



ANNUAL REPORT 2022

Mission

Our competence –
for therapeutic products you can trust.

Guiding principles of Swissmedic

CONTENTS

6 Forewords

- 6 2019–2022 strategy period successfully completed
- 7 Indispensable for safe therapeutic products in Switzerland for 20 years

8 Swissmedic at a glance

- 8 Core tasks of Swissmedic
- 9 20 years of Swissmedic
- 12 Stakeholder

13 Corporate Governance

- 13 Organisation
- 14 Agency Council
- 16 Management Board
- 17 Human resources
- 18 Organisational chart
- 19 Consultant experts
- 20 Risk management and compliance
- 20 Sustainability

22 Medicinal Products – Standards product group

- 22 Legal Framework product
- 22 Technical Standards product

24 Medicinal Products – Information product group

- 24 Informing the General Public product
- 24 Informing the Therapeutic Products Sector product

27 Medicinal Products – Market Access product group

- 27 Authorisation product
 - 27 Overview
 - 28 Authorisation procedure
 - 29 Time limits and international benchmarking
 - 30 Human medicinal products
 - 32 Transplant products
 - 32 Special human medicinal product and transplant product categories
 - 34 Complementary and herbal medicines
 - 35 Veterinary medicinal products
 - 35 Appeals procedure
 - 36 Medicinal products: facts and figures
- 40 Licensing product
 - 40 Overview
 - 41 Establishment licences
 - 41 Licences for handling controlled substances
 - 41 Licences for clinical trials
 - 42 Import licences for vaccines and blood products
 - 42 Special licences

- 43 Certificates for medicinal and transplant products
- 43 Inspections
- 45 Other monitoring activities
- 46 Batch release
- 46 Other OMCL activities
- 46 Appeals procedure
- 47 Establishment licences issued under the old and new legislation in facts and figures

49 Medicinal Products – Market Surveillance product group

49 Vigilance product

- 49 Human medicinal products vigilance
- 49 Vigilance for veterinary medicinal products
- 50 International signals and safety reports

52 Market Monitoring product

- 52 Quality defects and batch recalls
- 53 Out-of-stock products
- 53 Control of advertising
- 53 Measures against illegal medicinal products
- 54 Appeals procedure

55 Medicinal Products – Penal Law product group

55 Penal Law product

57 Medical Devices – Standards product group

- 57 Legal Framework product
- 57 Technical Standards product

58 Medical Devices – Information product group

- 58 Informing the General Public product
- 58 Informing the Therapeutic Products Sector product

60 Medical Devices – Market Access product group

60 Licensing product

- 60 Placing on the market
- 60 Clinical trials
- 61 Export certificates
- 61 Unique identification number

62 Medical Devices – Market Surveillance product group

62 Vigilance product

- 62 Materiovigilance

63 Market Monitoring product

- 63 Independent monitoring
- 63 Market monitoring procedures
- 64 Notified bodies and inspections
- 64 Hospital inspections
- 64 Appeals procedure

65 Medical Devices – Penal Law product group

65 Penal Law product

- 66 Balance sheet**
- 67 Income statement**
- 67 Statement of comprehensive income**
- 68 Cash flow statement**
- 69 Statement of changes in equity**
- 70 Annex**
- 70 Operating activities**
- 70 Summary of the main accounting principles**
- 75 Risk assessment and risk management**
- 76 Valuation uncertainties**
- 76 Notes on the balance sheet**
 - 76 1 Cash and cash equivalents
 - 77 2 Receivables from sales and services
 - 78 3 Uninvoiced procedural fees
 - 78 4 Prepaid expenses
 - 78 5 Financial assets
 - 79 6 Fixed assets
 - 80 7 Real estate
 - 81 8 Intangible assets
 - 82 9 Right of use
 - 83 10 Commitments on sales and services towards third parties
 - 83 11 Other commitments
 - 83 12 Deferred income
 - 83 13 Financial commitments
 - 84 14 Pension provision
- 88 Notes on the income statement**
 - 88 15 Procedural fees and income pursuant to Article 69 Therapeutic Products Act
 - 88 16 Personnel
 - 89 17 IT
 - 89 18 Financial income
 - 89 19 Financial expense
- 90 Other notes**
- 93 Report of the statutory auditors**

FOREWORDS

2019–2022 strategy period successfully completed

Lukas Bruhin, President of the Agency Council

2022 was the last year of the 2019–2022 strategy period. Swissmedic achieved the ambitious goals it had set itself for the period. My pride in this accomplishment is enhanced by the fact that no one expected to have to deal with the tumultuous events of the past few years at the time the goals were approved. At Swissmedic as elsewhere, recent years have been dominated by the COVID pandemic. In March 2022, Switzerland made the decision to return to “normal” and lift the remaining precautions to contain the coronavirus. Swissmedic adopted totally new processes during the pandemic to ensure that medicinal products and vaccines were assessed promptly yet thoroughly in rolling procedures. Overall, the Agency complied with processing times in all four years of the strategy period.

The pandemic also presented major challenges for Swissmedic’s medical device-related activities. These were compounded by the recurring need to align with the new European regulation at short notice. Moreover, cooperation with our European partners, which had been very close up to that point, fell away from one day to the next following the breakdown in negotiations on the institutional framework agreement in May 2021.

At international level, Swissmedic made an active contribution to the development of regulatory and quality standards. Its close links and dialogue with partner authorities were also a key factor in managing the pandemic.

I would like to thank all employees and the Management Board for their exemplary and successful commitment in the past four years. It does not go without saying that a therapeutic products authority that is comparatively small by international standards ranks alongside the best agencies. Swissmedic’s employees are highly motivated, professional and innovative, and they identify strongly with the Agency and its mandate. Last year’s employee satisfaction survey showed this to be the case. The fact that this is so gives me great optimism for the future.

Swissmedic celebrated its 20th anniversary in 2022. This milestone was marked in appropriate style by various events and an uplifting ceremony at Bern Rathaus attended by Federal Councillor Alain Berset and keynote speakers from science, business, government and international partner authorities.

The Agency Council set out Swissmedic’s approach to upcoming challenges in the new strategic goals for 2023–2026, which were approved by the Federal Council in December 2022. Supporting innovation and progressing digitalisation are set to gain even greater significance as tools for ensuring that Swissmedic remains a world-leading networked therapeutic products authority – in the interests of the health of people and animals in Switzerland.



Indispensable for safe therapeutic products in Switzerland for 20 years

Raimund Bruhin, Executive Director

For the third time in succession, the past year was dominated by the coronavirus, with new variants of the virus, new bivalent vaccines and wide-ranging changes to vaccines that had already been authorised. Once again, all Swissmedic's Sectors had to put in significant additional work.

Apart from day-to-day operations, the activities to mark Swissmedic's 20th anniversary were a key feature of 2022. These included "Regulatory and Beyond", an event for the therapeutic products sector attended by around 580 people; a VIP event attended by key national and international representatives of government, the regulatory environment, research, science and industry; monthly media letters; and a family event for all employees. The anniversary was firstly a good opportunity to celebrate and show pride in what is now an international leader among therapeutic products authorities. Secondly, it was a chance to further raise awareness of Swissmedic among politicians, the business community and the public, and to position it as a systemically important authority for public health and patient safety.

In the course of the year, the framework for assuming responsibility for veterinary immunological products, including pet and livestock vaccines, was set in place. The Federal Council approved the necessary amendments to the relevant ordinance in November 2022. For historical reasons, veterinary immunological products had always been the responsibility of the Institute for Virology and Immunology. Since 1 January 2023, authorisation, monitoring and market surveillance of immunological veterinary medicinal products has been the task of Swissmedic. By amalgamating responsibilities and leveraging synergies between specialist fields, it was possible to implement a sustainable and efficient solution.

A further operational landmark was the implementation of the new legal provisions governing in vitro diagnostic medical devices and the relevant clinical trials of

medical devices. The new requirements came into force in May 2022. Swissmedic gave a comprehensive briefing on the new regulation at an online event attended by over 700 people.

Operational goals were mostly achieved once again in 2022, the exceptions being a small number of cases in which timelines were not met. This was a delayed effect of the additional workload during the pandemic and the priority processing of applications for COVID vaccines.

Despite the huge amount of extra work during this strategy period, Swissmedic was able to fulfil its strategic targets for 2022, successfully achieve its strategic goals for 2019–2022 and post a healthy financial result. The current 2023–2026 strategy period is generally geared to strengthening Swissmedic's position in the national and international therapeutic products sector. This will safeguard Swissmedic's operational competence and function across the full width of its legal mandate.



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, effective and safe medicinal products and medical devices (therapeutic products) are placed on the market in Switzerland.

Specifically, the main tasks of Swissmedic 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.

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)

The key achievements and figures for 2022 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 75 percent of operating costs.

The 2022 financial statements with accompanying commentary start on page 66.



20 years of Swissmedic

2022 marked Swissmedic's 20th anniversary. Since 1 January 2002, Switzerland has had a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act) and a decentralised, neutral federal authority that protects the health of humans and animals by ensuring that only high-quality, safe and effective therapeutic products are placed on the market.

The decision to create a federal authority stemmed from the constant evolution of therapeutic products regulation and the therapeutic products market. Over the preceding decades, the therapeutic products sector developed into an increasingly global business with international standards. Switzerland needed a national point of contact for international cooperation between therapeutic products authorities. The intercantonal convention was no longer suitable for this task or for the task of regulating a strong therapeutic products industry. In light of this, the government wanted a national authority and nationwide uniform regulation with authorisation, manufacture, quality control and market surveillance built on a legal basis that would apply throughout Switzerland. As the first piece of nationwide legislation applicable to all medicinal products and medical devices, the Therapeutic Products Act created the framework for international cooperation and harmonisation.

Today, Swissmedic is one of the world's leading medicinal product authorities and is extremely well connected at international level. In 2022, one fifth of human medicinal products with new active substances were authorised under international procedures (work sharing in the Access Consortium and the FDA's Project Orbis). The regulatory requirements that apply in Switzerland have been largely standardised and harmonised with international requirements. Swissmedic contributes to and takes leadership roles in international organisations such as the International Council for Harmonisation (ICH), where the Agency holds the vice-chairship of the ICH Assembly. Furthermore, the development cooperation it undertakes in pursuit of the strategic goals of Switzerland's health foreign policy help strengthen regulatory systems and thus improve access to therapeutic products, primarily in the sub-Saharan countries of Africa.

International cooperation on medical devices came to an abrupt halt in May 2021. Since 1 June 2002, Switzerland's Mutual Recognition Agreement (MRA) with the European Union (EU) had made the country an integral part of the EU single market, which meant that Swissmedic was in turn part of the EU's market surveillance network. Medical devices surveillance and the ongoing



development of the regulatory framework took place in cooperation with the EU states. When negotiations on an institutional framework agreement were broken off on 26 May 2021, the EU refused to update the MRA and declared it void as regards medical devices. Swissmedic was excluded from all steering and enforcement committees and lost access to the new European central database on medical devices. Since then, the Agency has been focusing international cooperation activities on the International Medical Device Regulators Forum (IMDRF), a global standardisation initiative whose semi-annual Management Committee Meetings it has been attending as an invited observer since March 2021.

Therapeutic products regulation has also evolved in the last 20 years, prompting the updating of the legal framework. Initial urgent measures to increase security of supply were enacted on 1 October 2010. Furthermore, the Therapeutic Products Act underwent a comprehensive process of revision starting in 2009. With more than half of its provisions revised, the Act had effectively undergone a complete overhaul when it was ratified by the Swiss parliament on 18 March 2016. In addition to amending therapeutic products provisions, it included the Confederation's new governance standards, embedding corporate governance principles at Swissmedic for the first time. In particular, Chapter 5 of the revised Therapeutic Products Act contains provisions on the Agency's governing bodies and their tasks, competencies and responsibilities, Swissmedic's autonomy and supervision by the Federal Council. This now also includes management by strategic goals over periods of four years. For implementation purposes, the Therapeutic Products Act was substantiated by 16 ordinances of the Federal Council and Agency Council, which had to be amended in turn. The revised Therapeutic Products Act and its associated ordinances entered into force on 1 January 2019. Having previously comprehensively re-aligned its business and IT processes, Swissmedic thus embarked on its first four-year strategy period on the basis of its 2019–2022 strategy.

Swissmedic's supervisory and monitoring activities have become more complex and work-intensive since 2002. The breakneck pace of scientific and technological change, novel technologies and developments in digital technology are spawning new forms of evidence generation and new product types and combinations, while stakeholders' expectations of dialogue with the authority, decision-making speed and transparency have risen markedly. Furthermore, the Agency has assumed new

tasks in recent years, notably expanded official surveillance of medical devices, transplant product regulation and surveillance, combating medicinal products-related crime (medicrime), microbiological laboratories licensing and expanded narcotics control. On top of this, it has to contend with a dramatic across-the-board rise in communication and information demands and the challenges of social media communication, data protection and information security.

As an organisation, Swissmedic has developed and grown accordingly. Formed from the merger of the Federal Office of Public Health's Main Unit Medicines and the Intercantonal Office for the Control of Medicines, it originally employed 300 people in around 240 full-time-equivalent positions. By 2022, this figure had grown to more than 530 people in 450 full-time-equivalent positions. These employees are split between three locations at Hallerstrasse 7, Erlachstrasse 8 and Freiburgstrasse 139 in Bern. In addition to office workstations, Swissmedic has a modern laboratory infrastructure. Stakeholder dialogue and communication take place to a large extent through digital channels. With the introduction of the eCTD format in 2010, paper – an application for authorisation of a new active substance could consist of up to 1,000 ring binders – began to gradually disappear from Swissmedic's offices.





Swissmedic's ranking in international benchmarking

2,685
person days

for contributions to working groups set up to develop international standards

137
articles in the Therapeutic Products Act

21

Memoranda of Understanding

11%

more human medicinal products authorised compared with 2002

22

innovative medicinal products and additional indications authorised under international work-sharing procedures

2.5 times as many establishment licences

for medicinal products manufacturing and distribution compared with 2002

40%

more applications for authorisation or variations compared with 2002

7.5 times as many reports

of adverse drug reactions processed compared with 2002



29 kilometres of archived files

30,400
followers on social media channels

Stakeholder

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

- The public, consisting of patients, consumers, their organisations and media
- Healthcare and medical professionals
- The therapeutic products industry and its service providers, including research and innovation
- The regulatory environment, consisting of parliament and federal and cantonal authorities
- The international environment, consisting of international organisations and other countries' authorities

National cooperation

Swissmedic engages in regular national-level dialogue with a range of stakeholders.

There is closer cooperation with federal offices and cantonal authorities. Enforcement of the Therapeutic Products Act is coordinated with representatives of the Association of Cantonal Pharmacists and the Cantonal Pharmacists themselves. The key topics discussed in 2022 were the amended medical devices regulation and the new requirements that healthcare institutions have to fulfil in terms of quality assurance and device traceability.

Swissmedic has been meeting patient and consumer organisations in a working group for several years. This working group met three times in 2022. The safety of vaccines and medicinal products for COVID-19 was a key topic, as were the assessment of causal connections and the compensation process for people who suffer vaccine injuries.

Dialogue with the therapeutic products industry and industry associations takes place at various round table meetings (e.g. Regulatory Affairs, Good Manufacturing and Distribution Practices GMP/GDP, medical technology). A total of ten such round table meetings took place in 2022. The topics discussed included speeding up processes, accelerated application hearings, QR codes on packaging, incorporating real-world evidence, the new platform for the medical professions register, legislation

for medical devices and in vitro diagnostic medical devices, Swissdamed (Swiss Database on Medical Devices), supplies in hospitals and the regulation of in-house devices manufactured and used in hospitals.

International cooperation

International bilateral and multilateral cooperation are extremely important for Swissmedic and for Switzerland as a location. The Agency's activities in this area include a commitment to harmonising regulatory requirements and active participation in committees and information- and knowledge-sharing forums, which proved to be extremely valuable during the COVID-19 pandemic.

Swissmedic plays an active role in the following organisations and bodies:

- Access Consortium (therapeutic products authorities of Australia, Canada, Singapore, the United Kingdom and Switzerland)
- International Council for Harmonisation (ICH)
- International Pharmaceutical Regulators Programme (IPRP)
- International Coalition of Medicines Regulatory Authorities (ICMRA)
- International Medical Device Regulators Forum (IMDRF)
- Council for International Organizations of Medical Sciences
- Pharmaceutical Inspection Co-operation Scheme
- European Directorate for the Quality of Medicines and HealthCare
- European Pharmacopoeia Commission
- European Patients' Academy on Therapeutic Innovation (EUPATI)
- World Health Organization (WHO)



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.

Two new Divisions were set up during 2022, for which additional staffing resources were provided. The Advanced Therapy Medicinal Products (ATMP) Division is attached to the Licensing Sector and responsible for all official licensing and surveillance tasks associated with medicinal products based on novel therapies (e.g. gene therapy products, somatic cell therapy products, tissue-engineered products, products comparable with gene therapy products, autologous transplants, blood and pathogen inactivation procedures). ATMPs give many patients hope of alleviation and recovery from illnesses that are currently incurable. The Swissmedic Platforms Transformation Division attached to the Infrastructure Sector is responsible for building new digital corporate solutions and for coordinating the technical, organisational and transformational activities needed to supersede the existing applications.

Agency Council

The Agency Council consists of a maximum of seven members who are elected by the Federal Council. The Federal Council also nominates the President. The Cantons have the right to propose three members for consideration. 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; owner, Layout Consulting GmbH
- **Giovan Maria Zanini**, Vice President; Cantonal Pharmacist, Canton of Ticino
- **Daniel Betticher**, Prof. Dr. med.; 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 Neuchâtel
- **Monika Rüegg 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 goals and submits them to the Federal Council for approval; prepares an Annual Report for Swissmedic's owner; oversees the Management Board and ensures appropriate internal control and risk management systems are in place; approves business planning and the statement of estimates; and issues regulations guaranteeing the neutrality of experts mandated by Swissmedic.

The Agency Council appoints a strategy committee, a finance and controlling committee, an appointments and remuneration committee and a 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.



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)

One key task during 2022 was drawing up the strategic goals for 2023–2026. These were approved by the Federal Council in early December 2022 and published on Swissmedic's website. The Agency Council held several discussions on medical device surveillance and the consequences for Swissmedic of the failure to update the MRA.

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. In addition, the Agency Council undertook an appraisal of its activities in conjunction with an external facilitator and defined measures to optimise its continuous training activities.

Remuneration for the Agency Council in 2022 totalled CHF 202,000 including expenses (previous year: CHF 213,000), of which CHF 58,000 (same as previous year) was paid to the President.

 www.swissmedic.ch



Management Board



Raimund Bruhin, Dr. med.
Executive Director



Claus Bolte, Dr. med.
Deputy Executive Director



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, competencies 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
- **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
- **Jörg Schläpfer**, Dr. med. vet., PhD; Head of Management Services and International Affairs Sector
- **Barbara Schütz Baumgartner**, Head of Human Resources and Finance Sector

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 2,059,811 (previous year: CHF 1,980,815) of which CHF 322,690 (previous year: CHF 307,812) was paid to the Executive Director.

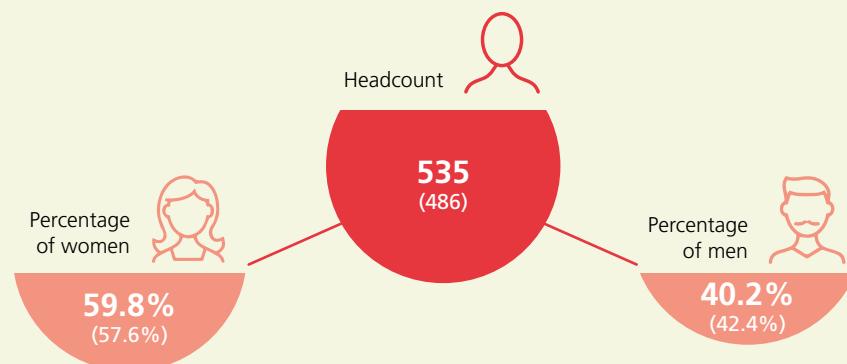


www.swissmedic.ch

Human resources

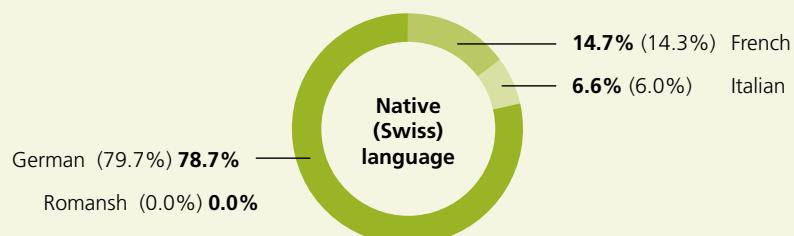
Swissmedic pursues a sustainable, progressive human resources policy. It has its own Personnel Ordinance issued by the Agency Council and subject to approval by the Federal Council.

The employee survey conducted every two years produced a positive result for job satisfaction, scoring 80 on a scale from 0 to 100 (80 in 2020), while the score for commitment was 87 points (89 in 2020). The response rate of 86 percent was very high (75 percent in 2020).

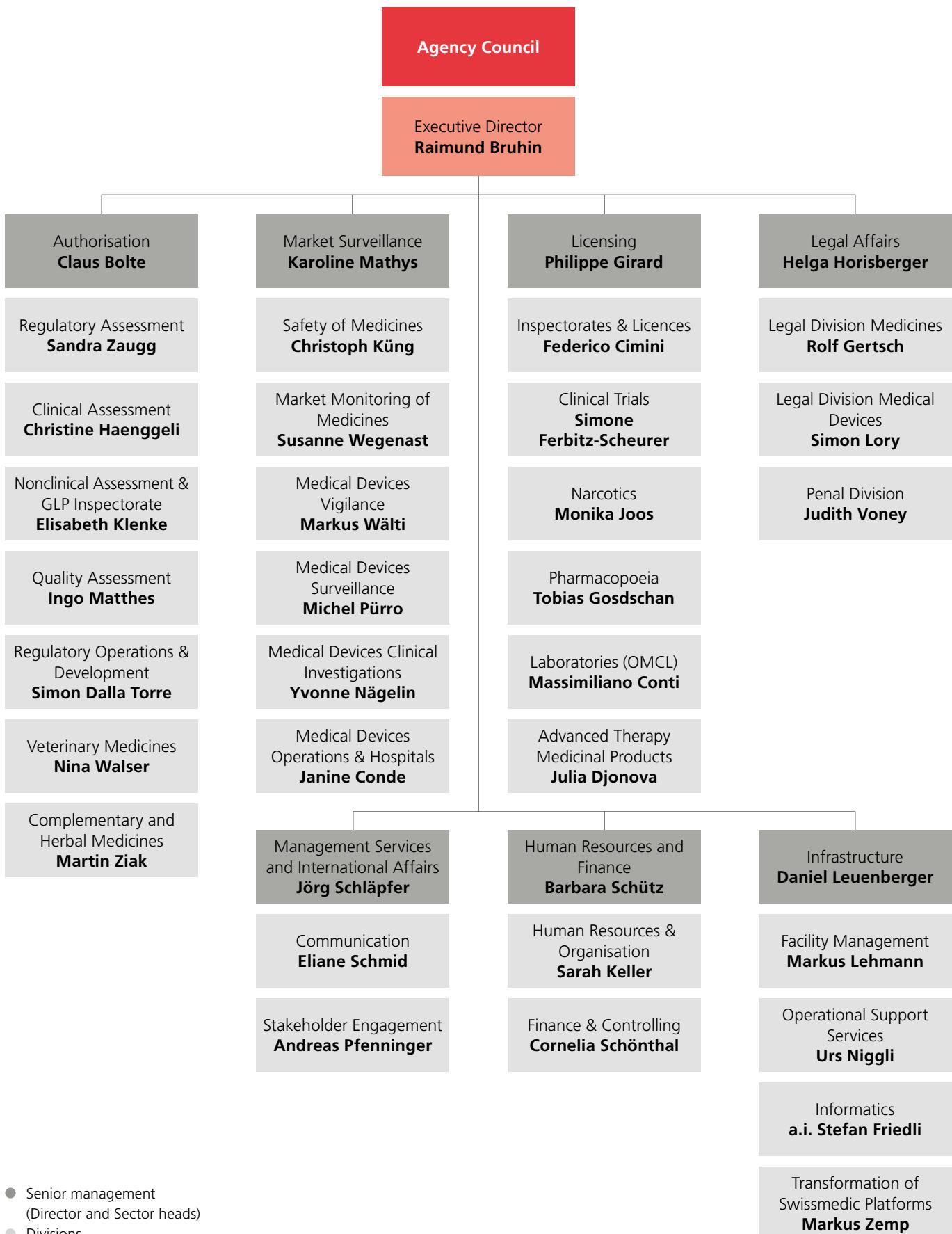


451 Full-time equivalents (409) Percentage of women in executive positions (40.3%) **40.6%** **46.8** Average age (47.6)

Part-time working (up to 89% FTE) (49.2%) **50.7%** **5.1%** Fluctuation rate (5.5%)



Organisational chart



Consultant experts

Swissmedic Medicines Expert Committees

When required, Swissmedic consults external experts in medicine, pharmacy and science. Two advisory committees have been set up for this purpose – the Human Medicines Expert Committee (HMEC) and the Veterinary Medicines Expert Committee (VMEC). The members of these committees issue recommendations on authorisation documentation reviews, the market surveillance of medicinal products and medical devices and other procedures. Swissmedic factors these recommendations into its decisions.

The Agency Council elects the experts 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.

 www.swissmedic.ch

The HMEC, chaired by Prof. Dr. Stephan Krähenbühl, met 12 times (previous year: 15) and issued 46 recommendations (previous year: 64). The majority concerned new authorisations or additional indications for medicinal products. In addition, HMEC experts carried out 26 assessments of parts of dossiers (previous year: 25) and 24 individual expert opinions (previous year: 45) were obtained.

The VMEC, chaired by Dr. Barbara Knutti, met three times (previous year: zero) and issued eight recommendations. The majority of these concerned applications for new authorisations of veterinary medicinal products, additional indications and new target animal species for authorised veterinary medicinal products. The experts were consulted as needed on individual issues associated with veterinary medicinal products. A total of 14 individual expert opinions were obtained.

Expert Commission for Radiopharmaceuticals

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

Pharmacopoeia experts

Around 120 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 coor-dinated by the EDQM in Strasbourg for the European Pharmacopoeia (Ph. Eur.).

The Swiss Pharmacopoeia (Ph. Helv.) is prepared by five specialist committees that also assist Swissmedic in reviewing draft requirements for the Ph. Eur. The Ph. Helv. texts are approved by the Swiss Pharmacopoeia Commission. The Commission is made up of user representatives and advises Swissmedic on compiling the Ph. Helv. A total of 74 mandates (previous year: 77) are currently held across all Swiss pharmacopoeia committees.

Swiss experts currently hold 98 of the approximately 900 mandates in the active Ph. Eur. expert and working groups, of which there are around 60 (previous year: 91 of 800 mandates). The relevant tasks are overseen by the European Pharmacopoeia Commis-sion, which is made up of delegations from the Ph. Eur. member states. The Swiss delegation is elected by the Federal Council and comprises three principal and three alternate members. The delegation is led by the Head of Swissmedic's Pharmacopoeia Division.

Risk management and compliance

Swissmedic operates a comprehensive risk management system with the appropriate processes and tools. The Agency Council classified the lack of a legal framework and financial and human resources required to monitor the Swiss medical devices market as the biggest strategic risk facing Swissmedic. Various measures were taken to mitigate this risk 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 2022 and reported that the level of documentation was appropriate for Swissmedic's size and complexity.

Looking ahead to the entry into force of the revised Data Protection Act and new Information Security Act in 2023, Swissmedic embarked on conceptual and organisational preparations for the implementation of the data protection legislation during 2022 and began the process of setting up an institutionalised information security management system (ISMS) that will comply with ISO/IEC 27001.

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.



Sustainability

Heat and energy from renewable sources

Swissmedic has for many years attached great importance to using renewable energy at its premises at Hallerstrasse 7 (headquarters and office building), Erlachstrasse 8 (office building) and Freiburgstrasse 139 (office and laboratory building) and continuously endeavours to expand its own renewable energy production.

The new heat and cooling production system for Hallerstrasse 7 came on stream in summer 2022. The system uses a borehole heat exchanger as its primary source of energy. In summer, it relies on the earth's cold supply temperatures to cool the building, while the borehole heat exchanger provides energy for the heat pump during the winter. Mechanical cooling production was reduced by 70 percent, the remaining cooling energy being obtained from the geothermal heat collector. Use of the heat pump halved the amount of heating energy purchased from the district



heating grid. The new installation marked a significant upgrade in renewable energy use as well as reducing total energy consumption at Hallerstrasse 7 by 220 MWh.

An additional photovoltaic system was installed on the flat roof at Erlachstrasse 8; this came on stream in late October 2022. The 19.5 kWp system produces approximately 20,000 kWh of electricity a year. The electricity generated by the photovoltaic system is sufficient to meet around a quarter of the property's total electricity consumption.

Finally, an exergy system came on stream in Freiburgstrasse in September 2022. This works like a conventional heat pump, but generates substantially higher temperatures. A gas boiler provided hot water until the new system came on stream. This is now surplus to requirements and serves only as a back-up. Having switched hot water production technology, Swissmedic is no longer reliant on fossil fuels at any of its three properties.

Lighting

All lights on three floors of the Hallerstrasse property were converted to LED technology during 2022. The changeover will significantly reduce electricity consumption.

Mobility

Since Swissmedic's office and laboratory buildings are in a central location with good rail links, a large number of employees use public transport to get to work. Swissmedic teams took part in the Bike to Work initiative. The Agency's working from home rules enable employees to do much of their work from home. Four charging points – two at Hallerstrasse 7 and two at Freiburgstrasse 139 – were installed for employees with electric vehicles during 2022.

MEDICINAL PRODUCTS – STANDARDS PRODUCT GROUP

Legal Framework product

Technical Standards product

Narcotics Act revision

The revised Narcotics Act came into force on 1 August 2022. The purpose of revising the Act was to make it easier for patients to gain access to cannabis for medical purposes. The total ban on the use of cannabis for medical purposes was lifted, laying the foundation for moving cannabis for medical purposes to List a of the Narcotics Lists Ordinance. It thus became subject to the regular control measures that apply to other narcotics.

The Narcotics Control Ordinance regulates the cultivation of cannabis for medical purposes. Licences for cultivation are issued in a two-stage approval process. An establishment licence for cultivation is used as the basis for issuing individual cultivation licences for each growing facility.

The revised legislation excludes cannabis that is not intended for medical purposes. In these cases, blanket prohibition still applies.

Revision of veterinary medicinal products legislation

Switzerland's revised veterinary medicinal products legislation came into force on 28 January 2022 on the same date as the EU's new legislation on the same subject. The revision covers enactments of therapeutic products legislation at Federal Council and Swissmedic level. The Veterinary Medicinal Products Ordinance, the Therapeutic Products Ordinance, the Medicinal Products Licensing Ordinance and the Therapeutic Products Licensing Requirements Ordinance are all affected. The amendments are intended to prevent potential barriers to trade and avoid additional regulatory work for the veterinary medicinal products industry in Switzerland compared to the EU.

Transfer of immunological veterinary medicinal products to Swissmedic

On 23 November 2022, the Federal Council ratified the legal amendments needed to transfer immunological veterinary medicinal products from the Institute for Virology and Immunology to Swissmedic. Since 1 January 2023, Swissmedic has been responsible for authorising and monitoring the safety, quality and efficacy of immunological veterinary medicinal products such as vaccines.

Revision of the Fees Ordinance

Preparations for the revision of the Fees Ordinance were made during 2022. Existing fees were updated and new ones – such as for the simplified review of clinical trials of medical devices – were added. The fee for additional indications, which did not cover Swissmedic's costs, was increased, while the fees for major changes to medicinal product information and quality and new authorisations of herbal medicinal products were reduced. The revised Fees Ordinance entered into force on 1 January 2023.

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 tissues
- Ordinance for advanced therapy medicinal products (ATMPs)

Mutual Recognition Agreement

During 2022, Swissmedic and the State Secretariat for Economic Affairs (SECO) completed negotiations with the US FDA and US Trade Representative (USTR) on the substance of a Mutual Recognition Agreement (MRA) covering Good Manufacturing Practice (GMP) inspections for medicinal products. The Federal Council approved the Agreement in December 2022 and it was due to be signed in Washington on 12 January 2023. Entry into force is scheduled for mid-2023.

Memorandum of Understanding

In October 2022, the Federal Council ratified a Memorandum of Understanding (MoU) with the United Kingdom's Veterinary Medicines Directorate (VMD). The MoU was due to be signed on 26 January 2023, after which it will provide the basis for cooperation between Swissmedic and the VMD.

Pharmacopoeia

The pharmacopoeia that is valid in Switzerland consists of the European Pharmacopoeia (Pharmacopoeia Europea, Ph. Eur.) and the Swiss Pharmacopoeia (Pharmacopoeia 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.

Three supplements to the 10th edition of Ph. Eur. came into effect during 2022.

The 12th edition of Ph. Helv. was published in October 2022. New editions are now published approximately six months before they come into force. This gives users an opportunity to implement the amended requirements before they are enacted. As part of work on the current new edition, the "General requirements applicable to the manufacture of formula-based medicinal products" chapter was comprehensively revised. This introduces specific requirements governing the content and form of labelling on formula-based medicinal products.



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 Art. 67 of the Therapeutic Products Act is to provide information for the general public. Swissmedic aims to provide the public with balanced, objective and audience-appropriate information and thus to build confidence in the Agency. In addition to its website and various newsletters, the channels and media it uses include "Visible", a biannual magazine that appears in printed form and as an online version with added video content. During 2022 the magazine reported on various aspects of Swissmedic's 20-year history and looked at ATMPs.

Social media

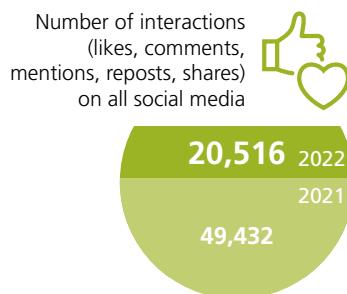
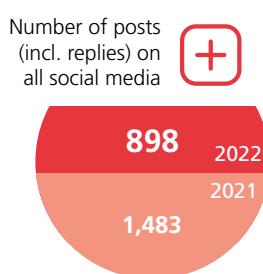
Swissmedic expanded its social media presence during 2022. Its LinkedIn, Facebook and Twitter feeds were augmented mid-year by a new presence on Instagram. Using visual and interactive formats, it hopes to reach a younger, predominantly female audience that takes an interest in politics. At the end of 2022, Swissmedic had over 30,400 followers across all channels. Although posting and interaction have declined since

the pandemic year of 2021, rates remain high. Swissmedic employs rapid, transparent and demands-driven community management to promote confidence in its activities.

Press relations

Once again, Swissmedic's activities attracted a lot of interest from media representatives in 2022. The media team responded to more than 1,100 enquiries, Swissmedic specialists gave 20 (previous year: 18) interviews and the Agency held three (previous year: four) media events.

Swissmedic's efforts to combat illegal trade in therapeutic products and prosecute violations of therapeutic products legislation attracted particular interest. The pandemic, COVID-19 vaccines and the side effects of those vaccines remained a major topic throughout the year. Death and birth statistics or reports of prolonged symptoms triggered questions about the benefits of vaccination versus the risks. These questions required answers that were effective in terms of both science and communications.



Enquiries

Each year, Swissmedic answers questions from laypeople, medical professionals, other specialists and stakeholders. Just under 7,000 questions were received during 2022, dealing particularly with the authorisation and availability of COVID vaccines, cannabis for medical purposes, the general rules applicable to medicines needed when travelling and importing medicines for personal use.

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 in 2022 was about the same as in 2019 and 2020, but significantly down on 2021. In particular, requests to access official documents connected with COVID-19 vaccines declined during 2022. Access was completely refused in three cases.

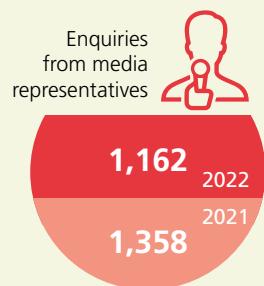
No appeals are currently pending before the Federal Administrative Court or Federal Supreme Court regarding freedom of information requests.

Parliamentary proposals and expert evidence to parliamentary committees

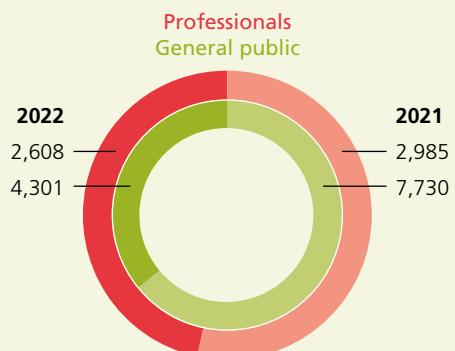
Swissmedic acted as lead agency on 12 (previous year: five) parliamentary proposals, the majority of which dealt with market surveillance issues and aspects of digitalisation in the healthcare sector, such as accessing patient information via QR codes.

Swissmedic representatives attended various parliamentary committees throughout the year, providing information on matters such as vaccine supplies.

Press relations



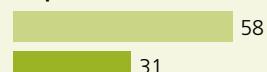
Enquiries



Transparency / FoIA

2021 2022

Requests under FoIA



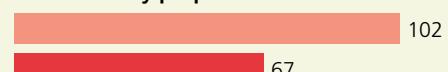
Time requirement (in hours) for processing requests



Parliamentary proposals and expert evidence to parliamentary committees

2021 2022

Parliamentary proposals



Other political business items in which Swissmedic was involved



Publications and events for professionals

The most important information channels for professionals are the Swissmedic website, various newsletters and information events. These have been an important part of information dissemination and dialogue for many years.

As part of activities to mark its 20th anniversary, Swissmedic held an event entitled "Regulatory & Beyond" for regulatory affairs professionals working in the medicinal products and medical devices sectors. Some 500 people attended in person and 150 attended online. The annual training event for inspectors was held in Lausanne and attracted 60 national and international GMP and GDP inspectors from all round the world.

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, complementary and herbal medicine and Good Manufacturing and Distribution Practice (GMP/GDP) areas were held during 2022.



MEDICINAL PRODUCTS – MARKET ACCESS PRODUCT GROUP

Authorisation product

Overview

11,720 authorisation applications and applications for variations comprising 20,823 individual applications were completed in 2022. The 2,948 multiple applications that were submitted contained between two and 127 individual applications. Compared with 2021, applications fell by just under 1 percent, while individual applications declined by 2 percent. 95 percent (previous year: 97 percent) of all completed applications were processed within the prescribed time limits. The compliance target values for first authorisations and major variations were not achieved. 42 out of the 47 applications for medicinal products with new active substances – or just under 90 percent – were completed within the time limits. The delays are attributable to the very heavy pandemic-related workload during 2020 and 2021, when applications for medicinal products to combat or prevent the pandemic were prioritised at the expense of other applications. 77 (previous year: 79) company meetings were held before or during the authorisation process.

Applications received	2022	2021
First authorisations of innovative medicinal products	101	120
First authorisations of non-innovative medicinal products	188	239
Extensions	48	37
Major variations	2,213	2,401
Minor variations	7,377	6,739
Other applications	2,603	2,405

Applications completed	2022	2021
First authorisations of innovative medicinal products	109	127
First authorisations of non-innovative medicinal products	230	187
Extensions	42	46
Major variations	1,937	2,591
Minor variations	6,511	6,658
Other applications	2,741	2,447

Deadline compliance	Result	Target
First authorisations of innovative medicinal products	84 %	97 %
First authorisations of non-innovative medicinal products	91 %	97 %
Extensions	96 %	97 %
Major variations	87 %	97 %
Minor variations	99 %	95 %
Other applications	98 %	95 %

Authorisation procedure

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. Once Swissmedic has issued a positive assessment, the request for the FTP is approved and the relevant application may be submitted. Swissmedic's time limit for processing the application is reduced from 330 to 140 days.

Activities:

Swissmedic reviewed 13 FTP requests in 2022, seven of which it approved. Five of the six applications assessed under the fast-track procedure were completed on time.

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. Swissmedic's time limit is reduced from 330 to 264 days.

Activities:

Six new applications for a PPN were submitted during 2022. Five applications were approved, while the sixth was withdrawn. All ten of the applications assessed under a PPN were for innovative medicinal products; there were no applications for transplant products. Six applications were completed within the prescribed time limits.

Number of assessments under fast-track procedures

2021 2022

Innovative first authorisation



Indication extension



Number of assessments under a PPN

2021 2022

Innovative first authorisation



Indication extension



Number of temporary authorisations

2021 2022

Innovative first authorisation, medicinal product



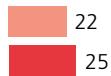
Completed applications under Art. 13 TPA and Art. 14 TPA

2021 2022

Art. 13 TPA



Art. 14 TPA



Temporary authorisation

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. Swissmedic's time limit for processing the application is reduced from 330 to 140 days.

Activities:

Two of the three applications for temporary authorisation received in 2022 were approved. A total of 15 (previous year: 12) temporary authorisations were completed. These included seven applications for which Swissmedic issued temporary authorisation ex officio.

Authorisation under Articles 13 and 14 Therapeutic Products Act

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 and correspond to the authorisation status in the other country, and that full final assessment reports exist.

Activities:

A total of 180 applications under Article 13 of the Therapeutic Products Act were processed and completed in 2022. The majority of applications concerned variations (91), known active substances without innovation (58) and known active substances with innovation (10).

Since 2019, it has been 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 (Art. 14 para. 1 let. a^{bis-quater} Therapeutic Products Act).

Time limits and international benchmarking

Viewed across all procedures, the lead time (companies' time and Swissmedic's time) for the authorisation of human medicinal products with new active substances has increased compared with 2021. The median figure for 2022 was 456 days (previous year: 396 days). However, the lead time has been reduced by around 14 percent since 2019 (522 days).

The average lead time for the six applications for medicinal products with new active substances authorised by work sharing in the Access Consortium was 340 days (previous year: 371). The median time for the oncologicals reviewed and authorised in a parallel procedure with the US FDA and other regulatory authorities was 403 days (previous year: 285). Participation in Orbis had a positive effect on submission gaps (timing of submissions to the different authorities), which were just 31 days compared with the FDA and the other regulatory authorities.

In terms of international benchmarking, a report by the Centre for Innovation in Regulatory Science (CIRS; www.cirsci.org) named Swissmedic as one of the five leading regulatory authorities in the world after the FDA.

Median lead time for the different authorisation procedures

2021 2022

All procedures



Fast-track authorisation procedure (FTP)



Procedure with prior notification (PPN)



Temporary authorisation



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 rose by just under 8 percent year-on-year.

A total of 47 (previous year: 45) medicinal products with new active substances were authorised.

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 38 percent. A total of 1,668 (previous year: 2,301) were completed.

Minor variations and other applications

➤ Any variation to an authorised medicinal product requires approval by Swissmedic. A distinction is made between type IB variations, which have to be notified prior to implementation, and type IA/IA_{IN} minor 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.

Number of applications completed

2021 2022

Innovative new authorisations



Non-innovative new authorisations



Extensions



Number of completed type II variations

2021 2022

Additional indications



Change in recommended dosage



All other type II variations



Number of completed variations

Collective applications were counted as one application

2021 2022

Type IB variations



Type IA/IA_{IN} variations



Other applications



Activities:

Applications in this category increased slightly, with 7,953 (previous year: 7,754) being completed.



Transplant products

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:

Two (previous year: 12) transplant products with new active substances were authorised during 2022. Swissmedic reviewed two applications for a fast-track authorisation procedure and conducted ten presubmission/clarification or scientific advice meetings.

In addition, 163 (previous year: 108) applications for a quality variation requiring approval and 59 (previous year: 22) applications for a variation in clinical documents (Information for healthcare professionals/Patient information, indication extension, new dosage recommendation and authorisation extensions such as a new pharmaceutical form or new dosage strength) were completed.

Finally, Swissmedic assessed documentation that had been submitted on 52 quality conditions (previous year: seven), 42 clinical conditions (previous year: seven) and 25 Periodic Safety Update Reports (previous year: 15).



Special human medicinal product and transplant product categories

Orphan drugs

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

Activities:

Orphan drug status was recognised in 40 out of 44 cases. This status was discontinued for four products. 20 innovative new applications were authorised as orphan drugs, seven of them temporarily.

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:

Five (previous year: nine) authorisation applications for biosimilars were completed. Four were approved.

Paediatric medicinal products

Applicants must submit their Paediatric Investigation Plan (PIP) to Swissmedic and develop their medicinal products for use in children in line with these investigation plans.

Activities:

19 authorised medicinal products with new active substances were investigated and authorised under Paediatric Investigation Plans during 2022. A total of 29 (previous year: 24) 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 guarantee a broad-based assessment of the efficacy and safety of these products.

Activities:

Various company meetings were held with authorisation holders in the course of 2022. Swissmedic reviewed six applications for new vaccines, five of which it authorised. It also reviewed additional indications (six applications), new dosage recommendations (four applications) and authorisation extensions such as new pharmaceutical forms (six applications).

Furthermore, Swissmedic processed 243 applications for quality variations, 29 changes to clinical documentation (medicinal product information), 36 applications concerning clinical/preclinical conditions, 48 concerning quality conditions and three concerning drug safety conditions, as well as 73 regulatory variations.

Manufacturing processes for non-standardisable medicinal products

➤ Swissmedic also authorises special manufacturing processes when a comprehensive appraisal of the quality of the end product is not possible or can only be achieved by guaranteeing the safety of the manufacturing procedure.

Activities:

14 applications for the authorisation of production of non-standardisable medicinal products were reviewed during 2022. 11 of these involved autologous/allogeneic serum eye drops, while three concerned allogenic products for faecal microbiotic transplant.



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: 13) applications for complementary medicinal products with indication were completed.

Significantly more single products without indication (homeopathic and anthroposophic medicines and medicinal products for gemmotherapy) were authorised under the notification procedure during 2022, as, for the first time, were 20 Chinese medicinal products without indication.

Complementary medicinal products

2021 2022

Medicinal products with indication under simplified procedure incl. co-marketing medicinal products



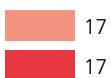
Simplified authorisation with reduced dossier



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:

Ten (previous year: six) applications were completed under the simplified authorisation procedure including one co-marketing medicinal product. Veterinary medicinal products.



Veterinary medicinal products

New authorisations and extensions

➤ 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 or extensions) and non-innovative medicinal products (medicinal products with known active substances and co-marketing medicinal products). Authorisation extensions (e.g. a new pharmaceutical form of a medicinal product) require a new authorisation procedure. 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 cattle, poultry or bees.

Activities:

Fifteen (previous year: 22) new applications and applications for extensions were completed in 2022, including one temporary authorisation. All of these applications were processed within the prescribed time limits.

Number of new applications completed

Non-innovative new authorisations

Innovative new authorisations and extensions



Major and minor variations

Activities:

A total of 500 (previous year: 474) applications for variations were processed and completed.

Number of completed variations

Collective applications were counted as one application.

2021 2022

Type II variations assessed as "major"



Type IA/IA_{IN} variations not assessed



Type IB variations assessed as "minor"



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:

Five (previous year: three) official decisions connected with product authorisation were contested before the Federal Administrative Court in 2022. Nine cases are still pending before the Federal Administrative Court, while one appeal is pending before the Federal Supreme Court.

Medicinal products: facts and figures

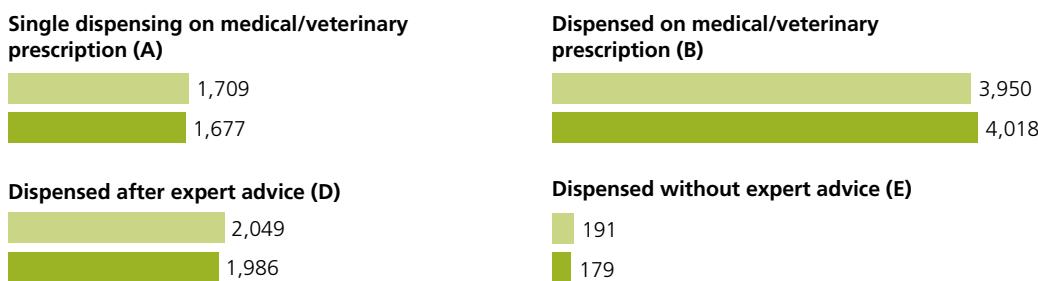
Number of authorisations by type of product

Number of authorisations by type of product	2022	2021
Human medicinal products	5,765	5,756
Synthetics	4,805	4,827
Biotechnologicals	429	401
Vaccines	66	60
Blood products	64	63
Radiopharmaceuticals	54	53
Allergen products	285	292
Bacterial and yeast products	22	22
Antidotes/antivenins	40	41
Transplant products	16	14
Complementary and herbal medicines	12,273	12,302
Phytopharmaceuticals	413	434
Homeopathics	606	617
Anthroposophics	355	368
Ayurvedic medicinal products	1	1
Tibetan medicinal products	5	7
Other alternative treatments	5	5
Homeopathic and anthroposophic medicinal products and medicinal products for gemmotherapy without indication	10,868	10,870
Chinese medicines with no indication	20	0
Lozenges	36	46
Veterinary medicinal products	674	693

Number of authorisations by dispensing category

Number of authorised medicinal products

2021 2022



20 (previous year: 45) medicinal products are still assigned to dispensing category C (in pharmacies without a medical prescription) because the reassignment process could not be completed.



First authorisations of human medicinal products with a new active substance

	Medicinal product	Active substance	Indication
Endocrinology and metabolism	Colibiogen oral	Escherichia coli lysate (strain Laves)	Irritable bowel syndrome
	Lamzede	Velmanase alfa	Alpha-mannosidosis
	Mounjaro	Tirzepatide	Type 2 diabetes mellitus
	Ngenla	Somatrogon	Growth hormone deficiency in children and adolescents
	Nityr	Nitisinone	Tyrosinaemia type 1 (HT-1)
Cardiology	Rapibloc	Landiolol	Supraventricular tachycardia, sinus tachycardia
	Vazkepa	Icosapent ethyl	Reduction of the risk of cardiovascular events
Immunology	Idefirix	Imlifidase	Desensitisation treatment before kidney transplantation
	Saphnelo	Anifrolumab	Systemic lupus erythematosus (SLE)
	Tavneos	Avacopan	ANCA-associated vasculitis
	Orladeyo	Berotralstat	Hereditary angioedema (HAE)
Dermatology and allergology	Adtralza	Tralokinumab	Atopic dermatitis
	Bimzelx	Bimekizumab	Plaque psoriasis
	Cibinqo	Abrocitinib	Atopic dermatitis
	Klisyri	Tirbanibulin	Actinic keratosis
	NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	Skin burns
Urology and sexual medicine	Drovelis	Drospirenone, estetrol	Oral contraception
	Softigyn	Lactobacillus plantarum	Protection of the vaginal flora
Infectiology and vaccines	Evusheld	Tixagevimab, cilgavimab	Pre-exposure prophylaxis and treatment of COVID-19
	Fluenz Tetra	Live, attenuated influenza virus of the strains A/H1N1, A/H3N2, B/Yamagata, B/Victoria	Active immunisation for the prevention of influenza
	MenQuadfi	Polysaccharides of Neisseria meningitidis groups A, C, W-135, Y	Active immunisation to prevent invasive meningococcal disease
	Nuvaxovid	Spike protein of SARS CoV-2	Active immunisation to prevent COVID-19
	Paxlovid	PF-07321332, ritonavir	Treatment of COVID-19
	Regkirona	Regdanvimab	Treatment of COVID-19
	Tenkasi	Oritavancin	Bacterial skin and skin structure infections
	Xevudy	Sotrovimab	Treatment of COVID-19
Pulmonology	Lyfnua	Gefapixant	Chronic cough
	Solmucol Bronchoprotect	Lyophilised bacterial lysate	Prevention of recurrent respiratory tract infections
	Tezspire	Tezepelumab	Asthma

	Medicinal product	Active substance	Indication
Oncology and haematological malignancies	BCG Apogehpa	Bacillus Calmette-Guérin, live, attenuated (Moreau strain)	Urothelial carcinoma of the bladder
	Blenrep	Belantamab mafodotin	Multiple myeloma
	Breyanzi	Lisocabtagene maraleucel	Large B-cell lymphomas (DLBCL, PMBCL)
	Brukinsa	Zanubrutinib	Waldenström's macroglobulinaemia
	Carvykti	Ciltacabtagene autoleucel	Multiple myeloma
	Exkivity	Mobocertinib	Non-small cell lung cancer (NSCLC)
	Jemperli	Dostarlimab	Endometrial cancer
	Koselugo	Selumetinib	Neurofibromatosis type 1 (NF 1), plexiform neurofibromas
	Minjuvi	Tafasitamab	Large B-cell lymphoma (DLBCL)
	Opdualag	Nivolumab, relatlimab	Melanoma
	Rybrevant	Amivantamab	Non-small cell lung cancer (NSCLC)
	Scemblix	Asciminib	Chronic myeloid leukaemia (CML)
	Tecvayli	Teclistamab	Multiple myeloma
Neurology and psychiatry	Ontozry	Cenobamate	Epilepsy
	Quviquq	Daridorexant	Sleep disorders (insomnia)
	Sunosi	Solriamfetol	Narcolepsy, obstructive sleep apnoea (OSA)
	Kapruvia	Difelikefalin	Pruritus associated with chronic kidney disease
Ophthalmology	Vabysmo	Faricimab	Wet age-related macular degeneration (AMD), diabetic macular oedema (DMO)

First authorisations of veterinary medicinal products with a new active substance

	Medicinal product	Active substance	Indication
Diseases of the musculoskeletal system	Galliprant ad us. vet.	Grapiprant	Relief of pain and inflammation associated with osteoarthritis in dogs
Antiepileptics	Epityl flavour 60 mg ad us. vet.	Phenobarbital	Antiepileptic for dogs
Antibacterials	Rilexine DC 375 mg ad us. vet.	Cefalexin benzathine	Intramammary suspension for dry cows



Licensing product

Overview

Number of authorisations	2022	2021
Establishment licences TPA/Epidemics Act	1,126	1,252
Licences for handling controlled substances	394	383
Licences for the cultivation of cannabis for medical purposes	6	0
Licences for new clinical trials	186	179
Import licences for vaccines and blood products	1,236	1,277
Import/export permits for controlled substances	5,597	6,055
Special licences	286	432

Number of inspections	2022	2021
GLP inspections	10	11
GCP inspections	35	13
GVP inspections	13	7
GMP/GDP inspections	529	564
Microbiological laboratory inspections	35	32
Autologous cell and tissue inspections	4	6
Inspections for third parties	19	13

Time limits	Result	Target
Establishment licences TPA/Epidemics Act	100%	97%
Licences for handling controlled substances	99%	95%
Licences for new clinical trials	88%	95%
Import licences for vaccines and blood products	100%	97%
Import/export permits for controlled substances	100%	95%
Special licences	100%	95%

Establishment licences

Establishment licences are required by companies that manufacture or distribute medicinal or transplant products in Switzerland (manufacturing, wholesale, import, export and trade abroad) or which act as brokers or agents for medicinal products. 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:

680 (previous year: 746) establishment licences were issued, extended, modified or revoked during 2022. 93 percent (previous year: 85 percent) of licence-holding 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 80 (previous year: 83) applications from microbiological laboratories for new establishment licences or changes to or renewal of existing licences. It assured the quality of the constantly changing range of COVID test services provided by laboratories, a task that in some cases necessitated administrative measures to prohibit test activities or revoke licences.

Licences for handling controlled substances

Swissmedic issues establishment licences to companies and individuals that handle controlled substances. Since 1 August 2022, these activities have also included the cultivation of cannabis for medical purposes. The import and export of controlled substances has to be licensed on a case-by-case basis. Swissmedic must be notified of deliveries within Switzerland of narcotics in Lists a, b, d and e. Accounts must be kept by the licence holder of all transactions involving controlled substances. 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 217 (previous year: 209) applications for new establishment licences or changes to or renewal of existing licences. The annual accounts of 481 company sites were examined for the report to the INCB. The Agency also reviewed 16 substances, and applied to the Federal Department of Home Affairs for inclusion of these substances in its Ordinance on the Lists of Narcotics, Psychotropic Substances, Precursors and Auxiliary Chemicals.

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.

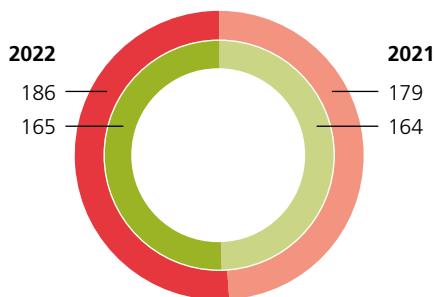
Activities:

Swissmedic received 186 applications for new clinical trials of medicinal products during 2022. A total of 165 clinical trials were approved. The complexity of the application dossiers continued to rise in line with the growth in product complexity.

In addition, Swissmedic processed 2,698 (previous year: 2,612) 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 118 (previous year: 98) reports of suspected unexpected serious adverse reactions (SUSAR).

Clinical trials with medicinal products

New clinical trial submissions
Approved clinical trials

**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 1,236 (previous year: 1,227) individual import licences for immunological medicinal products, blood and blood products during 2022.

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. This reduced the number of special licences issued by Swissmedic. The number of licences issued during 2022 was 286 (previous year: 432).



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 the EudraGMDP database operated by the European Medicines Agency. Thus the number of GMP/GDP certificates issued continued to decline during 2022.

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 (FOEN) and the Federal Office of Public Health (FOPH) within the framework of the GLP monitoring programme.

Activities:

Swissmedic inspected GLP compliance at a total of nine (previous year: ten) assessment facilities and one (previous year: one) service provider. The Agency led six of these inspections, including one first inspection. Two service providers 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. In addition, the Swiss GLP monitoring programme carried out an on-site evaluation of the Korean GLP programme on behalf of the OECD Working Party on GLP.

GCP and GVP inspections

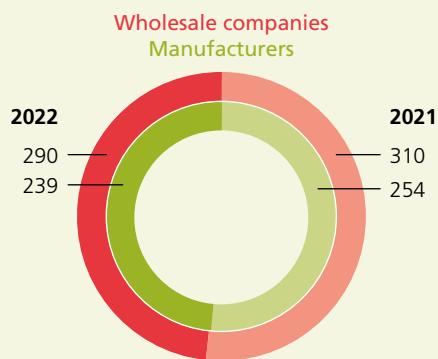
Swissmedic inspects clinical trials carried out in Switzerland by sponsors, contract research organisations, trial locations, facilities and laboratories. The inspections are carried out according to defined risk criteria and assess compliance with the rules of Good Clinical Practice (GCP). They also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

Activities:

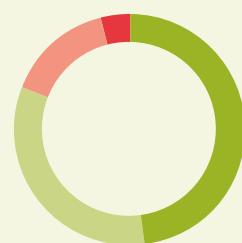
Regular inspections of clinical trials in hospitals resumed following the pandemic.

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

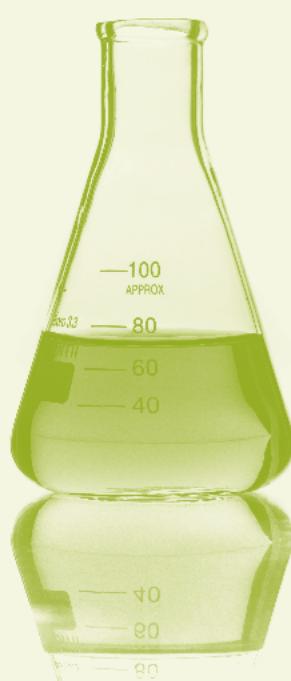
Number of GMP/GDP inspections (Swissmedic and regional inspectorates)



The 87 inspections conducted by Swissmedic covered the following areas:



- **48%** Pharmaceuticals
- **33%** Transplant products
- **15%** Blood transfusion services
- **4%** For-cause inspections



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 35 (previous year: 13) clinical trials. In addition, it conducted 13 (previous year: seven) 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 carried out a total of 529 (previous year: 564) GMP/GDP inspections of manufacturers and wholesale companies. Reports of major changes to installations, facilities and procedures that impacted GMP/GDP remained high at 166 reports (previous year: 163).

Swissmedic resumed participation in international inspection programmes run by partner authorities from other countries.

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:

Many of Swissmedic's checks and inspections during 2022 focused on testing activities associated with COVID testing. The Agency also conducted a large number of routine laboratory inspections. A total of 35 (previous year: 32) 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:

19 (previous year: 12) inspections were carried out for the FOPH in 2022.

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 of pharmaceutical companies in Switzerland conducted by foreign authorities rose again year-on-year after travel restrictions had been largely lifted. 34 (previous year: 15) of the 37 scheduled inspections took place. 18 of these were by the USA, the remaining 16 by Russia, Mexico, Libya, Belarus, Brazil and Jordan. As a result, requests from foreign authorities to share inspection reports declined (one request; previous year: 11).

Swissmedic accompanied one GCP inspection by the European Medicines Agency in Switzerland.

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:

Various discussions on blood donation criteria took place at government and scientific level during 2022. Among the topics discussed was reviewing donor exclusions connected with transmissible spongiform encephalopathies (TSEs), the potential transmission risks for monkey pox and the exclusion of people with a particular sexual behaviour (MSM).

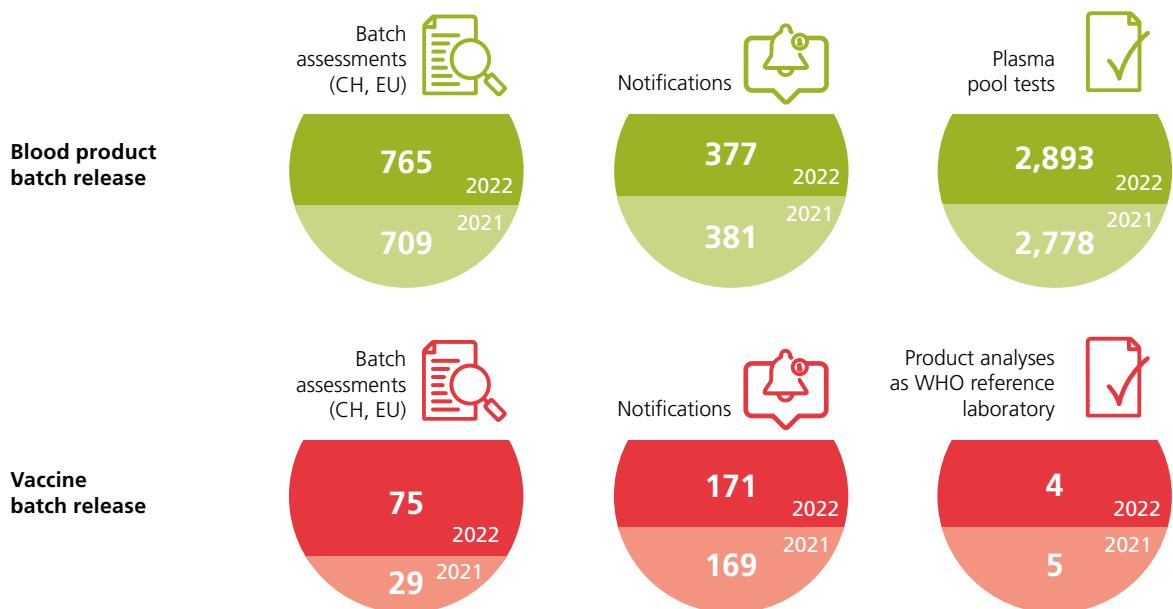
Monitoring of autologous transplantation

➤ 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 2022, Swissmedic had been notified of 22 (previous year: 22) institutions that work with tissues and cells for autologous transplantation.

The Agency conducted four (previous year: six) inspections. These focused on institutions that process, forward or store blood stem cells.



Batch release

➤ Swissmedic's accredited Official Medicines Control Laboratory (OMCL) is responsible for the official batch release of stable blood products and vaccines.

Activities:

The number of batch inspections increased compared with the previous year. As more stable blood products were produced once again, the OMCL tested more batches and plasma pools. In the case of vaccine batches, the increase is due to a rise in demand for one Swiss manufacturer's travel vaccine. In addition, the OMCL was subcontracted by a European counterpart to test 19 batches of a COVID vaccine.

Since 1 January 2023, the OMCL has been responsible for the official batch testing of immunological veterinary medicinal products. The preparatory work for this took place during 2022.

Other OMCL activities

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

Activities:

In 2022, the OMCL once again tested nitrosamines that had been detected in active pharmaceutical ingredients of various products worldwide. A further major area of

activity involved market monitoring-related analysis of mRNA vaccines and the investigation of a large number of illegally imported products.

Appeals procedure

Activities:

As in 2021, no official decision issued in connection with licences was contested. One case is currently still pending before the Federal Administrative Court. No cases are still pending before the Federal Supreme Court after two appeals were rejected during 2022.

New authorisations and market monitoring

2021 2022

Medicinal products analysed as part of authorisation

10
38

Medicinal products analysed as part of market monitoring

697
547

Other (pharmacopoeia, ring trials)

2,546
1,660

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

Manufacturing of medicinal products (under the old legislation)	2022	2021
Manufacturing of medicinal products (with a licence for distribution)	8	29
Manufacturing of medicinal products (without a licence for distribution)	7	24
Institutions with a Swissmedic licence for handling blood or labile blood products (blood transfusion activities)	3	12

Distribution of medicinal products (under the old legislation)	2022	2021
Import of medicinal products	26	69
Wholesale trading in medicinal products	57	136
Export of medicinal products	22	58
Trading in medicinal products abroad	20	46

Manufacturing of medicinal and transplant products (under the new legislation)	2022	2021
Manufacture of ready-to-use medicinal products and transplant products	395	361
Manufacture of active pharmaceutical ingredients	177	161
Handling of blood or labile blood products (blood transfusion activities)	77	59

Distribution of medicinal and transplant products (under the new legislation)	2022	2021
Import of medicinal products and transplant products	672	608
Wholesale trading in medicinal products and transplant products	950	879
Export of medicinal products and transplant products	526	479
Trading in medicinal products abroad and transplant products abroad	374	348
Brokerage or agency activities for medicinal products and transplant products	13	9

Microbiological laboratories	2022	2021
With a Swissmedic licence issued under the old procedure (1 January 2016 to 31 December 2018; activities A, B and/or C)	10	23
With a Swissmedic licence issued under the new procedure (from 1 January 2019; activities SE 1, SE 2 and/or SE 3)	117	101



MEDICINAL PRODUCTS – MARKET SURVEILLANCE PRODUCT GROUP

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 by specialists. Some are also assessed on Swissmedic's behalf at six regional pharmacovigilance centres (RPvCs). Pharmaceutical companies also submit a large number of reports of adverse reactions from within Switzerland to Swissmedic.

Activities:

Once again, surveillance activities centred on COVID-19 vaccines. However, the number of reports of suspected ADRs declined substantially on the previous year.

The Vigilance One Ultimate database used to process ADR reports from Switzerland was upgraded so that it can perform specialised analyses to detect new safety signals. The new tool launched in 2022 to enable patients to report ADRs themselves has proven valuable in practice.

A new tender for pharmacovigilance services for the 2023–2027 period was issued, a heavy focus being placed on specific specialised medical skills.

Close collaboration with other countries' authorities and in multinational specialist organisations continued,

for example as part of a regular dialogue on safety signals. Swissmedic regularly briefed the public on reports connected with COVID vaccines and the findings obtained. By the end of 2022, it had published 28 COVID-19 reports as well as other associated information and answered a large number of enquiries from the public and the media.

Haemovigilance

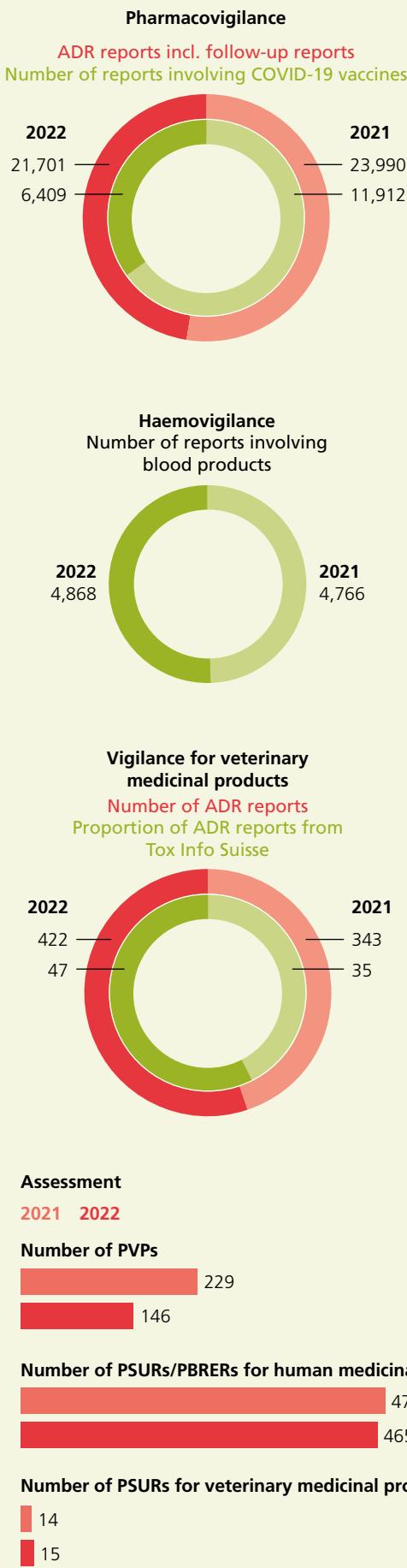
➤ Haemovigilance is the monitoring system employed for blood and unstable blood products. It covers the entire transfusion chain from donation through processing and transport to administration to patients. The purpose of a haemovigilance system is to minimise transfusion risks and dangers associated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

Activities:

Swissmedic stepped up dialogue with parties under a reporting obligation during 2022 by means of a well attended workshop and targeted inspections and working visits. The haemovigilance webpage and reporting forms for transfusion reactions and errors were updated.

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. The Federal Food Safety and Veterinary Office's Institute of Virology and Immunology is responsible for reports of vaccine reactions in animals.



Activities:

The number of ADR reports for veterinary medicinal products was comparable with recent years. Reports primarily involved dogs (254) and cats (104), followed by cattle (31) and horses (11). Six reports of users experiencing reactions were also submitted.

Tox Info Suisse submitted 107 cases of humans being exposed to veterinary medicinal products in the course of the year. Mix-ups, consumption by children and accidental contact with the veterinary medicinal product in question each account for about one third of these reports. No signals were discovered during 2022.

Swissmedic published a report on the evaluation of reports of ADRs to veterinary medicinal products on its website in December 2022.

International signals and safety reports

Assessment of pharmacovigilance plans and safety reports

As part of the procedure for authorising new medicinal products, companies must submit for assessment a pharmacovigilance plan (PVP) in accordance with ICH guidelines. In the PVP, 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 PVP up-to-date and to submit it as an update in the course of regular post-authorisation reporting. 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 2022, Swissmedic assessed 146 PVPs for medicinal products that had been submitted for authorisation plus 465 safety reports for medicinal products that had already been approved (including 107 PVP updates).

Risk mitigation measures

When new findings concerning the safety of a medicinal product come to light, marketing authorisation holders are obliged to apply for a change to its product information. Swissmedic also initiates action ex officio when it becomes aware of new risks. The circular letters issued in response to the findings – Direct Healthcare Professional Communications or DHPCs – are reviewed by Swissmedic and sent to the recipients. These DHPCs and 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 international signals fell slightly during 2022. Efficient process management and close internal and external cooperation on signal processing meant that risk minimisation measures could be implemented promptly.

Warnings to healthcare professionals were published in 17 (previous year: 37) cases in the form of HPCs and DHPCs.

A total of 243 (previous year: 304) signals were completed.



Market Monitoring product

Quality defects and batch recalls

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

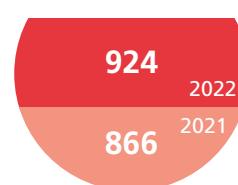
Activities:

There was a further increase in the number of quality defects processed during 2022. The quality issues resulted in 27 batch recalls and six DHPCs. 24 of the 27 batches recalled were human medicinal products, three others were veterinary medicinal products. Three recalls extended to patient or end-user level. In addition to antihypertensives, opioids and biotechnologicals, it was surprisingly necessary to withdraw generally unproblematic products such as lozenges, disinfecting solutions and homeopathics from the market on several occasions. The most frequent causes of the recalls were stability problems and impurities in the products (eight cases each). The second most common cause was packaging issues and mix-ups (six cases).

Reports of “bubbles” in one of the COVID-19 vaccines made headlines and created a public stir in autumn. In this case, Swissmedic's laboratory was able to use highly sensitive analytical techniques (gas chromatography-mass spectrometry) to demonstrate that the bubbles had not been caused by contamination of the vaccine. In light of these results and further investigations, the alert was withdrawn within a few days.

Quality defects and batch recalls

Number of reports of quality defects



Number of reports relating to Switzerland



Number of batch recalls



Out-of-stock products

If an essential medicinal product that is authorised in Switzerland is unavailable for a limited period 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 for a limited length of time.

Activities:

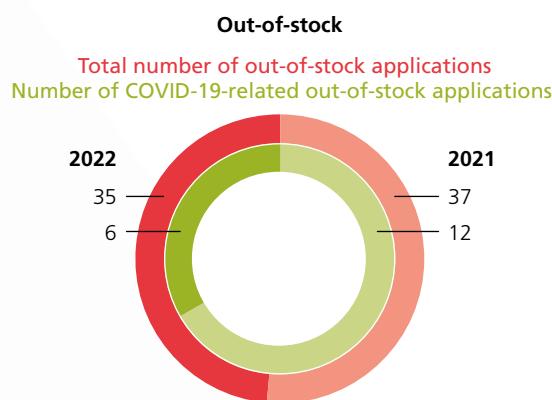
The total number of applications to temporarily distribute a foreign version of a medicinal product received during 2022 was at a similar level to 2021. Of the 35 applications – including COVID-19-related applications – submitted to Swissmedic, just two had to be rejected. One of the 33 applications approved was subsequently withdrawn by the applicant. Six of the licences issued to distribute a foreign version of a medicinal product were for medicinal products to treat COVID patients. The remainder included contrast media, antibiotics, opioids, blood products and oncologicals. On receipt of applications, Swissmedic conducts a routine needs assessment in collaboration with the Federal Office for National Economic Supply to prevent market distortion.

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 relevant 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 50 (previous year: 47) cases were dealt with as part of post-publication advertising inspection activities during 2022. Administrative proceedings had to be opened in 33 cases for the purpose of restoring legal compliance. Criminal proceedings were initiated in three cases. An information letter was sent to the authorisation holder in eight cases. 29 cases involved print advertising, while 14 involved advertising on electronic media, including TV commercials. In the remaining six cases, Swissmedic found no infringements of advertising rules or was not responsible for enforcement and therefore forwarded the reports to the relevant agency.

One application was submitted for an advertising permit for a medicinal product that may be dependence-forming or susceptible to abuse.



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

Measures against illegal medicinal products

If 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:

The great majority of the approximately 6,500 packages of illegally imported medicinal products impounded by customs offices were dealt with under the simplified procedure and destroyed. Only around three percent of the illegal imports that were seized

resulted in ordinary administrative proceedings at the intended recipients' expense. The fall in the number of illegal imports could be attributable to certain pandemic-related restrictions in international trade. There was a shift in the main countries of origin of medicinal product consignments during the year. Whereas an increasing number of consignments from eastern Europe have been seized in recent years, India overtook all eastern European countries towards the end of the year to become the biggest country of origin.

Appeals procedure

Activities:

During 2022, 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 2022.

Measures against illegal medicinal products

2021 2022

Administrative proceedings connected with illegal imports



Illegal distribution of medicinal products



Counterfeit medicinal products



Cases evaluated and forwarded to the responsible cantonal agencies



Enquiries



Other (notifications from abroad, theft abroad, etc.)



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:

Swissmedic received significantly fewer reports of offences in 2022 than in 2021, primarily because the number of cases involving illegal imports by the general public has fallen. The practice of rigorously pursuing and prosecuting such cases has acted as a general deterrent. A large number of 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 2022 concerned the illegal placing on the market and manufacturing of medicinal products, contraventions of advertising regulations, unlicensed trading abroad and counterfeit medicinal products.

The powers to prosecute therapeutic products crime demand close collaboration between all participating agencies. Swissmedic is in contact with the cantonal prosecution authorities and the Customs Administra-

tion and engages in dialogue on specific cases. Once again, various information events were held during 2022, including the Swiss Medicrime meeting and a meeting with the Board of the Conference of Swiss Public Prosecutors.

Swissmedic exercised the rights of a private claimant in several prosecutions conducted by the Cantons during 2022. In one case against the Responsible Person of a medicinal products manufacturer heard before the Federal Supreme Court, the Court supported Swissmedic's argument that the due diligence obligations required under therapeutic products legislation extend to medicinal products that are intended for disposal but are only being stored separately. In doing so, the Federal Supreme Court acknowledged the importance of protecting against counterfeits and preventing the misappropriation of medicinal products. This is a positive step from the patients' perspective.

A different, cantonal case explored the issue of how binding the treatment guidelines issued by the Federal Food Safety and Veterinary Office are on vets administering antibiotics to livestock. The competent Cantonal Supreme Court agreed with the appeal against the court of first instance's verdict to the extent that this guideline is binding in nature and practitioners can be expected to be familiar with it when using antibiotics. This verdict recognises the efforts of the Confederation and Cantons to restrict the spread of antibiotic resistance by means of suitable measures.



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 nine house searches and 28 hearings. 30 cases were unified with cantonal prosecution authorities. Swissmedic handled two of these cases. The Federal Criminal Court rejected one appeal against coercive measures imposed by Swissmedic.

Swissmedic requested international legal assistance from neighbouring and eastern European countries in five cases and dealt with three requests from eastern European countries. These requests were the first time that the accused party took part in foreign proceedings by videoconference.

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.

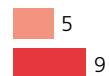
Activities:

67 penalty decisions were issued during 2022. 31 decisions, most of which involved illegal imports of medicines by the general public, were dealt with under the abridged procedure.

Two companies trading in medicinal products were fined for unlicensed trading abroad and corporate liability. In addition, two cases of trading in counterfeit medicinal products or falsely labelling medicinal products were prosecuted. One penalty order for contraventions of transplant product legislation is going to court. Proceedings were abandoned in five cases, while one was tried before the cantonal courts.

2021 2022

House searches



Examination hearings



Unification with cantonal proceedings



2021 2022

Penalty orders, penalty rulings and rulings abandoning proceedings



Cantonal judgements



MEDICAL DEVICES – STANDARDS PRODUCT GROUP

Legal Framework product Technical Standards product

Medical Devices Regulation

The new Ordinance on In Vitro Diagnostic Medical Devices (IVDO) entered into force on 26 May 2022. This marked the completion of the final stage of implementing the new, stricter EU regulations (Medical Devices Regulation, MDR, and In Vitro Diagnostic Medical Devices Regulation, IVDR) and the establishment of more stringent safety and efficacy requirements for medical devices in Switzerland. However, a parliamentary intervention shortly before the new regulation was ratified resulted in amendments to reduce industry requirements for labelling. This is a temporary divergence, the advantages and disadvantages of which will be evaluated during 2023.

In addition, provisions were added to cushion the impact of the failure to update the MRA and to compensate for the loss of information exchange and enforcement cooperation with the EU. The revised Medical Devices Ordinance (MedDO) and the new Ordinance on Clinical Trials with Medical Devices (ClinO-MD) came into force on 26 May 2021 and were aligned with IVDO in certain areas.

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 general public through various channels (website, social media and its "Visible" magazine). One of the topics covered by the November 2022 issue of "Visible" was in vitro diagnostic medical devices. The article followed the entire life cycle of this special class of medical devices, from development and placing on the market to monitoring by Swissmedic.

Press relations

Around 50 (previous year: 150) media enquiries referring specifically to medical devices were received in 2022, significantly fewer than in 2021. Most enquiries were about various aspects of COVID self-tests or the new medical devices regulation, but there were also enquiries about various implants.

Enquiries

Swissmedic answered some 3,100 enquiries about medical devices. At the beginning of the year, the questions from laypeople and professionals were still frequently about COVID-19 tests and face masks, but subsequently shifted to Swiss authorised representatives, the Swissdamed medical devices database and market access.

Transparency / FoIA

Six requests for access to official documents associated with medical devices were received during 2022.

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

Parliamentary proposals

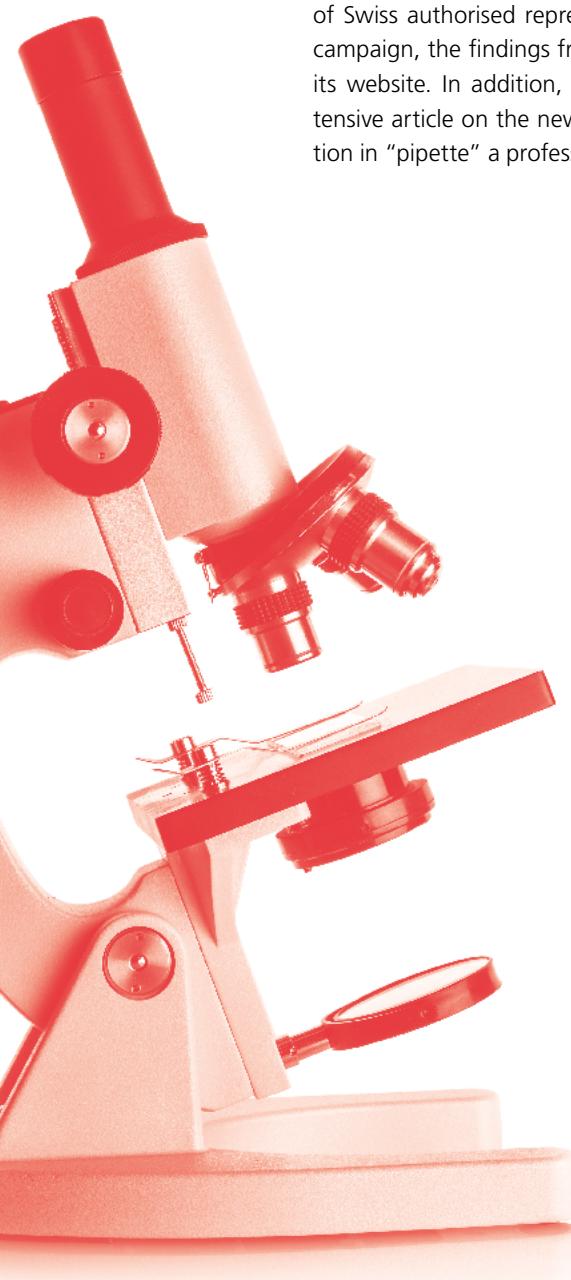
On 28 November 2022, parliament transferred the motion of Councillor of States Damian Müller, which demands greater scope in procuring medical devices to supply the Swiss population. Since medical device authorisation and certification systems outside the EU differ significantly from the current system used by the EU and Switzerland, the Federal Council is currently investigating whether it is possible to implement the motion.

The number of parliamentary proposals concerning medical devices declined on the previous year. Political issues included the situation following the failure to update the MRA, the field safety notice submitted by a manufacturer of respiration, sleep apnoea and respiratory therapy devices, and the fees for non-commercial clinical trials with medical devices.

Information and publications for professionals

Publications on the Swissmedic website and raising awareness at medtech round table meetings are an important resource for providing information to professionals in the medical devices sector. Furthermore, Swissmedic draws attention to relevant publications through the newsletter that it publishes several times a year. Activities in 2022 primarily involved the high volume of information associated with the introduction of the new regulation for in vitro diagnostic medical devices (e.g. blood glucose tests, reagents, laboratory devices).

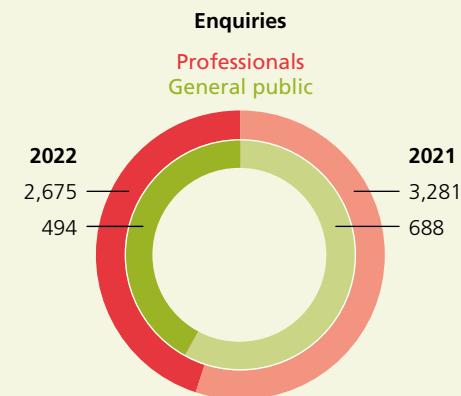
Furthermore, Swissmedic regularly published and updated answers to frequently asked questions associated with the new regulation as well as new or updated enforcement aids. In addition to information sheets on the roles and obligations of the various economic op-



erators, these included a circular letter in which Swissmedic made management at all hospitals aware of the new requirements for healthcare institutions ushered in by the IVD medical device regulation. These concern both the appointment of contact persons for IVD medical devices in hospitals and requirements applicable to quality assurance or the self-manufacturing or procurement of IVD medical devices.

In early November, Swissmedic held an online information event. Attracting around 700 participants from the medical technology and diagnostics industry, as well as people from hospitals and laboratories, it was well attended and the feedback was very positive.

During 2022, Swissmedic inspected a large number of Swiss authorised representatives as part of a focus campaign, the findings from which were published on its website. In addition, Swissmedic published an extensive article on the new IVD medical devices regulation in "pipette" a professional journal for laboratories.



Transparency/FoIA

2021 2022

Requests under FoIA

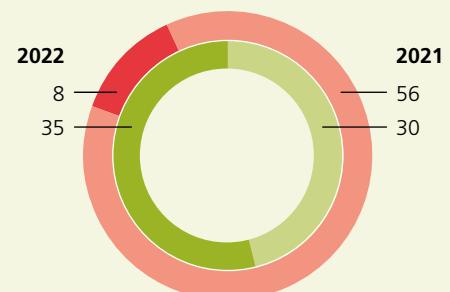
14
6

Time requirement (in hours) for processing requests

462
71

Parliamentary proposals

Parliamentary proposals
Other political business items in which
Swissmedic was involved



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. Following Switzerland's exclusion from the EUDAMED database in the wake of the failure to update the MRA, Swissmedic has been unable to take part in inter-authority data entry and coordination since June 2021.

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 by more than 38 percent during 2022. However, notifications concerning in vitro diagnostic medical devices rose by more than six percent.

Placing on the market

2021 2022

Class I notifications



IVD notifications (Switzerland)



Notifications rejected



Five notifications were submitted for classic and active implantable medical devices produced using or containing devitalised human tissue. In addition, 17 change notifications concerning devitalised human tissue were processed.

In 67 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. 26 applications were submitted and reviewed during 2022, with around half the procedures that have been completed in the meantime being approved.

Clinical trials

Swissmedic approves and monitors clinical trials of medical devices in humans if the devices or intended applications are not yet CE-certified. While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events, and reports on participant safety.

Activities:

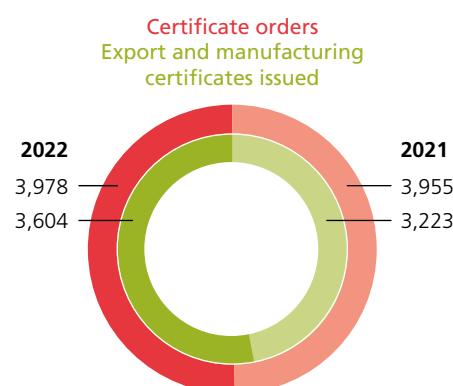
Swissmedic approved 37 first-time applications for clinical trials and 100 variations requiring approval. A total of 143 variations to clinical trials were monitored, as were 106 annual safety reports and 41 safety reports from ongoing trials in Switzerland.

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 3,978 orders in 2022 and issued 3,604 export and manufacturing certificates. 82 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:

Since the revised Medical Devices Ordinance came into force on 26 May 2021, Swissmedic has received 3,126 applications and issued 3,051 identification numbers. 96 percent of applications were processed within 30 days.



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:

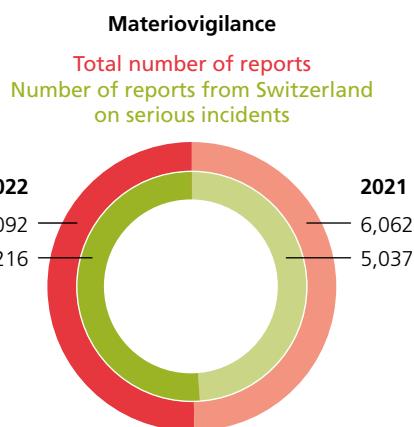
Following a steep rise in previous years, the number of reports of serious incidents from Switzerland continued to climb during 2022, albeit only slightly. 5,216 cases were reported during 2022. This is an increase of around four percent on the previous year.

The implementation of safety measures in Switzerland was monitored in 532 cases. The number of reported Field Safety Corrective Actions thus fell by 17 percent on the previous year.

As part of cooperation with European partner authorities (on all devices until 25 May 2021, then only those covered by the old law), Swissmedic issued four National Competent Authority Reports (NCARs) on defective medical devices and received 634 reports from other authorities.

In 537 cases, Swissmedic published a safety report on its website to bring the matter to the attention of users.

Throughout 2022, Swissmedic retained access to the monthly telephone conferences of the European surveillance authorities, which discuss new suspected incidents and coordinate concrete action on pending cases



Market Monitoring product

Independent monitoring

The Mutual Recognition Agreement with the EU Member States on conformity assessments for medical devices was not updated with effect from 26 May 2021. As a direct consequence, Switzerland ceased to be a closely integrated part of the European monitoring system, losing access to simplified administrative assistance, participation in joint market monitoring activities and the new EU information system provided by the EUDAMED database. Swissmedic carried out its own independent monitoring in Switzerland throughout 2022 to maintain an equivalent level of protection.

Market monitoring procedures

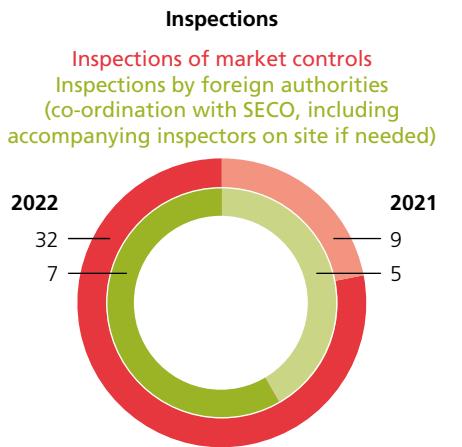
Efficient state-organised controls are essential in guaranteeing a high level of patient safety. Distributors of medical devices in Switzerland must guarantee the conformity of their products. Swissmedic receives suspicion reports, initiates the necessary corrective

measures and monitors implementation. This is an area where the Agency works closely with other national and cantonal authorities.

Activities:

The number of reports of suspected non-conforming medical devices was approximately the same as in 2021. Swissmedic ordered corrective action in 66 cases. The focus of the reports has shifted from devices specifically for coronavirus to the new, stricter requirements of the medical devices regulation. One of Swissmedic's responses to this situation was to conduct a focus campaign. In the first half of the year, Swissmedic inspected a random sample of 20 Swiss authorised representatives from across Switzerland who were registered with the Agency. This was supplemented by 12 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 2022, 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 2022.

Swissmedic was able to massively step up its own inspection activities following the lifting of COVID restrictions. However, inspections by foreign authorities of market operators in Switzerland remained low.

Swissmedic conducted two inspections in Switzerland on behalf of the Swiss Accreditation Service SAS.

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 such as nursing homes, 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:

A total of 45 areas in 15 hospitals were inspected. The inspections covered reprocessing in central reprocessing units and departments that perform endoscopies (e.g. gastroenterology or urology), maintenance or vigilance reporting systems.

Appeals procedure

Activities:

During 2022, 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 2022, 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:

Following the increase in criminal proceedings recorded in 2021 as a result of COVID, activities returned to pre-pandemic levels in 2022. Criminal prosecutions in the medical devices sector are largely dependent on market surveillance reports. The majority of such reports focused on registered economic operators during the year under review. The non-conformities in question were not criminal in nature and were corrected in the course of administrative proceedings.

Criminal prosecution

2021 2022

New complaints



Administrative proceedings opened



Completed administrative proceedings



Investigative measures

Activities:

No examination hearings or house searches were conducted in connection with medical devices.

Investigative measures

2021 2022

House searches



Examination hearings



Unification with cantonal proceedings



Decisions/verdicts by Swissmedic and the courts

Activities:

No penalties were imposed for medical devices. Proceedings were abandoned in two cases. In ongoing criminal proceedings involving the placing on the market for commercial gain of contaminated and damaged surgical instruments and the infringement of the reporting obligations, the court of second instance annulled the court of first instance's verdict on the grounds of procedural irregularities. The main trial in the court of first instance had to be repeated. The accused were acquitted because the limitation period had expired. However, all the medical devices that had been seized were confiscated and destroyed.

Decisions/verdicts by Swissmedic and the courts

2021 2022

Penalty orders, penalty rulings and rulings abandoning proceedings



Cantonal judgement



BALANCE SHEET

(in KCHF)	Annex	31.12.22	31.12.21
Cash and cash equivalents	1	5,195	41,978
Receivables from sales and services	2	58,719	64,759
Uninvoiced procedural fees	3	5,294	5,809
Prepaid expenses	4	351	265
Financial assets (debenture bonds)	5	25,203	0
Current assets		94,762	112,811
Financial assets (debenture bonds)	5	25,136	0
Pension assets	14	10,010	0
Fixed assets	6	2,282	2,294
Real estate	7	63,229	64,772
Intangible assets	8	2,786	1,342
Right of use	9	2,533	2,714
Capital assets		105,976	71,122
Total assets		200,738	183,933
Commitments on sales and services	10	7,513	6,147
Other commitments	9+11	1,053	1,517
Short-term financial commitments	13	0	5,000
Deferred income	12	3,878	4,179
Short-term commitments		12,444	16,843
Lease liabilities	9+11	2,378	2,551
Liability for loyalty bonuses		2,650	2,855
Pension obligations (net)	14	0	46,374
Long-term commitments		5,028	51,780
Annual gain		11,505	21,852
Reserves		101,360	79,508
Endowment capital		14,500	14,500
Accumulated actuarial gains (+)/losses (-)		55,901	-550
Own capital		183,266	115,310
Total liabilities		200,738	183,933

INCOME STATEMENT

(in KCHF)	Annex	2022	2021
Procedural fees and income pursuant to Art. 69 TPA (net)	15	42,277	43,335
Supervisory levies		55,723	62,547
Other income		316	307
Federal contribution		19,228	16,728
Other operating income		63	68
Net income		117,607	122,985
Services for third parties		-2,107	-3,070
Personnel	16	-80,927	-76,138
Rental, maintenance, energy, transport and insurance		-2,612	-2,391
Administration		-4,934	-3,790
IT	17	-11,017	-10,504
Other expenses		-516	-595
Amortisation	6–9	-3,659	-4,076
Total operating expenditure		-105,772	-100,564
Operating income		11,835	22,421
Financial income	18	14	7
Financial expense	19	-344	-576
Financial result		-330	-569
Annual gain		11,505	21,852

STATEMENT OF COMPREHENSIVE INCOME

(in KCHF)	Annex	2022	2021
Annual gain		11,505	21,852
Actuarial gains (+)/losses (–)	14	56,451	35,612
Total		67,956	57,464

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

CASH FLOW STATEMENT

(in KCHF)	Annex	2022	2021
Income / (expenditure) from business activities			
Annual gain		11,505	21,852
Depreciation of tangible fixed assets	6	543	922
Writedowns on real estate	7	2,463	2,402
Amortisation of intangible assets	8	472	571
Writedowns on right of use	9	181	181
Reversal (–)/recognition (+) of liability for loyalty bonuses		–205	44
Reversal (–)/recognition (+) of pension obligations, (excl. actuarial (losses) gains)	14	68	–105
Interest expense (+)/interest income (–)		338	567
Cash flow before change in net current assets		15,365	26,434
Increase (–)/decrease (+) in receivables from sales and services	2	6,040	–3,395
Increase (–)/decrease (+) in uninvoiced procedural fees	3	515	–179
Increase (+)/decrease (–) in prepaid expenses	4	–86	–162
Increase (+)/decrease (–) in commitments from sales and services	10	1,366	797
Increase (+)/decrease (–) in other current, non-interest-bearing commitments	11	–464	633
Increase (+)/decrease (–) in deferred income	12	–301	–317
Cash flow from business activities		22,435	23,811
Income / (expenditure) from investing activities			
Investments in short- and long-term financial assets	5	–50,339	0
Investments in tangible fixed assets	6	–531	–485
Disposals of tangible fixed assets	6	0	1
Investments in real estate	7	–912	–870
Investments in intangible assets	8	–2,163	–829
Interest received		238	0
Cash flow from investing activities		–53,707	–2,183
Income / (expenditure) from financing activities			
Repayment of interest-bearing commitments	13	–5,000	0
Interest paid		–338	–567
Repayment of lease liabilities	9	–173	–171
Cash flow from financing activities		–5,511	–738

(in KCHF)	Annex	2022	2021
Net increase/(decrease) in cash and cash equivalents		-36,783	20,890
Cash and cash equivalents at start of year	1	41,978	21,088
Cash and cash equivalents at year end	1	5,195	41,978



STATEMENT OF CHANGES IN EQUITY

(in KCHF)	Annual gain	Reserves	Endow- ment capital	Accum. actuarial gains (+) / losses (-)	Total equity
Opening balance on 1 January 2021	28,936	50,572	14,500	-36,162	57,846
Annual gain	21,852	0	0	0	21,852
Other income	0	0	0	35,612	35,612
Total	21,852	0	0	35,612	57,464
Appropriation of gain	-28,936	28,936	0	0	0
Closing balance on 31 December 2021	21,852	79,508	14,500	-550	115,310
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

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 International Financial Reporting Standards (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 2022 to 31 December 2022. The balance sheet date is 31 December 2022. 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 21 April 2023.

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 and interpretations with effect from 1 January 2022.

- Amendments to IFRS 3 – reference to the Conceptual Framework
- Amendments to IAS 16 – Property, Plant and Equipment: Proceeds before Intended Use
- Amendments to IAS 37 – Onerous Contracts: Cost of Fulfilling a Contract
- Amendments to IFRS 1, IFRS 9, and IAS 41: Annual improvements to IFRS 2018–2020

None of these amendments had a material impact on these accounts. Furthermore, Swissmedic has not prematurely applied any standards or interpretations 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 state-guaranteed debenture bonds. Cash flows consist entirely of "solely payments of principal and interest" (SPPI) on the outstanding capital. Swissmedic has no intention of selling these bonds before they mature. All acquisition costs (fair value of the bond and the transaction costs 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 is reviewed at the end of each reporting period and adjusted as necessary. If the carrying amount of an asset exceeds the estimated achievable amount, the asset is devalued by the resulting difference. 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, and only then if 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 is reviewed at the end of each reporting period and adjusted as necessary. If the carrying amount of an asset exceeds the estimated achievable amount, the asset is devalued by the resulting difference.

Right of use

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

Lease liabilities

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

Lease payments are discounted using the interest rate underlying the lease. This is the interest rate at which the present value of lease payments 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 that 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.

Liability 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	31.12.22	31.12.21
Euro	0.99580	1.06750
US dollar	0.98530	0.92920
British pound	1.14570	1.25950
Swedish kronor	0.0916	0.1071

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 Art. 69 of the Therapeutic Products Act comprises speakers' fees for presentations given by Swissmedic 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

The federal contribution is the remuneration paid by the Swiss Confederation for services that are deemed to be public services and the cost of which is financed by the Confederation in accordance with the strategic goals for the 2019-2022 period approved by the Federal Council. In the case of medicinal products, this applies to the legal framework and penal law products; in the case of medical devices, the Confederation pays for all activities with just a few exceptions. The Federal Council determines contributions for one calendar year in each case.

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 interest expenses for fixed advances and fixed mortgages, 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 bonds or on Swissmedic's mortgage 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)	31.12.22	31.12.21
Current accounts at banks	5,195	41,978
Total cash and cash equivalents	5,195	41,978

In 2022, Swissmedic invested surplus liquid resources in state-guaranteed debenture bonds. This is the primary reason for the substantial year-on-year fall in cash and cash equivalents.

2 Receivables from sales and services

Trade receivables from third parties

(in KCHF)	31.12.22	31.12.21
Not overdue	58,489	64,652
1–30 days overdue	83	59
More than 30 days overdue	287	85
Total receivables from sales and services (gross)	58,859	64,796
Individual value adjustments	-134	-35
Flat-rate value adjustment	-6	-2
Total receivables from sales and services (net)	58,719	64,759

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 (99.5%), Confederation and Cantons (0.14%) and private individuals (0.36%).

Payment schedules

(in KCHF)	31.12.22	31.12.21
Non-overdue receivables for which the payment deadline was subsequently extended (payment schedules)	228	63
Total payment schedules	228	63

As at the end of 2022, there were 15 payment schedules (previous year: 18) for an unpaid amount of KCHF 228. There are no foreign currency receivables.

Value adjustments on receivables

(in KCHF)	31.12.22	31.12.21
Total value adjustments on receivables 1 January	-37	-21
Recognition	103	16
Reversal	0	0
Use	0	0
Total value adjustments on receivables as at 31 December (total of individual and flat-rate adjustments)	-140	-37

3 Uninvoiced procedural fees

(in KCHF)	31.12.22	31.12.21
Uninvoiced procedural fees	5,294	5,809
Total uninvoiced procedural fees	5,294	5,809

4 Prepaid expenses

(in KCHF)	31.12.22	31.12.21
Prepaid expenses	351	265
Total prepaid expenses	351	265

The following transactions are reported under prepaid expenses:

- Individual invoices for services due for delivery in 2023 but which had to be paid for in 2022.
- Individual invoices for contracts dating from 2023.

5 Financial assets

As at 31.12.22 (in KCHF)	Carrying amounts	Fair values
CHF 10 mn Basler Kantonalbank, matures 10 Aug. 2023, interest rate 0.375%	10,050	9,926
CHF 10 mn Thurgauer Kantonalbank, matures 28 Aug. 2023, interest rate 1.375%	10,140	10,007
CHF 5 mn Walliser Kantonalbank, matures 15 Dec. 2023, interest rate 0.625%	5,013	4,936
CHF 10 mn Aargauische Kantonalbank, matures 21 Feb. 2024, interest rate 0.11%	10,023	9,833
CHF 5 mn Freiburger Kantonalbank, matures 3 June 2024, interest rate 1.25%	5,121	4,998
CHF 10 mn Walliser Kantonalbank, matures 19 Aug. 2024, interest rate 0.2%	9,992	9,737
Total debenture bonds	50,339	49,437
of which short-term	25,203	24,869
of which long-term	25,136	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.

No financial assets were held in 2021.

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 2021	2,856	1,963	5,723	87	10,629
Additions	5	0	438	42	485
Disposals	0	-34	-154	0	-188
31 December 2021	2,861	1,929	6,007	129	10,926
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
Accumulated depreciation					
1 January 2021	-2,198	-1,931	-3,682	-87	-7,898
Additions	-463	-20	-435	-4	-922
Disposals	0	34	154	0	188
31 December 2021	-2,661	-1,917	-3,963	-91	-8,632
Net carrying amounts as at 31 December 2021	200	12	2,044	38	2,294
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

Various fixed assets, such as laboratory equipment and furnishings, were acquired and capitalised during 2022. 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 2021	212	83,818	11,730	95,760
Additions	938	0	0	938
Reclassifications	-1,150	1,082	0	-68
Disposals	0	-12	0	-12
31 December 2021	0	84,888	11,730	96,618
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
Accumulated depreciation				
1 January 2021	0	-29,456	0	-29,456
Additions	0	-2,402	0	-2,402
Disposals	0	12	0	12
31 December 2021	0	-31,846	0	-31,846
Net carrying amounts as at 31 December 2021	0	53,042	11,730	64,772
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 2021	112	51,387	11,730	63,229

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 2022, investments in the flat roof at Hallerstrasse and in building services installations (e.g. fire alarm system, sliding doors) 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 2021	116	16,147	16,263
Additions	829	0	829
Reclassifications	-634	634	0
31 December 2021	311	16,781	17,092
1 January 2022			
Additions	2,163	0	2,163
Reclassifications	-247	0	-247
31 December 2022	2,227	16,781	19,008
Accumulated depreciation			
1 January 2021	0	-15,179	-15,179
Additions	0	-571	-571
31 December 2021	0	-15,750	-15,750
Net carrying amounts as at 31 December 2021	311	1,031	1,342
1 January 2022			
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

Although Swissmedic contracts out software development to IT specialists, it defines specifications and requirements and bears responsibility for the projects itself. For this reason, the software counts as self-developed. No intangible assets were capitalised during 2022. As at the balance sheet date, there were no indications of any unanticipated impairments.

9 Right of use

Statement of changes (in KCHF)	Right of use	Total right of use
Acquisition cost		
1 January 2021	3,257	3,257
Additions/disposals	0	0
31 December 2021	3,257	3,257
1 January 2022	3,257	3,257
Additions/disposals	0	0
31 December 2022	3,257	3,257
 Accumulated depreciation		
1 January 2021	-362	-362
Additions/disposals	-181	-181
31 December 2021	-543	-543
Net carrying amounts as at 31 December 2021	2,714	2,714
 1 January 2022		
Additions/disposals	-181	-181
31 December 2022	-724	-724
Net carrying amounts as at 31 December 2022	2,533	2,533

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)	31.12.22	31.12.21
Starting balance as at 1 January	2,746	2,917
Redemption	-195	-195
Accrued interest	23	24
Final balance as at 31 December	2,574	2,746
of which short-term	195	195
of which long-term	2,378	2,551

There are no further lease liabilities (e.g. short-term or low-value leases).

10 Commitments on sales and services towards third parties

(in KCHF)	31.12.22	31.12.21
In CHF	7,495	6,110
In foreign currencies	18	37
Total commitments on sales and services towards third parties	7,513	6,147

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

11 Other commitments

(in KCHF)	31.12.22	31.12.21
Short-term lease liabilities	195	195
Other short-term commitments towards third parties	858	1,322
Total other short-term commitments	1,053	1,517

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)	31.12.22	31.12.21
Deferred income	113	231
Amount deferred for leave and flexitime	3,765	3,948
Total deferred income	3,878	4,179

Deferred income comprises individual outstanding invoices from 2022.

13 Financial commitments

(in KCHF)	31.12.22	31.12.21
Short-term commitments	0	5,000
Total short-term financial commitments	0	5,000

The properties owned by Swissmedic were financed by fixed-rate mortgages. Swissmedic repaid its final mortgage of CHF 5 million in November 2022. There were thus no further financial commitments on the balance sheet date.

14 Pension provision

Description of pension plans and pension institution

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

Responsibilities of the joint committee and fund commission

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

Special situations

The pension fund regulations and pension plan 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 and/or pension plan. In addition, employers can also pay one-off contributions or advances into the pension fund (employer contribution reserve). These contributions are then tied up and may not be paid back to the employer. By law, minimum annual contributions still have to be paid even if a surplus exists. Both employer and employee contributions are paid for active members. The employer contribution must be at least the same as the employee contribution.

Pension fund status is calculated as follows:

(in KCHF)	2022	2021
Change in commitments and assets		
Dynamic present value of benefit obligations at start of year	-381,085	-390,472
Actuarial pension benefit expenses	-10,848	-11,283
Employee contributions	-4,390	-4,148
Past benefit expenses	0	0
Interest expense	-1,334	-589
Curtailment, settlement	0	0
Benefits paid	4,235	4,125
Actuarial gain (+)/loss (-) on commitments	88,447	21,282
Dynamic present value of benefit obligations at year-end	-304,975	-381,085
Plan assets at market value at start of year	334,711	308,381
Interest income	1,172	466
Employer contributions	11,060	11,625
Employee contributions	4,390	4,148
Benefits paid	-4,235	-4,125
Administrative expenses	-118	-114
Actuarial gain (+)/loss (-) on assets	-31,995	14,330
Plan assets at market value at year-end	314,985	334,711
Balance sheet	31.12.22	31.12.21
Plan assets at fair value	314,985	334,711
Dynamic present value of benefit obligations (DBO)	-304,975	-381,085
Assets (+)/liability (-) in the balance sheet	10,010	-46,374
Duration	15,20	18,10

Income statement (in KCHF)	2022	2021
Actuarial pension benefit expenses	-10,848	-11,283
Interest expense	-1,334	-589
Interest income	1,172	466
Past service cost	0	0
Gain (loss) from curtailment, settlement	0	0
Administrative expenses	-118	-114
Net expenses for benefit obligations	-11,128	-11,520
Change in the balance sheet	31.12.22	31.12.21
Liabilities on the balance sheet at start of year	-46,374	-82,091
Net benefit expenses (employer)	-11,128	-11,520
Employer contributions	11,060	11,625
Actuarial gains (+)/losses (-)	56,452	35,612
Liabilities on the balance sheet at year-end	10,010	-46,374
Anticipated employer contribution payment in following year	8,446	7,296
Effective return on plan assets	-30,823	14,796
Key actuarial assumptions as at balance sheet date	31.12.22	31.12.21
Discount rate	2.25%	0.35%
Future payroll increases	2.00%	1.25%
Future pension increases	0.00%	0.00%
Projected interest rate	2.00%	1.00%
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	24.30/26.10	24.17/25.99
Asset allocation	31.12.22	31.12.21
Cash and cash equivalents	5.00%	3.30%
Bonds	46.30%	51.90%
Equities	27.80%	26.80%
Real estate	18.50%	15.80%
Other	2.40%	2.20%
Total	100.00%	100.00%
Of which stock exchange-traded	79.70%	82.10%

Defined benefit pension plans	31.12.22	31.12.21
Revaluation of actuarial gain (+)/loss (-) from obligations	88,447	21,282
Owing to changes in holdings	-7,842	-6,943
Owing to demographic assumptions	0	14,009
Owing to financial assumptions	96,289	14,216
Revaluation of actuarial gain (+)/loss (-) from investments	-31,995	14,330
Total amount recognised in equity	56,452	35,612

Sensitivities – impact on DBO (in KCHF)	2022	2021
Discount rate +0.25%	-11,044	-16,716
Discount rate -0.25%	11,733	17,914
Payroll increase +0.25%	871	1,211
Payroll increase -0.25%	-851	-1,182
Pension increase +0.25%	7,892	-12,444
Pension increase -0.25% (not lower than 0%)	0	0
1-year increase in life expectancy	12,273	15,426

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

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

(in KCHF)	2022	2021
Authorisation (with no fee rebates)	31,391	35,957
Licensing	13,168	12,805
Therapeutic products information	1	10
Informing the general public	5	3
Market supervision	3,519	3,270
Penal law	83	308
Fee surcharges	567	490
Earnings from conferences (Art. 69 TPA)	299	17
Earnings from publications (Art. 69 TPA)	1	4
Earnings from services for third parties (Art. 69 TPA)	153	110
Fee reductions	-6,910	-9,639
Total procedural fees and income pursuant to Art. 69 TPA	42,277	43,335

The year-on-year decline in procedural fees is primarily due to the reduction in fees for minor variation applications. These fees were reduced as of 1 January 2021. However, the reduction only took full effect in 2022.

16 Personnel

(in KCHF)	2022	2021
Wages and salaries	-61,564	-57,845
Net expenses for benefit obligations	-11,128	-11,520
Social security	-5,557	-5,242
Other personnel expenses	-2,012	-1,370
Work by third parties	-666	-161
Total personnel expenses	-80,927	-76,138

Headcount rose as planned by around 40 full-time positions. Accordingly, personnel expenses rose by CHF 4.8 million. This increase in staffing was primarily the result of the additional tasks associated with medical devices surveillance, the assessment of innovative medicinal products such as Advanced Therapy Medicinal Products (ATMPs) and Swissmedic's digital transformation.

17 IT

(in KCHF)	2022	2021
Operating services	-5,944	-6,118
Hardware	-274	-272
Software licences	-1,013	-614
Development and project management services	-1,973	-2,445
Maintenance and support services	-1,813	-1,055
Total IT	-11,017	-10,504

18 Financial income

(in KCHF)	2022	2021
Interest income from receivables and debenture bonds	2	3
Exchange rate gains	12	4
Total financial income	14	7

19 Financial expense

(in KCHF)	2022	2021
Interest expense, banks	-315	-543
Interest expense, leases	-23	-24
Exchange rate losses	6	-9
Total financial expense	-332	-576



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
Financial commitment towards third parties	11	5,030	0	0	5,041
Commitments on sales and services towards third parties	3,739	0	0	0	3,739
Commitments on sales and services towards related parties	2,408	0	0	0	2,408
Lease obligations toward third parties	49	146	780	1,950	2,925
Total contractual cash flows from financial commitments 2021	6,207	5,176	780	1,950	14,113
Financial commitment towards third parties	0	0	0	0	0
Commitments on sales and services towards third parties	4,186	0	0	0	4,186
Commitments on sales and services towards related parties	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

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 Tele-communication (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. In accordance with IAS 24 revised, only material transactions (i.e. those exceeding CHF 1 mn) with the Confederation and organisations related to the Confederation are disclosed in the notes to the financial statements. The following transactions were conducted with related parties:

(in KCHF)	31.12.22	31.12.21
PUBLICA, social insurance contributions	1,095	1,009
FOITT, IT expenses	1,520	1,394
CFC, social insurance contributions	623	0
Total commitments towards related parties	3,238	2,403

(in KCHF)	2022	2021
GS FDHA, federal contribution	19,227	16,727
Total net income involving related parties	19,227	16,727
PUBLICA, social insurance contributions	15,445	15,773
FOITT, IT expenses	5,708	5,421
CFC, social insurance contributions	8,250	6,640
Total operating expenses involving related parties	29,403	27,834

Remuneration of individuals in key positions

The following fees and salaries were paid:

(in KCHF)	2022	2021
Short-term benefits due to the Management Board	2,059	1,980
Benefits following termination of employment contract	354	339
Benefits occasioned by termination of employment contract	0	0
Share-based compensation	0	0
Total remuneration of individuals in key positions	2,413	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, 21 April 2023

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 2022 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 2021, 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.



Page 3

**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

A blue ink signature of Andreas Schwab-Gatschet.

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

A blue ink signature of Cédric Meyer.

Cédric Meyer
Licensed audit expert



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

