Notifications, in vitro diagnostic medical devices	114	312
Licences for new clinical trials	36	37
Export and manufacturing certificates	3,461	3,604
Swiss Single Registration Number	3,563	3,051

Number of reports	2023	2022
Serious incidents	5,498	5,216
Suspicion reports	274	304

Monitoring activities	2023	2022
FSCA implementation	577	532
Safety reports published	588	537
Inspections of market controls	51	32
Hospital inspections	25	15

MEDICAL DEVICES – **MARKET SURVEILLANCE PRODUCT GROUP**

Vigilance product

Materiovigilance

Manufacturers and users of medical devices are obliged to report to Swissmedic incidents that are deemed to be serious and which have taken place in Switzerland. Companies are also obliged to inform Swissmedic of safety measures they have taken, such as product recalls, which the Agency then monitors.

Activities:
The number of reports from Switzerland on serious incidents rose slightly again. 5,498 cases were reported during 2023.

The implementation of safety measures in Switzerland was monitored in 577 cases. The number of reported Field Safety Corrective Actions thus increased by just under 9 percent on the previous year.

A safety report was published in 588 cases to bring the matter to the attention of users.

Swissmedic once again took part in regular international meetings on serious incidents during 2023. These monthly international medical device safety meetings are attended by a large number of supervisory authorities, including the USA, Australia and Canada, and are intended to speed up identification of safety issues associated with medical devices that are marketed internationally.

Materiovigilance

2022 **2023**

Total number of reports

6,092
6,420

Number of reports from Switzerland on serious incidents

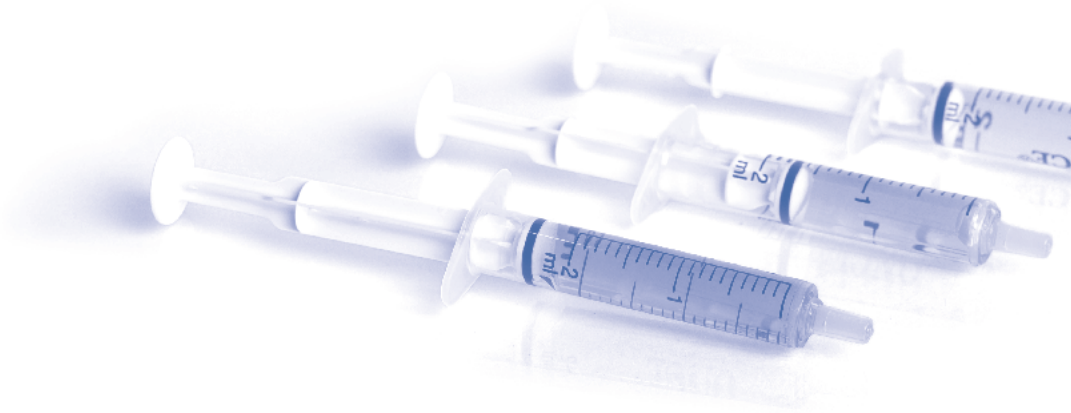
5,216
5,498

Monitoring of FSCA implementation

532
577

Safety reports published by Swissmedic

537
588



Market Monitoring product

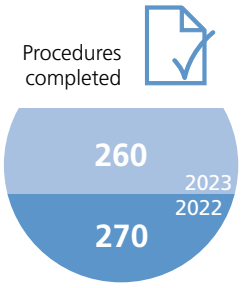
Independent monitoring

Swissmedic has been independently monitoring the Swiss medical devices market since 2021 and continues to expand activities to ensure an equivalent level of protection 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 authority-level access to the new EU information system provided by the 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 the conformity of their products. Swissmedic receives suspicion reports, initiates the necessary corrective measures and monitors 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 non-compliant medical devices was somewhat lower than in 2022. However, Swissmedic ordered corrective action in significantly more cases. In addition to processing reported suspicions, the random sampling programme was also expanded compared with 2022 in compliance with the new requirements of the more stringent medical devices regulation. Against this background, Swissmedic conducted three focus campaigns. In the first half of 2023, Swissmedic published the results of a review of 27 manufacturers of Class I medical devices for compliance with the new requirements and market surveillance. Furthermore, all Swiss authorised representatives registered with Swissmedic were asked to check their mandates for certifications by ECM, a notified body for medical devices in Europe. Finally, Swissmedic inspected 30 medical devices importers for compliance with the legal requirements and published the results. This was supplemented by 21 on-the-spot inspections of Swiss companies undertaken as part of market surveillance procedures.



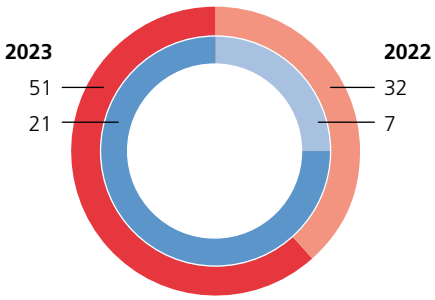
Notified bodies and inspections

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

Activities:
As at the end of 2023, there was one body designated by Swissmedic to conduct conformity assessment procedures under the revised Medical Devices Ordinance. The corresponding monitoring activities were carried out as scheduled in 2023.

Swissmedic also extended its own inspection activities once more as part of the drive to step up random inspection programmes. However, inspections by foreign authorities of market operators in Switzerland remained relatively low.

Inspections of market controls
Inspections by foreign authorities (co-ordination with SECO, including accompanying inspectors on site if needed)

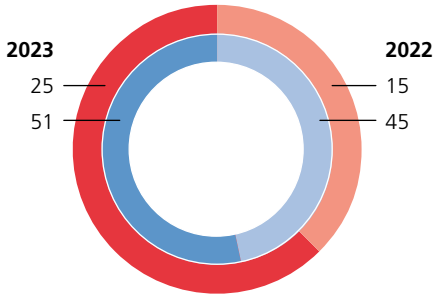


Hospital inspections

While the Cantons are responsible for inspecting the reprocessing of medical devices such as surgical instruments and endoscopes and 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 hospital inspections conducted in 2021 and 2022 and published the findings and action areas. Inspection activities were further intensified during 2023 and a total of 51 areas in 25 hospitals were inspected. 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.

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



Appeals procedure

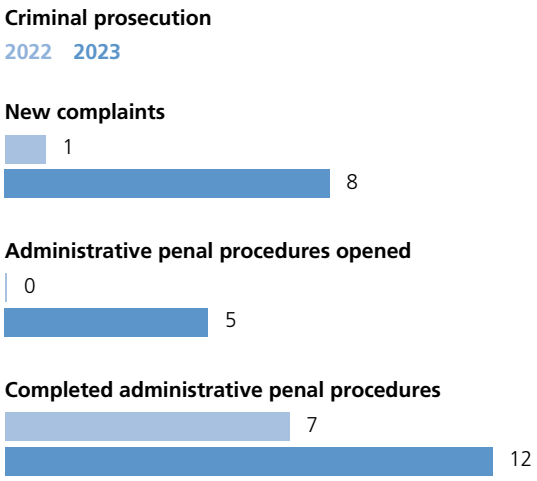
Activities:
During 2023, appeals were submitted to the Federal Administrative Court against two official decisions in connection with the market surveillance of medical devices. Five cases are currently still pending before the Court. The Federal Administrative Court ruled on three appeals during 2023, one of which was rejected and two of which were dismissed as being without merit.

MEDICAL DEVICES – **PENAL LAW PRODUCT GROUP**

Penal Law product

Criminal prosecution

Activities:
Criminal prosecutions in the medical devices sector are largely dependent on market surveillance reports. Activities in 2023 primarily involved the obligations of Swiss medical devices importers and manufacturers of Class I medical devices in Switzerland. The non-conformities in question were corrected in the course of administrative proceedings. However, there was still a need to take action against operators in Switzerland who were selling tests for in vitro diagnostic medical devices (IVDs) intended solely for professional users to laypeople.



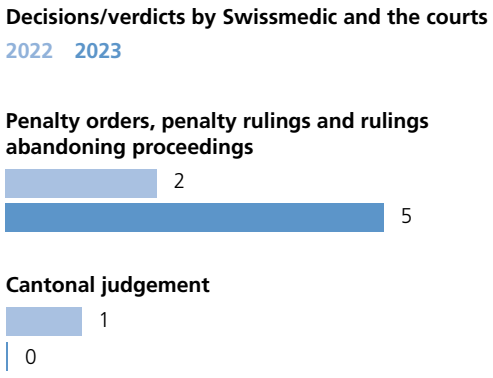
Investigative measures

Activities:
Two examination hearings were conducted in connection with medical devices; however, there were no house searches.

Decisions / verdicts by Swissmedic and the courts

Activities:
Two penalty orders were issued against two online dealers who had sold IVDs to laypeople. One penalty order was issued against a company for failure to comply with its duty of cooperation, the company in question having failed to adequately implement market surveillance-related corrective actions.

In addition, four employees of a company that manufactures Class IIb and III medical devices were found guilty of placing on the market medical devices that did not meet the requirements of the Therapeutic Products Act and of violating their duty of care and reporting obligation. They were given penalty orders.



BALANCE SHEET

(in KCHF)	Annex	31.12.23	31.12.22
Cash and cash equivalents	1	12,432	5,195
Receivables from sales and services	2	59,832	58,719
Uninvoiced procedural fees	3	5,549	5,294
Prepaid expenses	4	896	351
Financial assets (debenture bonds)	5	34,941	25,203
Current assets		**113,650**	**94,762**
Financial assets (debenture bonds)	5	5,057	25,136
Pension assets	13	0	10,010
Fixed assets	6	2,620	2,282
Real estate	7	61,197	63,229
Intangible assets	8	6,431	2,786
Right of use	9	2,366	2,533
Capital assets		**77,671**	**105,976**
Total assets		**191,321**	**200,738**
Commitments on sales and services	10	8,328	7,513
Other commitments	9+11	1,318	1,053
Deferred income	12	4,440	3,878
Short-term commitments		**14,086**	**12,444**
Lease liabilities	9+11	2,221	2,378
Liability for loyalty bonuses		3,184	2,650
Pension obligations (net)	13	23,700	0
Long-term commitments		**29,105**	**5,028**
Annual gain		1,708	11,505
Reserves		112,865	101,360
Endowment capital		14,500	14,500
Accumulated actuarial gains (+) / losses (–)		19,057	55,901
Own capital		**148,130**	**183,266**
Total liabilities		**191,321**	**200,738**

INCOME STATEMENT

(in KCHF)	Annex	2023	2022
Procedural fees and income pursuant to Art. 69 TPA (net)	14	38,818	42,277
Supervisory levies		56,614	55,723
Other income		318	316
Federal contribution		20,007	19,228
Other operating income		63	63
Net income		**115,820**	**117,607**
Services for third parties		–1,644	–2,107
Personnel	15	–85,235	–80,927
Rental, maintenance, energy, transport and insurance		–2,705	–2,612
Administration		–5,016	–4,934
IT	16	–16,034	–11,017
Other expenses		–262	–516
Amortisation	6-9	–3,504	–3,659
Total operating expenditure		**–114,400**	**–105,772**
Operating income		**1,420**	**11,835**
Financial income	17	627	14
Financial expense	18	–339	–344
Financial result		**288**	**–330**
Annual gain		**1,708**	**11,505**

STATEMENT OF COMPREHENSIVE INCOME

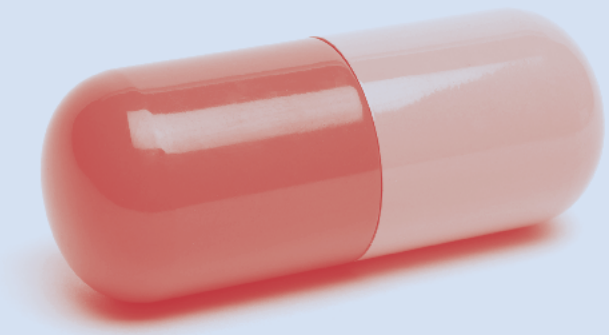
(in KCHF)	Annex	2023	2022
Annual gain		1,708	11,505
Actuarial gains (+) / losses (–)	13	–36,844	56,451
Total		**–35,136**	**67,956**

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

CASH FLOW STATEMENT

(in KCHF)	Annex	2023	2022
Income / (expenditure) from business activities			
Annual gain		1,708	11,505
Depreciation of tangible fixed assets	6	512	543
Writedowns on real estate	7	2,541	2,463
Amortisation of intangible assets	8	284	472
Writedowns on right of use	9	167	181
Reversal (–) / recognition (+) of liability for loyalty bonuses		534	–205
Reversal (–) / recognition (+) of pension obligations, excl. actuarial (losses) gains	13	–3,134	68
Interest expense (+) / interest income (–)		–281	338
Cash flow before change in net current assets		**2,331**	**15,365**
Increase (–) / decrease (+) in receivables from sales and services	2	–1,113	6,040
Increase (–) / decrease (+) in uninvoiced procedural fees	3	–255	515
Increase (+) / decrease (–) in prepaid expenses	4	–545	–86
Increase (+) / decrease (–) in commitments from sales and services	10	815	1,366
Increase (+) / decrease (–) in other short-term, non-interest-bearing commitments	11	265	–464
Increase (+) / decrease (–) in deferred income	12	562	–301
Cash flow from business activities		**2,060**	**22,435**
Income / (expenditure) from investing activities			
Investments in short- and long-term financial assets	5	–14,934	–50,339
Disposals of financial assets	5	25,275	0
Investments in tangible fixed assets	6	–850	–531
Investments in real estate	7	–509	–912
Investments in intangible assets	8	–3,929	–2,163
Interest received		615	238
Cash flow from investing activities		**5,668**	**–53,707**
Income / (expenditure) from financing activities			
Repayment of interest-bearing commitments		0	–5,000
Interest paid		–334	–338
Repayment of lease liabilities	9	–157	–173
Cash flow from financing activities		**–491**	**–5,511**

(in KCHF)	Annex	2023	2022
Net increase / (decrease) in cash and cash equivalents		**7,237**	**–36,783**
Cash and cash equivalents at start of year	1	5,195	41,978
Cash and cash equivalents at year end	1	12,432	5,195



STATEMENT OF CHANGES IN EQUITY

(in KCHF)	Annual gain	Reserves	Endowment capital	Accum. actuarial gains (+) / losses (–)	Total equity
Opening balance on 1 January 2022	**21,852**	**79,508**	**14,500**	**–550**	**115,310**
Annual gain	11,505	0	0	0	11,505
Other income	0	0	0	56,451	56,451
Total	**11,505**	**0**	**0**	**56,451**	**67,956**
Appropriation of gain	**–21,852**	**21,852**	**0**	**0**	**0**
Closing balance on 31 December 2022	**11,505**	**101,360**	**14,500**	**55,901**	**183,266**
Opening balance on 1 January 2023	**11,505**	**101,360**	**14,500**	**55,901**	**183,266**
Annual gain	1,708	0	0	0	1,708
Other income	0	0	0	–36,844	–36,844
Total	**1,708**	**0**	**0**	**–36,844**	**–35,136**
Appropriation of gain	**–11,505**	**11,505**	**0**	**0**	**0**
Closing balance on 31 December 2023	**1,708**	**112,865**	**14,500**	**19,057**	**148,130**

ANNEX

Operating activities

Swissmedic is the Swiss authority for the authorisation and monitoring of 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. 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 2023 to 31 December 2023. The balance sheet date is 31 December 2023. 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 26 April 2024.

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 2023.

- New IFRS 17 – Insurance Contracts
- Amendments to IAS 1 and IFRS Practice Statement 2 – Information on accounting principles
- Amendments to IAS 8 – Definition of accounting estimates
- Amendments to IAS – Narrowed scope of the initial recognition exception (IRE)»
- Amendments to IAS 12 – International Tax Reform – Pillar Two Model Rules

None of these amendments had a material impact on these accounts. Furthermore, Swissmedic has not prematurely applied any standards that have been published but are not yet mandatory.

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 invests 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 transactions costs 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	IT equipment (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	IT software	3–10 years

The residual value, useful life and amortisation method of each intangible 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.

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 is the same as 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.

Financial commitments

Financial commitments are valued at updated acquisition cost.

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. A reduction in contributions for the purposes of IFRS exists when the employer has to pay contributions that are lower than the service cost. Extraordinary events such as changes to benefit plans that change employees' entitlements or curtailments and settlements are immediately recognised 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. If the reserves exceed one annual budget, fees and levies have to be reduced accordingly.

Foreign currency conversion

Rate as at	31.12.23	31.12.22
Euro	0.97060	0.99580
US dollar	0.90490	0.98530
British pound	1.11350	1.14570
Swedish kronor	0.0834	0.0916

Income

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 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. Legislative work, enforcement of provisions of criminal law and medical devices surveillance are funded in their entirety from the federal contribution (Article 77 paragraph 2bis Therapeutic Products Act). The federal contribution is defined annually as part of the federal budget.

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

Financial risks tend to be slight for the following reasons:

Market risks

Foreign currency risk
Swissmedic is not exposed to any foreign currency risks. It invoices in Swiss francs and payments to suppliers abroad are negligible.

Price risk
Swissmedic is not exposed to any price risks. It does not hold any financial assets or financial instruments that are exposed to market price fluctuations.

Interest rate risk
Swissmedic holds financial assets in the form of state-guaranteed debenture bonds. The effect of changes in market interest rates on these debenture bonds is not considered to be material.

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 because customers are obliged to use Swissmedic's services by virtue of its monopoly position. 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.

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. Material estimates are applied for example when determining pension obligations, and when determining the useful life of fixed and intangible assets. Although these estimates are based on the Management Board's best assessment of current events and possible future actions on the part of Swissmedic, actual results may differ from these estimates. The nature and carrying amounts of relevant assets and liabilities as at the balance sheet date are listed in the Annex.

Notes on the balance sheet

1 Cash and cash equivalents

(in KCHF)	31.12.23	31.12.22
Current accounts at banks	2,568	5,195
Money market investments	9,864	0
Total cash and cash equivalents	**12,432**	**5,195**

Cash and cash equivalents increased on the previous year. They now include immediately available money market investments.

2 Receivables from sales and services

Trade receivables from third parties

(in KCHF)	31.12.23	31.12.22
Not overdue	59,613	58,489
1–30 days overdue	17	83
More than 30 days overdue	257	287
Total receivables from sales and services (gross)	59,887	58,859
Individual value adjustments	–50	–134
Flat-rate value adjustment	–5	–6
Total receivables from sales and services (net)	**59,832**	**58,719**

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. Receivables are due mainly from the therapeutic products industry (99.27%), Confederation and Cantons (0.16%) and private individuals (0.57%).

Payment schedules

(in KCHF)	31.12.23	31.12.22
Non-overdue receivables for which the payment deadline was subsequently extended (payment schedules)	180	228
Total payment schedules	**180**	**228**

As at the end of 2023, there were 10 payment schedules (previous year: 15) for an unpaid amount of CHF 180,000. There are no foreign currency receivables.

Value adjustments on receivables

(in KCHF)	31.12.23	31.12.22
Total value adjustments on receivables 1 January	–140	–37
Recognition	0	103
Reversal	85	0
Use	0	0
Total value adjustments on receivables as at 31 December (total of individual and flat-rate adjustments)	**–55**	**–140**

3 Uninvoiced procedural fees

(in KCHF)	31.12.23	31.12.22
Uninvoiced procedural fees	5,549	5,294
Total uninvoiced procedural fees	**5,549**	**5,294**

4 Prepaid expenses

(in KCHF)	31.12.23	31.12.22
Prepaid expenses	896	351
Total prepaid expenses	**896**	**351**

The following transactions are reported under prepaid expenses:

- Accumulated interest on debenture bonds as at 31 December 2023
- Individual invoices for services due for delivery in 2024 but which had to be paid for in 2023
- Individual invoices for contracts dating from 2024

5 Financial assets

Carrying amounts (in KCHF)	31.12.23	31.12.22
– CHF 10 mn Basler Kantonalbank, matured 10 Aug. 2023, interest rate 0.375%	0	10,050
– CHF 10 mn Thurgauer Kantonalbank, matured 28 Aug. 2023, interest rate 1.375%	0	10,140
– CHF 5 mn Walliser Kantonalbank, matured 15 Dec. 2023, interest rate 0.625%	0	5,013
– CHF 10 mn Aargauer Kantonalbank, matured 21 Feb. 2024, interest rate 0.11%	10,012	10,023
– CHF 5 mn Freiburger Kantonalbank, matures 3 June 2024, interest rate 1.25%	5,060	5,121
– CHF 10 mn Walliser Kantonalbank, matures 19 Aug. 2024, interest rate 0.2%	9,992	9,992
– CHF 10 mn Mortgage Bond Centre, matures 2 Dec. 2024, interest rate 0.125%	9,877	0
– CHF 5 mn Basler Kantonalbank, matures 19 April 2025, interest rate 1.875%	5,057	0
Total debenture bonds	**39,998**	**50,339**
of which short-term	34,941	25,203
of which long-term	5,057	25,136

Fair values (in KCHF)	31.12.23	31.12.22
– CHF 10 mn Basler Kantonalbank, matured 10 Aug. 2023, interest rate 0.375%	0	9,926
– CHF 10 mn Thurgauer Kantonalbank, matured 28 Aug. 2023, interest rate 1.375%	0	10,007
– CHF 5 mn Walliser Kantonalbank, matured 15 Dec. 2023, interest rate 0.625%	0	4,936
– CHF 10 mn Aargauer Kantonalbank, matured 21 Feb. 2024, interest rate 0.11%	9,960	9,833
– CHF 5 mn Freiburger Kantonalbank, matures 3 June 2024, interest rate 1.25%	4,668	4,998
– CHF 10 mn Walliser Kantonalbank, matures 19 Aug. 2024, interest rate 0.2%	9,879	9,737
– CHF 10 mn Mortgage Bond Centre, matures 2 Dec. 2024, interest rate 0.125%	9,863	0
– CHF 5 mn Basler Kantonalbank, matures 19 April 2025, interest rate 1.875%	5,011	0
Total debenture bonds	**39,381**	**49,437**
of which short-term	34,370	24,869
of which long-term	5,011	24,568

Swissmedic invests all surplus liquid resources in state-guaranteed debenture bonds. The fair value of listed bonds is based on the asset price on the balance sheet date.

6 Fixed assets

Statement of changes (in KCHF)	Furnishing and off. equip.	Archive equipment	Laboratory equipment	Computer systems	Total fixed assets
Acquisition cost					
1 January 2022	**2,861**	**1,929**	**6,007**	**129**	**10,926**
Additions	35	0	496	0	531
Disposals	–10	0	–116	0	–126
31 December 2022	**2,886**	**1,929**	**6,387**	**129**	**11,331**
1 January 2023	**2,886**	**1,929**	**6,387**	**129**	**11,331**
Additions	110	0	546	194	850
Disposals	–10	0	–78	–34	–122
31 December 2023	**2,986**	**1,929**	**6,855**	**289**	**12,059**
Accumulated depreciation					
1 January 2022	**–2,661**	**–1,917**	**–3,963**	**–91**	**–8,632**
Additions	–130	–11	–388	–14	–543
Disposals	10	0	116	0	126
31 December 2022	**–2,781**	**–1,928**	**–4,235**	**–105**	**–9,049**
Net carrying amounts as at 31 December 2022	**105**	**1**	**2,152**	**24**	**2,282**
1 January 2023	**–2,781**	**–1,928**	**–4,235**	**–105**	**–9,049**
Additions	–48	–1	–411	–52	–512
Disposals	10	0	78	34	122
31 December 2023	**–2,819**	**–1,929**	**–4,568**	**–123**	**–9,439**
Net carrying amounts as at 31 December 2023	**167**	**0**	**2,287**	**166**	**2,620**

Various fixed assets, such as laboratory equipment and furnishings, were acquired and capitalised during 2023. As at the balance sheet date, there were no indications of any unanticipated impairments.

7 Real estate

Statement of changes (in KCHF)	Renovation account	Property	Land	Total real estate
Acquisition cost				
1 January 2022	**0**	**84,888**	**11,730**	**96,618**
Additions	912	0	0	912
Reclassifications	–800	800	0	0
Disposals	0	–79	0	–79
31 December 2022	**112**	**85,609**	**11,730**	**97,451**
1 January 2023	**112**	**85,609**	**11,730**	**97,451**
Additions	509	0	0	509
Reclassifications	–130	130	0	0
31 December 2023	**491**	**85,739**	**11,730**	**97,960**
Accumulated depreciation				
1 January 2022	**0**	**–31,846**	**0**	**–31,846**
Additions	0	–2,463	0	–2,463
Disposals	0	87	0	87
31 December 2022	**0**	**–34,222**	**0**	**–34,222**
Net carrying amounts as at 31 December 2022	**112**	**51,387**	**11,730**	**63,229**
1 January 2023	**0**	**–34,222**	**0**	**–34,222**
Additions	0	–2,541	0	–2,541
31 December 2023	**0**	**–36,763**	**0**	**–36,763**
Net carrying amounts as at 31 December 2023	**491**	**48,976**	**11,730**	**61,197**

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. During 2023, investments in the flat roof at Erlachstrasse and in building services installations (e.g. new photovoltaic installation, replacement chiller and water heating system) were made and capitalised. 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.

8 Intangible assets

Statement of changes (in KCHF)	Software in development	Software developed by Swissmedic	Total intangible assets
Acquisition cost			
1 January 2022	**311**	**16,781**	**17,092**
Additions	2,163	0	2,163
31 December 2022	**2,227**	**16,781**	**19,008**
1 January 2023	**2,227**	**16,781**	**19,008**
Additions	3,929	0	3,929
Reclassifications	–565	565	
31 December 2023	**5,591**	**17,346**	**22,937**
Accumulated depreciation			
1 January 2022	**0**	**–15,750**	**–15,750**
Additions	0	–472	–472
31 December 2022	**0**	**–16,222**	**–16,222**
Net carrying amounts as at 31 December 2022	**2,227**	**559**	**2,786**
1 January 2023	**0**	**–16,222**	**–16,222**
Additions	**0**	–284	–284
31 December 2023	**0**	**–16,506**	**–16,506**
Net carrying amounts as at 31 December 2023	**5,591**	**840**	**6,431**

One intangible asset – TRICIA, a tool for automatically sorting medical device vigilance reports – was capitalised during 2023. As at the balance sheet date, there were no indications of any unanticipated impairments.

9 Right of use

(in KCHF)	Right of use	Total right of use
Acquisition cost		
1 January 2022	**3,257**	**3,257**
Additions / disposals	0	0
31 December 2022	**3,257**	**3,257**
1 January 2023	**3,257**	**3,257**
Additions / disposals	0	0
31 December 2023	**3,257**	**3,257**
Accumulated depreciation		
1 January 2022	**–543**	**–543**
Additions / disposals	–181	–181
31 December 2022	**–724**	**–724**
Net carrying amounts as at 31 December 2022	**2,533**	**2,533**
1 January 2023	**–724**	**–724**
Additions / disposals	–167	–167
31 December 2023	**–891**	**–891**
Net carrying amounts as at 31 December 2023	**2,366**	**2,366**

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)	31.12.23	31.12.22
Starting balance as at 1 January	**2,574**	**2,746**
Redemption	–201	–195
Accrued interest	48	23
Final balance as at 31 December	**2,421**	**2,574**
of which short-term	201	195
of which long-term	2,221	2,378

There are no further lease liabilities.

10 Commitments on sales and services towards third parties

(in KCHF)	31.12.23	31.12.22
In CHF	8,317	7,495
In foreign currencies	11	18
Total commitments on sales and services towards third parties	**8,328**	**7,513**

Overdue commitments are an exception at Swissmedic because a payment run covering all due supplier invoices takes place weekly.

11 Other commitments

(in KCHF)	31.12.23	31.12.22
Short-term lease liabilities	201	195
Other short-term commitments towards third parties	1,117	858
Total other short-term commitments	**1,318**	**1,053**

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.

12 Deferred income

(in KCHF)	31.12.23	31.12.22
Deferred income	128	113
Amount deferred for leave and flexitime	4,312	3,765
Total deferred income	**4,440**	**3,878**

Deferred income comprises individual outstanding invoices from 2023.

13 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 old 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 provides supervision and control for PUBLICA's management board.

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.

Plan amendments

The PUBLICA fund commission has decided to align the conversion rates for men and women at ages 64 and 63. Until now they have been different. This is a plan amendment and yields CHF 1.68 million that has to be reported in the income statement.

Pension fund status is calculated as follows:

(in KCHF)	2023	2022
Change in commitments and assets		
Dynamic present value of benefit obligations at start of year	**–304,975**	**–381,085**
Actuarial pension benefit expenses	–7,650	–10,848
Employee contributions	–4,944	–4,390
Past benefit expenses	1,680	0
Interest expense	–6,859	–1,334
Benefits paid	–4,344	4,235
Actuarial gain (+) / loss (–) on commitments	–43,582	88,447
Dynamic present value of benefit obligations at year-end	**–370,674**	**–304,975**
Plan assets at market value at start of year	**314,985**	**334,711**
Interest income	7,084	1,172
Employer contributions	9,008	11,060
Employee contributions	4,944	4,390
Benefits paid	4,344	–4,235
Administrative expenses	–129	–118
Actuarial gain (+) / loss (–) on assets	6,738	–31,995
Plan assets at market value at year-end	**346,974**	**314,985**
Balance sheet	**31.12.23**	**31.12.22**
Plan assets at market value	346,974	314,985
Dynamic present value of benefit obligations (DBO)	–370,674	–304,975
Assets (+) / liabilities (–) in the balance sheet	**–23,700**	**10,010**
Duration	16.20	15.20

Income statement (in KCHF)	2023	2022
Actuarial pension benefit expenses	–7,650	–10,848
Interest expense	–6,859	–1,334
Interest income	7,084	1,172
Past service cost	1,680	0
Administrative expenses	–129	–118
Net expenses for benefit obligations	**–5,874**	**–11,128**
Change in the balance sheet	**31.12.23**	**31.12.22**
Liabilities on the balance sheet at start of year	**10,010**	**–46,374**
Net benefit expenses (employer)	–5,874	–11,128
Employer contributions	9,008	11,060
Actuarial gains (+) / losses (–)	–36,844	56,452
Liabilities on the balance sheet at year-end	**–23,700**	**10,010**
Anticipated employer contribution payment in following year	9,400	8,446
Effective return on plan assets	13,822	–30,823
Key actuarial assumptions as at balance sheet date	**31.12.23**	**31.12.22**
Discount rate	1.50%	2.25%
Future payroll increases	2.00%	2.00%
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	24.43/26.21	24.30/26.10
Asset allocation	**31.12.23**	**31.12.22**
Cash and cash equivalents	4.30%	5.00%
Bonds	42.10%	46.30%
Equities	32.70%	27.80%
Real estate	18.10%	18.50%
Other	2.80%	2.40%
Total	**100.00%**	**100.00%**
Of which stock exchange-traded	80.30%	79.70%

Defined benefit pension plans	31.12.23	31.12.22
Revaluation of actuarial gain (+) / loss (–) from obligations	**–43,582**	**88,447**
Owing to changes in holdings	–2,969	–7,842
Owing to demographic assumptions	0	0
Owing to financial assumptions	–40,613	96,289
Revaluation of actuarial gain/loss from investments	**6,738**	**–31,995**
Total amount recognised in equity	**–36,844**	**56,452**

Sensitivities – impact on DBO (in KCHF)	2023	2022
Discount rate +0.25%	–14,390	–11,044
Discount rate –0.25%	15,338	11,733
Payroll increase +0.25%	1,181	871
Payroll increase –0.25%	–1,152	–851
Pension increase +0.25%	10,231	7,892
Pension increase –0.25% (not lower than 0%)	0	0
1-year increase in life expectancy	14,714	12,273

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

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

(in KCHF)	2023	2022
Authorisation (with no fee rebates)	28,831	31,391
Licensing	12,851	13,168
Therapeutic products information	1	1
Informing the general public	0	5
Market supervision	3,779	3,519
Penal law	170	83
Fee surcharges	468	567
Earnings from conferences (Art. 69 TPA)	26	299
Earnings from publications (Art. 69 TPA)	0	1
Earnings from services for third parties (Art. 69 TPA)	179	153
Fee reductions	–7,487	–6,910
Total procedural fees and income pursuant to Art. 69 TPA	**38,818**	**42,277**

Income from procedural fees fell by CHF 3.4 million year-on-year. Fewer new authorisation applications and applications for extensions were completed. Moreover, fee reductions increased by more than CHF 0.5 million.

15 Personnel

(in KCHF)	2023	2022
Wages and salaries	–70,357	–61,564
Net expenses for benefit obligations	–5,874	–11,128
Social security	–6,207	–5,557
Other personnel expenses	–2,460	–2,012
Work by third parties	–337	–666
Total personnel expenses	**–85,235**	**–80,927**

Wage and salary expenses rose by CHF 8.8 million year-on-year. Around 70 percent of this increase is attributable to headcount increase, the remainder to regular (individual salary development and adjustments for inflation) and exceptional (adjustments in response to a salary benchmarking study to ensure labour market competitiveness) salary measures.

16 IT

(in KCHF)	2023	2022
Operating services	–8,595	–5,944
Hardware	–694	–274
Software licences	–1,349	–1,013
Development and project management services	–4,513	–1,973
Maintenance and support services	–883	–1,813
Total IT	**–16,034**	**–11,017**

IT expenses rose by around CHF 5 million in 2023. The causes of this increase are split roughly 50-50 between the increase in operating service costs (increased cost of services, larger number of applications, higher headcount) and the increase in development and project management service costs (innovation).

17 Financial income

(in KCHF)	2023	2022
Interest income from receivables and debenture bonds	615	2
Exchange rate gains	12	12
Total financial income	**627**	**14**

18 Financial expense

(in KCHF)	2023	2022
Interest expense, banks	–286	–315
Interest expense, leases	–48	–23
Exchange rate losses	–5	–6
Total financial expense	**–339**	**–344**

Other notes

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	4,186	0	0	0	4,186
Commitments on sales and services towards related parties (over CHF 1 mn)	3,327	0	0	0	3,327
Lease obligations toward third parties	49	146	780	1,755	2,730
Total contractual cash flows from financial commitments 2022	**7,562**	**146**	**780**	**1,755**	**10,243**
Commitments on sales and services towards third parties	4,973	0	0	0	4,973
Commitments on sales and services towards related parties (over CHF 1 mn)	2,990	0	0	0	2,990
Other commitments on sales and services towards related parties	365	0	0	0	365
Lease obligations toward third parties	49	156	804	1,603	2,612
Total contractual cash flows from financial commitments 2023	**8,377**	**156**	**804**	**1,603**	**10,940**

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:

- The Federal Administration, specifically the General Secretariat of the Federal Department of Home Affairs
- The Swiss federal pension fund PUBLICA, the Federal Office of Information Technology, Systems and Telecommunication (FOITT)
- The Federal Office for Buildings and Logistics (FOBL), the Federal Compensation Office (CFC), the Federal Office of Public Health (FOPH)
- 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)	31.12.23	31.12.22
PUBLICA, social insurance contributions	1,228	1,095
FOITT, IT expenses	1,761	1,520
CFC, social insurance contributions	604	623
Total commitments towards related parties	**3,593**	**3,238**

(in KCHF)	31.12.23	31.12.22
GS FDHA, federal contribution	20,007	19,227
Total net income involving related parties	**20,007**	**19,227**
PUBLICA, social insurance contributions	13,964	15,445
FOITT, IT expenses	6,626	5,708
CFC, social insurance contributions	8,669	8,250
Total operating expenses involving related parties	**29,259**	**29,403**

Remuneration of individuals in key positions

The following fees and salaries were paid:

(in KCHF)	2023	2022
Short-term benefits due to the Management Board	1,980	2,059
Benefits following termination of employment contract	340	354
Benefits occasioned by termination of employment contract	0	0
Share-based compensation	0	0
Total remuneration of individuals in key positions	**2,320**	**2,319**

The Management Board consists 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

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

Phone: +41 58 286 61 11
Fax: +41 58 286 30 04
www.ey.com/ch

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

Berne, 26 April 2024

Report of the statutory auditor

Report on the audit of the financial statements

Opinion
According to article 74 of the Federal Act on Medicinal Products and Medical Devices we have audited the financial statements of Swissmedic, Swiss Agency for Therapeutic Products, («the Agency»), which comprise the statement of financial position as at 31 December 2023 and the statement of income, statement of other comprehensive income, statement of cash flows, statement of changes in equity and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements (pages 66 to 92) give a true and fair view of the financial position of the Agency as at 31 December 2023, and its financial performance and its cash flows for the year then ended, in accordance with International Financial Reporting Standards (IFRS) and comply with Swiss law.

Basis for opinion
We conducted our audit in accordance with Swiss law 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 Agency in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, as well as the *International Code of Ethics for Professional Accountants (including International Independence Standards) of the International Ethics Standards Board for Accountants (IESBA Code)* and we have 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 in the annual report
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 and our auditor's report thereon.

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

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 that give a true and fair view in accordance with IFRS 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 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.

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

Andreas Schwab-Gatschet
Licensed audit expert
(Auditor in charge)

Cédric Meyer
Licensed audit expert

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
Fax +41 58 462 02 12
www.swissmedic.ch