swissmedic

ANNUAL REPORT 2021

Mission

Our competence – for therapeutic products you can trust.

Guiding principles of Swissmedic

CONTENTS

FOREWORDS

Truer last year than ever before: Swissmedic – for therapeutic products you can trust

Lukas Bruhin, President of the Agency Council

The last business year was once again dominated by the task of pandemic management. After Swissmedic became the first regulatory authority in the world to authorise a COVID-19 vaccine under an ordinary procedure on 19 December 2020, further decisions followed in rapid succession during 2021. The authorisation of a further COVID-19 vaccine in mid-January 2021 was quickly followed by decisions on vaccinations for young people and children, then finally, in autumn, by decisions on boosters. At the same time, a large number of authorisation procedures for COVID-19 treatments were underway. Here Swissmedic applied novel approaches, using rolling procedures to process applications quickly yet without compromising in any way on safety, efficacy or quality.

However, Swissmedic still had the courage to query applications where necessary. This made it clear that although expectations were high as regards the authorisation of further vaccines, review requirements were not simply being subordinated to the goal of faster authorisation. This willingness to make independent decisions in the interests of patient safety helps protect confidence in the therapeutic products available in Switzerland.

Overall, Swissmedic fulfilled its role very effectively during the pandemic. On behalf of the Agency Council, I would like to thank all Swissmedic staff and the Management Board for their tremendous and exemplary dedication and hard work. Last year, they once again proved that the Agency operates very smoothly in extremely challenging situations. Not only did it process and approve the COVID-related applications that were the focus of public attention, it also continued to deal with its remaining workload to a very high, reliable standard and, overall, achieved the targets defined in the Agency Council's strategic goals. Once again, Swissmedic demonstrated that Switzerland has one of the best-performing therapeutic products authorities in the world.

Swissmedic is celebrating its 20th anniversary in 2022 and, as the pandemic hopefully subsides, it will also be able to focus on the lessons learnt from the coronavirus pandemic. These will be incorporated into the new strategic goals that the Agency Council will revise in the course of this year.

I hope you enjoy reading this Annual Report, and I would be delighted if you were to continue to take an interest in the Agency and its activities during our anniversary year.

A strong therapeutic products regulatory agency is a key locational advantage

Raimund Bruhin, Executive Director

The second year of coronavirus is now behind us. Once again, it challenged all levels of our organisation, from authorisation and market surveillance to inspection and production facility licensing to communications.

The coronavirus pandemic has demonstrated clearly why we need a strong regulatory agency that safeguards the safety, efficacy and quality of therapeutic products. When it authorised the Pfizer vaccine in December 2020, Swissmedic enabled Switzerland to take its place on the global winners' podium for countries rolling out COVID vaccination campaigns. Experience in the two years we have been dealing with coronavirus shows that we have to be able to act autonomously in crisis situations such as this if we are to make our contribution to crisis management with sufficient agility, speed and efficacy.

Swissmedic's combination of scientific autonomy and financial and political independence, supplemented by its international network, enabled the Agency to take decisions free of any influence at a time when expectations were high. The trust this created was the springboard for the high – by Swiss standards – vaccination rate that led the Swiss economy, society and government out of the crisis.

The breakdown of negotiations on the framework agreement between Switzerland and the EU resulted in the MRA for medical devices not being updated, which in turn presented a fresh challenge for Swissmedic. With the medical technology industry unsettled by Switzerland's new status as a third country, a set of regulations that would offer a practicable solution had to be provided without delay. Swissmedic was thus able to make a significant contribution to safeguarding security of supply of medical devices in Switzerland while maintaining a level of protection and patient safety equivalent to that in the EU. At the same time and to safeguard supplies, the Cantons were given a legal framework within which to procure medical devices independently of domestic market players.

For the first time since it was created, Swissmedic was accredited by the Swiss Medical Association FMH as a category A training institution for candidates for FMH's specialist qualification in pharmaceutical medicine. As a result of this step, it is now possible to directly contribute to the academic development of up-and-coming professional regulators.

Further operating highlights and issues included the preparation of the IT strategy, the implementation of the new high-media-profile communication strategy and the preparation of decision-making support material for transferring the authorisation of veterinary vaccines and immunologicals from the FSVO/IVI to Swissmedic. Internationally, cooperation was established with the FDA on Project Orbis and with the Access Consortium.

We also achieved our strategic and operational goals for the year in addition to contributing to the pandemic response and handling our regular day-to-day business and are now entering the last year of the current strategy period.

SWISSMEDIC AT A GLANCE

Core tasks of Swissmedic

Swissmedic is the Swiss authority responsible for the authorisation and monitoring of medicinal products and medical devices, collectively known as therapeutic products. The Agency ensures that the therapeutic products it approves are of impeccable quality, effective and safe.

Specifically, the main tasks of Swissmedic comprise the approval of clinical trials of medicinal products; the authorisation of medicinal products and batch release; the issuing of establishment licences for the manufacture of, and wholesale trading in, medicinal products; the designation and monitoring of conformity assessment bodies for medical devices; market surveillance of medicinal products and medical devices (vigilance and market monitoring); monitoring the flow of controlled substances (narcotics); and publication of the Swiss Pharmacopoeia. 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)

Under Article 68 of the Therapeutic Products Act (TPA), Swissmedic has its own budget and manages its own accounts. Most of its income is derived from fees and supervisory levies, the remainder from 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 around 75 percent of operating costs.

In accordance with applicable ordinances on supervisory levies and charges, Swissmedic accumulates reserves to finance future investment or cover any losses it may incur. If the reserves exceed the sum of one annual budget, charges and fees have to be reduced in accordance with Article 79 TPA. Since 2019 it has been possible to quickly accumulate substantial reserves. Although these have yet to reach the sum of one annual budget, the levy rate on the ex-factory price of medicinal products has been reduced with effect from the start of 2022.

Three important issues

The COVID-19 pandemic and its impact on research and regulation

For the second year in succession, the Agency's work was dominated by the coronavirus pandemic. All sectors of Swissmedic were kept busy with a wide range of tasks and support services associated with the pandemic response.

Authorisation of the Pfizer/BioNTech vaccine Comirnaty® on 19 December 2020 was followed on 12 January 2021 by authorisation of Moderna's Spikevax®, then the viral vector vaccine produced by Janssen (Johnson & Johnson) on 22 March 2021. However, our work was not done once the vaccines had been authorised. There were numerous variation applications concerning shelf life and storage conditions, extensions to juvenile age groups and booster vaccinations.

While this was taking place, therapeutic agents such as the monoclonal antibodies Ronapreve®, Xevudy® and Regkirona® were being reviewed and temporarily authorised on a rolling basis.

Testing was a key part of the pandemic response, and it is therefore unsurprising that global demand for self-testing kits in particular surged during 2021. This resulted in supply bottlenecks and in non-conforming tests making their way onto the market. Working closely with the Federal Office of Public Health, Swissmedic issued exemptions in certain cases to help cope with demand while conducting proceedings to ban non-conforming tests. By mid-2021, Swissmedic had received more than 50 reports of suspected non-conforming tests. It banned further supply of 15 test kits and provided information on the legal requirements, having conducted various investigations, including test purchases.

Global supply bottlenecks and rising case numbers towards the end of the year resulted in a large number of applications to import foreign medicinal products. Swissmedic processed these applications in a matter of days and notified the users.

Vigilance measures had to be put securely in place before the vaccination campaigns were launched. Swissmedic carried out inspections to determine whether authorisation holders had made preparations for processing side effect reports. It also simplified access to adverse reaction reporting systems for medical professionals and by the end of 2021 had evaluated over 11,900 reports. The process took account of international findings. Swissmedic regularly issued publications to inform professional and public audiences about COVID-19 vaccine safety.

Furthermore, a Swiss company – Lonza AG in Visp – is playing a key role in the production of the active substance for a COVID vaccine. Swissmedic therefore found itself the focus of attention from other countries' regulatory agencies, since it was responsible for inspecting and approving the manufacturing facility prior to the vaccine being placed on the global market. The Agency had already issued a manufacturing licence for a first small facility at the end of 2020. The new building complex in Visp for COVID vaccine manufacturing was completed in 2021. Swissmedic inspected these new facilities promptly as the project progressed.

In addition to the ongoing inspection procedures, the Agency held scientific advice meetings with Lonza to review the inspection timetable and discuss plans to further expand the facility to double production capacity.

The Swiss government's efforts to expand nationwide testing capacity doubled the number of applications –

COVID-19 activities in figures

60 days
required to review and temporarily authorise Spikevax®

102
authorisation and variation applications associated with COVID vaccines and therapeutic agents processed

30 days
dedicated to vaccine manufacturer inspections

100%
more licence applications from microbiological laboratories

11,912
side effect reports
connected with COVID vaccines processed

66
reports of suspected
non-conforming COVID tests processed

965
COVID-related media enquiries answered

1,082
social media posts
on COVID-related subjects

often to expand activities to include COVID testing – received from microbiological laboratories. The additional workload involved in reviewing and inspecting new testing sites, new market players and test services was substantial. These checks often resulted in Swissmedic restricting or prohibiting testing activities.

26 May 2021 – negotiations with the EU broken off

On 26 May 2021 – the same day the new medical devices regulation came into force – the Federal Council announced that negotiations with the European Union on a institutional agreement had been broken off. Switzerland's Mutual Recognition Agreement (MRA) with the EU made it an integral part of the EU single market, which meant that Swissmedic was in turn part of the Union's market surveillance network. When negotiations were broken off, the EU refused to update the MRA and declared it void as regards medical devices. Swissmedic was excluded from all steering and enforcement committees for the new regulation and lost access to EUDAMED, the new European central database on medical devices.

The cushioning measures issued by the Federal Council on 19 May 2021 and intended to ensure Switzerland's access to reliable supplies of safe medical devices absorbed some of the negative impact.

Swissmedic had anticipated this worst-case scenario and had made preparations to ensure that the additional requirements, specifically including registration of economic operators, could be implemented from 26 May 2021. The short-notice nature of this change in environment coupled with the Swiss legislation's heavy reliance on the EU's Medical Devices Regulation (MDR) and the large number of missing implementing provisions associated with the MDR caused widespread uncertainty among the affected sectors of the medical technology industry.

By providing a number of enforcement aids, holding an information event attended by 1,600 people and coordinating with the Swiss Medtech industry association on critical issues, it was possible to create a framework within which all economic operators can implement the new regulation. These steps by Swissmedic made an important contribution to the ongoing improvement of medical device safety and, by extension, patient safety in Switzerland.

Digital transformation

During 2021, Swissmedic implemented a project to digitalise the evaluation and supervision processes for clinical trials. This has reduced the internal processing effort and time requirement. At the same time, the groundwork was prepared for electronic application submission, which should go live to stakeholders from 2022.

Just over a year ago, Swissmedic 4.0 was launched. This agile organisational unit deals with the challenges of digital transformation in the context of people and culture, processes and technology. This digital initiative has deliberately created a space for experimentation outside of daily business in which interdisciplinary teams can develop innovative solutions to operational issues and test out new approaches and technologies. The experience gained can then be efficiently transferred into the relevant host organisation.

A first application that can be used to efficiently search various information sources for medicinal product safety signals in clinical trials was successfully created and launched. Using machine learning has minimised search times and made it possible to interpret the results in the context of the severity of the reaction. The experience of using machine learning can be channelled into further applications, such as tracking down violations of the Therapeutic Products Act.

Swissmedic and its national stakeholder groups

Swissmedic is in regular dialogue at national level with its various stakeholders. These include:

- Patients and consumers and their associations and organisations
- Healthcare professionals and their associations and organisations
- The therapeutic products industry and its associations and organisations
- Start-up companies, innovators, universities and clinical research organisations
- Service providers from the therapeutic products industry
- Cantonal and federal authorities
- Switzerland's Parliament

The patient and consumer organisations working group met three times. As in 2020, the COVID-19 pandemic was a dominant issue. The "involving patient organisations in the drafting of patient information" pilot project was implemented on 1 November 2021. The option of involving patient organisations is now available to all authorisation holders. The Management Board's work planning for 2021 to 2024 confirmed that patient and consumer organisation involvement, including information sharing, would continue for the next few years.

Meetings were held with representatives of the Association of Cantonal Pharmacists to coordinate enforcement of the Therapeutic Products Act, while the annual meeting with all Cantonal Pharmacists took place in November. The topics discussed included the amended medical devices regulation and the new requirements that healthcare institutions have to fulfil in terms of quality assurance and device traceability.

Twelve round table meetings were held with the pharmaceutical industry and industry associations.

Regulatory Affairs round table meetings addressed various issues, including the results of the international benchmarking study on authorisation times; Project Orbis, the US FDA's oncologicals authorisation programme in which Swissmedic is taking part; and handling real-world data and evidence from empirical studies. In addition, the meetings discussed initial experience with the rolling procedure used to temporarily authorise pandemic vaccines and the requirements for submissions involving nanomedicinal products and nanosimilars.

At GMP/GDP (Good Manufacturing and Good Distribution Practice) round table meetings, Swissmedic provided information on the progress made in developing the medical professions register and the processes for updating authorisation holder entries in the European database (OMS and EudraGMP). For the first time, participants also took part in the revisions of the "Technical Interpretations" texts.

For the second time after 2019, Swissmedic held a round table meeting on innovation. The discussion on regulating digital endpoints was attended by all stakeholders – industry, researchers, the FOPH, swissethics and representatives of patient organisations.

A further meeting was held with stakeholders from the complementary and herbal medicine sector and two with a delegation from veterinary medicinal product distributors led by Scienceindustries.

Three MedTech round tables with representatives of the medtech industry took place. The most important issues addressed were the implementation of the amended medical devices regulation and its impact on stakeholders' responsibilities; the new in vitro diagnostic medical device regulation due to come into force in 2022; and various concerns raised by the medtech industry associations, including those connected with the failure to update the MRA and the impact of Brexit.

Swissmedic in international bodies

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 once again proved to be extremely valuable during the COVID-19 pandemic.

International cooperation and networking in the COVID-19 pandemic

As in 2020, international cooperation was dominated by the COVID-19 pandemic. Swissmedic made an active contribution to the discussions and workshops organised by the International Coalition of Medicines Regulatory Authorities (ICMRA) and World Health Organization (WHO). ICMRA promotes cooperation between medicinal product regulatory authorities, particularly coordinated responses to crisis situations where public health has to be protected.

The COVID-19 pandemic also affected cooperation with Swissmedic's Australian, Canadian, Singaporean and British counterparts in the Access Consortium. In addition to joint statements on issues such as regulatory requirements for submitting new vaccines using immunobridging data, there was an extensive dialogue on COVID-19 vaccines and medicinal products and their undesirable effects.

International collaboration on medicinal products

As in 2020, the meetings of the International Council for Harmonisation (ICH), which has been in existence for 30 years, and the International Pharmaceutical Regulators Programme (IPRP) were held virtually. With the election of Dr Gabriela Zenhäusern, Swissmedic holds the ICH Assembly Vice-Chair once more.

Swissmedic has been an active contributor to the European Patients' Academy on Therapeutic Innovation (EUPATI) right from the outset. It has been a member of the Regulatory group's Advisory Committee since 2021, which has given it the opportunity to discuss engagement with patient organisations with other regulatory authorities.

On 18 May 2021, Swissmedic and Germany's Federal Office of Consumer Protection and Food Safety (BVL) signed their first joint memorandum of understanding on veterinary medicinal products. Swissmedic attaches a lot of importance to cooperation with BVL, particularly in the context of the new regulations on veterinary medicinal products that are about to come into force.

In February 2021, Swissmedic and the Swiss Agency for Development and Cooperation (SDC) held a joint virtual event on the Marketing Authorisation for Global Health Products (MAGHP) procedure. The aim of this event was to present the procedure and its advantages

in terms of capacity building and fast-track access to therapeutic products in the countries in question. Over 160 representatives of the pharmaceutical industry and regulatory authorities took part, as did a number of interested parties from across the world.

Swissmedic held two regulatory training sessions for regulatory authorities during 2021, attracting 73 participants from 16 countries, and also organised a training course for senior assessors, which was attended by 28 participants from various regions of Africa.

International collaboration on medical devices

Up until the Federal Council's decision to break off negotiations with the European Union (EU) on the institutional framework agreement (InstA) on 26 May 2021 – the day the new Medical Devices Regulation came into force – Swissmedic was fully integrated into inter-authority cooperation in the EU. This was particularly the case in the CAMD (Competent Authorities for Medical Devices) and MDCG (Medical Device Coordination Group) organisations set up by the European Commission. In addition, Swissmedic contributed to preparations for implementation of the new EU Regulations in 13 working groups. It was then excluded from all the above groups.

Since March 2021, Swissmedic has been an invited observer in the semi-annual Management Committee Meetings of the International Medical Device Regulators Forum (IMDRF) and has applied to join some of this global organisation's working groups.

MEDICINAL PRODUCTS – **STANDARDS PRODUCT GROUP**

Legal Framework product

Technical Standards product

Clinical Trials Ordinance

In December 2019, the Federal Council gave instructions for a partial revision of the ordinances associated with the Human Research Act (HRA). Work subsequently started on revising the Ordinance on Clinical Trials with Medicinal Products. However, the coronavirus pandemic imposed other priorities, and work had to be suspended in 2021. It is scheduled to resume in spring 2022.

Cannabis control

On 19 March 2021, parliament approved the revised Narcotics Act, which lifted the total ban on the use of cannabis for medical purposes. Implementing this revised act will involve modifying the Narcotics Control Ordinance and Narcotics Lists Ordinance. The amendments will regulate the approval procedure for cultivating cannabis for medical purposes and pharmaceutical production as well as the reclassification of cannabis and cannabis preparations. Consultation on the proposed amendments ended on 24 November 2021. Revision work should be completed during 2022.

New ordinance for devitalised cells and tissue

Switzerland's requirements governing the use of devitalised human tissue or cells have been inadequate for many years and lag behind international developments. The dispatch on the amendment of the Therapeutic Products Act held out the prospect of authorisation for products containing devitalised human tissue or cells that cannot be qualified as medical devices. The relevant requirements will be set out in a new ordinance. During the year, Swissmedic contributed to the ongoing work on the draft ordinance under the lead of the Federal Office of Public Health. A consolidated version should be available for the first office consultation in 2022.

Revision of veterinary medicinal products legislation

The vast majority of Switzerland's veterinary medicinal products are sourced from the EU's veterinary pharmaceuticals industry. To prevent trade barriers, framework conditions for veterinary medicinal products have to be the same in Switzerland as they are in the EU. For this reason, Swiss veterinary medicinal products legislation was updated at the same time as its EU counterpart and harmonised with it.

The revised veterinary medicinal products legislation came into force on 28 January 2022 and contains provisions at Federal Council and Swissmedic levels. The changes concern the Veterinary Medicinal Products Ordinance, the Therapeutic Products Ordinance, the Medicinal Products Licensing Ordinance and the Therapeutic Products Licensing Requirements Ordinance. They primarily involve modifications to Good Manufacturing and Distribution Practice, the new system for submitting applications for variations and pharmacovigilance. The amended ordinances created a framework that saves pharmaceutical companies additional work when obtaining authorisation for veterinary medicinal products in Switzerland.

Revision of the Supervisory Levies Ordinance

At the Agency Council's request, the Federal Council agreed to reduce the levy rate from 0.8 to 0.65 percent in the light of the income generated since 2019 and the reserves in hand. The revised Supervisory Levies Ordinance entered into force on 1 January 2022.

Pharmacopoeia

The pharmacopoeia that is valid in Switzerland consists of the European Pharmacopoeia (Pharmacopoea

Europea, Ph. Eur.) and the Swiss Pharmacopoeia (Pharmacopoea Helvetica, Ph. Helv.). It contains legally binding quality requirements for common, known medicinal products and pharmaceutical excipients, as well as for certain medical devices. The requirements reflect the current state of science and technology and are legally binding. By setting out quality standards for vaccines, the Pharmacopoeia also makes an important contribution to the development of flawless COVID-19 vaccines.

Swissmedic participates in the drafting of the Ph. Eur. under the terms of a treaty, and issues the Ph. Helv. containing supplementary requirements of national importance.

Three supplements to the 10th edition of Ph. Eur. came into effect during 2021. In addition, various monographs on the sartans had to be updated as a matter of urgency. The amendment guarantees that medicinal products are not contaminated with carcinogenic nitrosamines wherever possible.

The editorial conference for the German edition of the Ph. Eur. celebrated its 50th anniversary and 300th meeting in 2021. The conference comprises representatives from Switzerland, Austria and Germany who make a contribution to medicinal product safety in German-speaking countries by translating the Ph. Eur.

The monographs and general chapters of the Ph. Helv. are being constantly updated as part of the process of ensuring that the publication always reflects the latest scientific findings. The existing revision programmes were continued, and the revised requirements will be incorporated into the next issue.

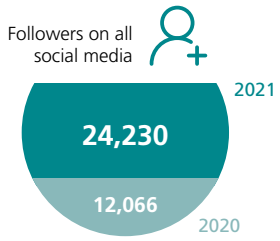
MEDICINAL PRODUCTS – **INFORMATION PRODUCT GROUP**

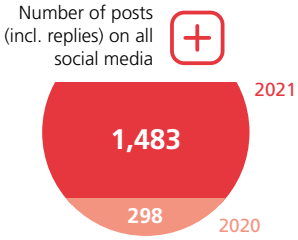
Informing the General Public product

Informing the Therapeutic Products Sector product

Informing the general public

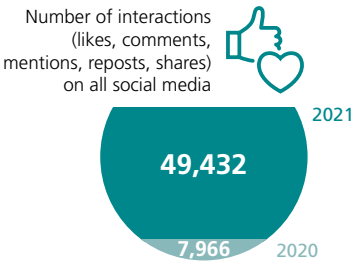
Informing the general public is part of Swissmedic's legal mandate under Art. 67 of the Therapeutic Products Act. It uses various media and channels to provide the public with balanced, objective and audience-appropriate information and to build confidence in the Agency. In addition to its website and various newsletters, these include "Visible", a biannual magazine that appears in printed form and as an online version with added video content. During 2021 the magazine looked at pharmacovigilance, the simplified authorisation of complementary and herbal medicinal products and mRNA COVID vaccines.





Social media

Swissmedic constantly expanded its LinkedIn, Facebook and Twitter presence during 2021, gaining extra attention and visibility on social networks not least because of the pandemic. With the aid of eye-catching content and active, rapid and transparent community management, the agency was able to double follower numbers. As of the end of 2021, Swissmedic had just under 24,000 followers across all the social media it uses.

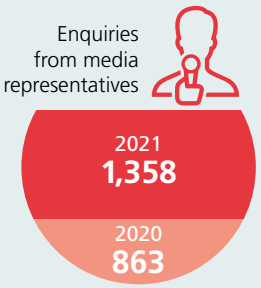


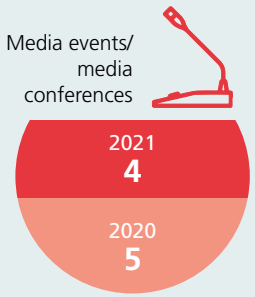
Press relations

Media representatives' interest remained consistently high throughout 2021. Swissmedic representatives commented on various matters in articles and interviews.

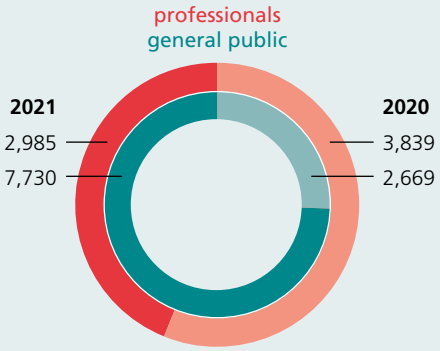
At the start of the year, the authorisation of a second mRNA vaccine made headlines in Switzerland, while the latter half of 2021 was dominated by questions on applications submitted for boosters, extending the indication of COVID-19 vaccines to children and safety signals.

Media relations





Enquiries about medicinal products



Enquiries

Each year, laypeople, medical professionals, other specialists and stakeholders approach Swissmedic with their questions. More than 10,000 questions were answered during 2021, relating in particular to the constituents of COVID vaccines, the timing of their approval and their side effects. Enquiries rose by more than 60 percent compared to 2020.

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.

Requests to access official documents connected with COVID-19 vaccines increased during 2021, more than doubling compared to 2020. On average, it takes Swissmedic about 20 hours to process an FoIA request. Access was completely refused in three cases. No appeals are currently pending before the Federal Administrative Court or Federal Supreme Court regarding access to official documents connected with medicinal products.

Parliamentary proposals and expert evidence to parliamentary committees

Swissmedic acted as lead agency on five parliamentary proposals, the majority of which were connected with the coronavirus pandemic. Specifically they concerned market surveillance, particularly adverse reactions to COVID vaccines, and the authorisation procedures used by Swissmedic.

A Swissmedic representative was involved in committee work connected with the amendment of the Federal Act on Health Insurance.

Publications and events for professionals

The most important information channels for professionals are the Swissmedic website (www.swissmedic.ch), various newsletters, "Visible" (the Swissmedic magazine) and information events. These have been an important part of information dissemination and dialogue for many years.

Swissmedic held two online events in 2021. The first, in February, was organised jointly with the Swiss Agency for Development and Cooperation (SDC) and dealt with international cooperation in the context of the MAGHP (Marketing Authorisation for Global Health Products) project. It attracted around 100 participants. The second, in June, was for pharmacopoeia experts and was attended by about 80 people.

2020 2021

Requests under FoIA

Time requirement (in hours) for processing requests

2020 2021

Parliamentary proposals on medicinal products

Other political business items in which Swissmedic was involved

MEDICINAL PRODUCTS – **MARKET ACCESS PRODUCT GROUP**

Authorisation product

Overview

12,056 authorisation applications and applications for a variation comprising 21,313 individual applications were completed in 2021. The 2,953 multiple applications that were submitted contained between two and 80 individual applications. Compared with 2020, applications rose by just under 3 percent, while individual applications increased by 25 percent. 97 percent of all completed applications were processed within the prescribed time limits. The target values for first authorisations and major variations were not achieved; however, compliance with time limits still exceeded 90 percent. Stakeholders were not affected by the delays, which primarily involved major variations. All applications connected with COVID-19 vaccines and therapeutic agents were fast-tracked and processed within the time limits. 79 (previous year: 80) company meetings were held before or during the authorisation process.

Applications received	**2021**	**2020**
First authorisations of innovative medicinal products	120	115
First authorisations of non-innovative medicinal products	239	193
Extensions	37	37
Major variations	2,401	2,942
Minor variations	6,739	6,568
Other applications	2,405	2,774

Applications completed	**2021**	**2020**
First authorisations of innovative medicinal products	127	131
First authorisations of non-innovative medicinal products	187	184
Extensions	46	27
Major variations	2,591	2,097
Minor variations	6,658	6,559
Other applications	2,447	2,739

Deadline compliance	**Result**	**Target**
First authorisations of innovative medicinal products	95%	97%
First authorisations of non-innovative medicinal products	93%	97%
Extensions	99%	97%
Major variations	91%	97%
Minor variations	99%	95%
Other applications	97%	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 2021, six of which it approved. Companies submitting applications for medicinal products to prevent or treat COVID-19 were not required to submit an FTP request since their applications were fast-tracked as a matter of priority. All applications assessed under the fast-track procedure were completed on time.

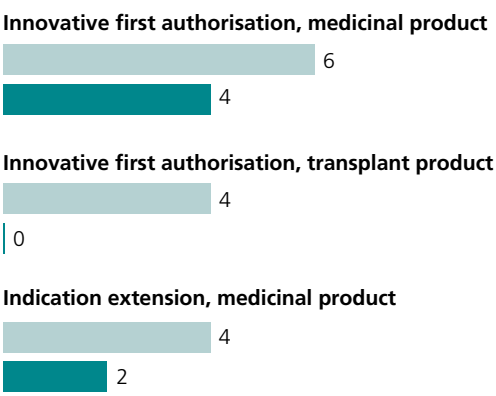
Procedure with prior notification

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:
17 applications for a PPN were submitted during 2021. Of these, four were withdrawn and one was rejected. All applications assessed under a PPN were completed on deadline.

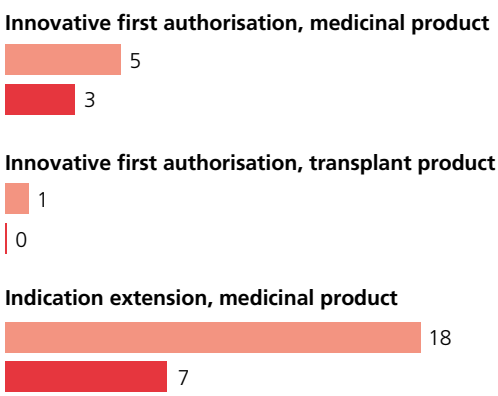
Number of assessments under fast-track procedures

2020 2021



Number of assessments under a PPN

2020 2021



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 for temporary authorisation is submitted only has to be provided once the official decision has been issued. Swissmedic assesses the data after the decision has been issued, and if its verdict is positive, the temporary authorisation can be turned into a regular authorisation. Swissmedic can issue temporary authorisations at applicants' request or ex officio.

Activities:
Six of the seven applications for temporary authorisation received in 2021 were approved. A total of 12 (previous year: eight) temporary authorisations were completed. These included five applications for unlimited authorisation for which Swissmedic issued temporary authorisation ex officio.

Authorisation under Article 13 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 190 applications under Article 13 of the Therapeutic Products Act were processed and completed in 2021, an increase of 45 percent on the previous year. The majority of applications concerned variations (71), known active substances without innovation (64) and known active substances with innovation (15).

Authorisation under Article 14 Therapeutic Products Act

Since 2019, it has been possible to request simplified authorisation of new and known active substances that have already been authorised for many years or with which practical experience has been acquired over a period of many years (Art. 14 para. 1 let. a$^{bis\text{-}quater}$ Therapeutic Products Act).

Activities:
22 applications (previous year: 14) were processed and approved under Article 14 of the Therapeutic Products Act. 19 applications concerned human medicinal products, three veterinary medicinal products.

Time limits and international benchmarking

The lead time (companies' time and Swissmedic's time) for new active substances has been reduced by around 25 percent since 2019. The median figure for authorised human medicinal products in 2021 was 396 days (2019: 522 days; 2020: 471 days).

Participation in Project Orbis, under which medicinal products are reviewed in parallel with the US FDA and other regulatory authorities, has significantly reduced processing time. In 2021, a total of 15 applications were submitted under the project, and 13 reviews were completed. The median time for the five new active substances was 285 days. One positive effect of participation in Project Orbis is the reduction in submission gaps (timing of submissions to the different authorities). In the last two years, the gap compared with the FDA and the other regulatory authorities has been only 31.5 days.

Five medicinal products with new active substances were approved by work sharing in the Access Consortium in 2021. The addition of the MHRA, the British regulatory authority, to Access has increased the Consortium's authorisation procedure stakeholder appeal.

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.

Completed applications under Art. 13 TPA

2020 **2021**

Human medicinal products

116

173

Transplant products

1

2

Veterinary medicinal products

14

15

Number of new applications completed

2020 **2021**

Innovative

86

112

Extensions

27

46

Non-innovative

102

135

Number of completed type II variations

2020 **2021**

Additional indications

76

89

Change in recommended dosage

19

34

All other type II variations

1,793

2,178

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 new innovative active substances and authorisation extensions and for non-innovative first authorisations rose by 30 percent year-on-year.

During 2021, 3,158 applications for new innovative active substances and authorisation extensions and 135 applications for non-innovative first authorisations were completed, 27 of which were for co-marketing products.

A total of 45 (previous year: 42) medicinal products with new active substances were authorised for the first time.

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 indication extensions, substantial changes in active substance or finished product manufacturing processes or changes in recommended dosage.

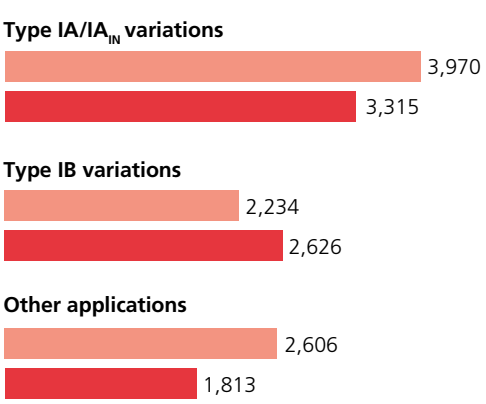
Activities:
Type II variations increased by some 20 percent. A total of 2,301 (previous year: 1,888) variations were completed.

Minor variations and other applications

Any variation to an authorised medicinal product requires approval by Swissmedic. A distinction is made between type IA/IA$_{IN}$ minor variations, which can be reported after the fact, and type IB variations, which have to be notified prior to implementation.
Of the remaining applications, around 70 percent were for authorisation renewals, quality conditions or discontinuation of authorisation.

Activities:
In total, 7,754 (previous year: 8,810) applications in these categories were completed in 2021.

Figures exclude applications submitted under the old legislation
collective applications are counted as one application



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 stricter 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:
Twelve (previous year: three) authorisation applications for products with new active substances were completed during 2021. Three applications were reviewed under the fast-track authorisation procedure, one under the procedure with prior notification.

In addition, 108 applications for a quality variation requiring approval and 22 applications for a variation in clinical documents (Information for healthcare professionals/Patient information, indication extension and new dosage recommendation) were completed.

Finally, Swissmedic assessed documentation that had been submitted on quality conditions (7) and clinical conditions (7) as well as 15 Periodic Safety Update Reports.

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 by an agency with comparable medicinal product control (particularly EMA or FDA). Orphan drugs can be authorised either while the recognition process is in progress or once the status has been recognised (usual case).

Activities:
Orphan drug status was recognised in 42 out of 43 cases. This status was discontinued for three products. 22 innovative new active substances were authorised as orphan drugs, while an additional orphan indication was approved for one existing drug.

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:
Nine (previous year: 12) new authorisation applications for biosimilars were completed. All 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:
A total of 24 (previous year: 19) paediatric trials were authorised in 2021.

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:
Having authorised a first mRNA vaccine in December 2020, Swissmedic authorised a second one in mid-January 2021. The first vector-based vaccine was authorised in March 2021. Applications for one mRNA and one vector vaccine were withdrawn by the submitting companies during the review process. Swissmedic reviewed all applications for COVID-19 vaccines under the rolling procedure.

In the second half of the year, Swissmedic assessed applications for authorisation and indication extensions for the COVID-19 vaccines (new dosage recommendations, boosters and use in children and adolescents).

The Agency also processed 74 applications for quality variations for the COVID-19 vaccines (e.g. for shelf life). Each of these applications was reviewed within a few days.

Four non-COVID-19 vaccines (three against influenza and one against shingles) and three indication extensions were processed and approved.

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:
Nine applications for the authorisation of production of non-standardisable medicinal products (Art. 9 para. 2 let. e Therapeutic Products Act) were submitted and reviewed. Applications for variations were also processed, including applications for blood pathogen inactivation processes.

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.

In total, 59 (previous year: 360) applications for complementary medicinal products were completed in 2021.

There was a dramatic fall in applications for authorisation of single products without an indication under the notification procedure (23 compared with 260 in 2020). 13 (previous year: 11) complementary medicinal products were authorised with an indication.

Complementary medicinal products

Complementary medicinal products comprise homeopathic, anthroposophic and Asian (Chinese, Tibetan or Ayurvedic) 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:
Since 1 October 2021, it has been possible to authorise Chinese medicinal products without an indication under the 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:
Six (previous year: ten) applications were completed under the simplified authorisation procedure, including four co-marketing medicinal products.

Complementary medicinal products

2020 2021

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

11
13

Complementary medicinal products without indication under simplified procedure incl. reduced dossier

21
6

Complementary medicinal products without indication under notification procedure (single products)

260
23

Complementary medicinal products without indication under notification procedure (combined products)

41
17

Veterinary medicinal products

New authorisations and extensions

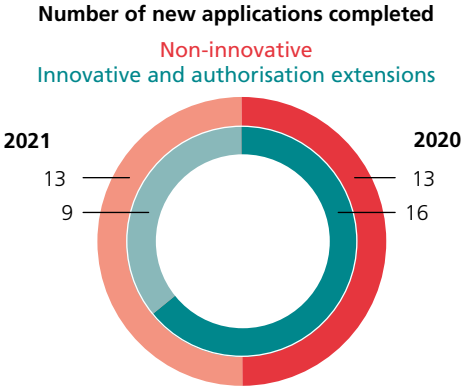
New authorisation of veterinary medicinal products is granted following a comprehensive review of the safety, efficacy and quality documentation submitted by the applicant. The authorisation procedure distinguishes between innovative medicinal products (medicinal products with new active substances or 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:
22 (previous year: 29) new applications and applications for extensions were completed in 2021. All of these applications were processed within the prescribed time limits.

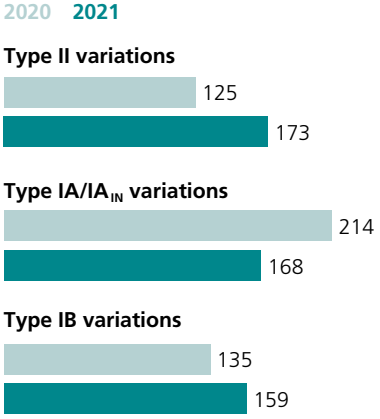
Major and minor variations

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

Number of new applications completed



Figures exclude applications submitted under the old legislation
Collective applications are counted as one application



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:
Three (previous year: five) official decisions connected with product authorisation were contested in 2021. 14 cases are still pending before the Federal Administrative Court, while five appeals are pending before the Federal Supreme Court.

Medicinal products: facts and figures

Number of authorisations by type of product

Number of authorised medicinal products	2021	2020
Human medicinal products	**5,756**	**5,745**
Synthetics	4,827	4,828
Biotechnologicals	401	382
Vaccines	60	63
Blood products	63	64
Radiopharmaceuticals	53	53
Allergen products	292	291
Bacterial and yeast products	22	23
Antidotes / antivenins	41	41
Transplant products	**14**	**9**
Complementary and herbal medicines	**12,348**	**12,428**
Phytopharmaceuticals	434	460
Homeopathics	617	620
Anthroposophics	368	383
Ayurvedic medicinal products	1	1
Tibetan medicinal products	7	8
Other alternative treatments	5	1
Homeopathics, anthroposophics and medicinal products for gemmo-therapy without indication	10,870	10,908
Lozenges	46	47
Veterinary medicinal products	**693**	**710**

Number of authorisations by dispensing category

Number of authorised medicinal products

2020 **2021**

Single dispensing on medical/veterinary prescription (A)

1,688
1,709

Dispensed on medical/veterinary prescription (B)

3,943
3,950

Dispensed after expert advice (D)

2,119
2,049

Dispensed without expert advice (E)

202
191

45 (previous year: 53) 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		
Givlaari	Givosiran	Acute hepatic porphyria
Lokelma	Sodium zirconium cyclosilicate	Hyperkalaemia
Leqvio	Inclisiran	Hypercholesterolaemia, mixed dyslipidaemia
Nexviadyme	Avalglucosidase alfa	Pompe disease
Oxlumo	Lumasiran	Primary hyperoxaluria
Haematology and haemostaseology		
Doptelet	Avatrombopag	Thrombocytopenia, chronic immune thrombocytopenia
Heparin Sintetica	Porcine heparin sodium	Thromboembolic disease
Cardiology and nephrology		
Kerendia	Finerenone	Chronic kidney disease with type 2 diabetes mellitus
Nicardipin Labatec	Nicardipine hydrochloride	Acute hypertension
Verquvo	Vericiguat	Chronic heart failure
Dermatology and allergology		
Palforzia	Peanut (Arachis hypogaea) allergen powder	Peanut allergy
Infectiology and vaccines		
COVID-19 Vaccine Janssen	Human adenovirus Ad26.COV2-S [recombinant]	COVID-19 disease (vaccine)
Efluelda	Influenza A (H3N2, H1N1) and B (Victoria, Yamagata) haemagglutinin	Influenza (vaccine)
Ervebo	Live rVSVΔG-ZEBOV-GP	Ebola (vaccine)
Ronapreve	Casirivimab / imdevimab	COVID-19 disease
Rukobia	Fostemsavir	HIV-1 infection
Shingrix	Varicella zoster virus glycoprotein E antigen	Herpes zoster (vaccine)
Spikevax	CX-024414: 5'-capped messenger RNA (mRNA) encoding the pre-fusion stabilised spike (S) glycoprotein of novel coronavirus 2019 (SARS-CoV-2) that is encapsulated in a lipid nanoparticle	COVID-19 disease (vaccine)
Supemtek	Influenza A (H1N1, H3N2) and B (Yamagata, Victori) haemagglutinin	Influenza (vaccine)
Vaborem	Meropenem / vaborbactam	Complicated urinary tract infections, complicated intra-abdominal infections, hospital-acquired pneumonia
Vocabria	Cabotegravir	HIV-1 infection

Medicinal product	Active substance	Indication
Oncology and haematological malignancies		
Abecma	Idecabtagene vicleucel	Multiple myeloma
Alunbrig	Brigatinib	Non-small-cell lung cancer
Calquence	Acalabrutinib	Chronic lymphatic leukaemia
Clofara	Clofarabine	Acute lymphatic leukaemia
Enhertu	Trastuzumab deruxtecan	Breast cancer
Gavreto	Pralsetinib	Non-small-cell lung cancer, thyroid cancer
Inrebic	Fedratinib	Myelofibrosis
Lumykras	Sotorasib	Non-small-cell lung cancer
Padcev	Enfortumab vedotin	Urothelial cancer
Pemazyre	Pemigatinib	Cholangiocarcinoma
Polivy	Polatuzumab vedotin	Diffuse large B-cell lymphoma
Poteligeo	Mogamulizumab	Mycosis fungoides, Sézary syndrome
Qinlock	Ripretinib	Gastrointestinal stromal tumours
Retsevmo	Selpercatinib	Non-small-cell lung cancer, thyroid cancer
Tabrecta	Capmatinib	Non-small-cell lung cancer
Tecartus	Autologous anti-CD19-transduced CD3+ cells	Mantle cell lymphoma
Tepmetko	Tepotinib	Non-small-cell lung cancer
Trodelvy	Sacituzumab govitecan	Breast cancer
Neurology and psychiatry		
Epidyolex	Cannabidiol	Seizures associated with Lennox-Gastaut syndrome or Dravet syndrome
Evrysdi	Risdiplam	Spinal muscular atrophy
Ponvory	Ponesimod	Multiple sclerosis
Tegsedi	Inotersen	Polyneuropathy with hereditary transthyretin amyloidosis
Vyepti	Eptinezumab	Migraine
Zolgensma	Onasemnogene abeparvovec	Spinal muscular atrophy

First authorisations of veterinary medicinal products with a new active substance

Medicinal product	Active substance	Indication
Anti-protozoal agent		
Parofor Crypto 140 mg/ml ad us. vet.	Paromomycin	To treat Cryptosporidium parvum in calves

Licensing product

Overview

Number of authorisations	**2021**	**2020**
Establishment licences TPA / Epidemics Act	1,252	1,099
Licences for handling controlled substances	383	376
Licences for new clinical trials	179	202
Import licences for vaccines and blood products	1,227	1,085
Import / export permits for controlled substances	6,055	6,459
Special licences	432	482

Number of inspections	**2021**	**2020**
GLP inspections	11	7
GCP inspections	13	9
GVP inspections	7	9
GMP / GDP inspections	564	472
Microbiological laboratory inspections	32	23
Autologous cell and tissue inspections	6	8
Inspections for third parties	13	22

Time limits	**Result**	**Target**
Establishment licences TPA / Epidemics Act	100%	97%
Licences for handling controlled substances	100%	95%
Licences for new clinical trials	100%	95%
Import licences for vaccines and blood products	100%	97%
Import / export permits for controlled substances	92%	95%
Special licences	96%	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 are required by the Federal Act on Combating Communicable Human Diseases (Epidemics Act) to obtain an establishment licence from Swissmedic. This requirement applies to microbiological laboratories that carry out diagnostic and epidemiological tests (patient diagnosis), tests to rule out a disease transmitted by blood, blood products or transplants (screening) or tests on environmental samples (environmental analytics).

Establishment licences for medicinal and transplant products

Activities:
746 (previous year: 729) establishment licences were issued, extended, modified or revoked during 2021.

The format of licences was changed following the entry into force of the revised Therapeutic Products Act in early 2019. Licences are now also valid for an indefinite period. 85 percent of licence-holding companies now have a licence issued under the new legislation. They are registered in the EudraGMDP database operated by the European Medicines Agency (EMA) in accordance with Switzerland's agreement with the EU on mutual recognition of conformity assessments.

Establishment licences for microbiological laboratories

Activities:
Swissmedic processed 83 applications from microbiological laboratories for new establishment licences or changes to or renewal of existing licences, almost twice the number it processed in 2020. This rise was attributable to the coronavirus pandemic, which created a massive surge in testing. A large number of new laboratory facilities were set up so that tests could be conducted at places such as airports, schools and factories. Swissmedic was responsible for assuring the quality of the COVID testing services provided by laboratories and for restricting or prohibiting testing activities if any shortcomings were found.

Licences for handling controlled substances

Swissmedic issues establishment licences to companies and individuals that handle controlled substances. The import and export of controlled substances has to be licensed on a case-by-case basis. Swissmedic must be notified of domestic deliveries 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 209 (previous year: 154) applications for new establishment licences or changes to or renewals of existing licences. The annual accounts of 458 company sites were examined for the report to the INCB. The Agency also reviewed the group listing of arylcyclohexylamines and 12 new psychoactive substances, and applied to the Federal Department of Home Affairs for inclusion of the substances in its Ordinance on the Lists of Narcotics, Psychotropic Substances, Precursors and Auxiliary Chemicals.

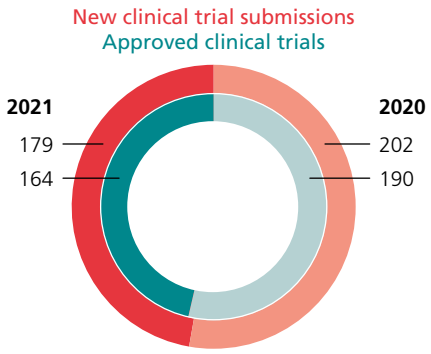
Licences for clinical trials

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 179 applications for new clinical trials of medicinal products during 2021. Of these, it processed 176 and rejected three because they were incomplete.

Clinical trials with medicinal products



A total of 164 clinical trials were approved. Two clinical trials were withdrawn by their sponsors while they were under review. The other applications are currently being processed. The complexity of the application dossiers continued to rise in line with the growth in product complexity.

In addition, Swissmedic processed 2,612 (previous year: 2,432) 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 98 (previous year: 96) reports of suspected unexpected serious adverse reactions (SUSAR).

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

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

Activities:
Swissmedic processed 14 (previous year: 19) applications for clinical trials with transplant products and 63 (previous year: 77) 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 1,227 individual import licences for immunological medicinal products, blood and blood products during 2021, an increase of 13 percent on the previous year.

Special licences

Activities:
Since 2019, and in accordance with the revised Therapeutic Products Act, Swissmedic has only been issuing special licences for the import of veterinary medicinal products. The number of licences issued during 2021 was 432 (previous year: 482).

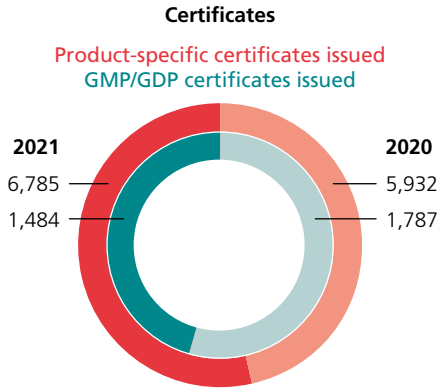
Certificates for medicinal and transplant products

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 EMA. Thus the number of GMP/GDP certificates issued continued to decline during 2021.

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. Inspections focus on compliance with statutory provisions and in particular 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 ten (previous year: six) assessment facilities and one service provider. Swissmedic led seven of these inspections involving first and final inspections. As a result of the pandemic, three inspections were in "hybrid", i.e. only partly on-site, format.

The three GLP units held quarterly meetings for the purpose of sharing information from important OECD and EU international working groups.

GCP and GVP inspections

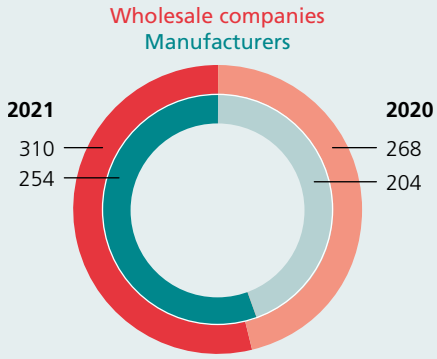
Swissmedic inspects clinical trials carried out in Switzerland by sponsors, contract research organisations, trial locations, facilities and laboratories. The inspections are carried out on a random basis according to defined risk criteria and assess compliance with the rules of Good Clinical Practice (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) are primarily designed to verify compliance with the legally prescribed duty to spontaneously report adverse drug reactions in clinical trials and the implementation of measures associated with urgent drug risks.

Activities:
In view of the pandemic, only a limited number of regular inspections of clinical trials in hospitals were conducted to avoid placing an additional burden on investigators and trial teams.

GCP and GVP inspections were carried out using the remote procedure and by videoconference. Swissmedic established a desk-based inspection process. In the course of these inspections, companies were asked to submit specific documents, which were then inspected for legal compliance.

In the year under review, Swissmedic inspected a total of 13 (previous year: eight) clinical trials. In addition, it conducted seven GVP inspections.

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



The 79 GMP/GDP inspections conducted by Swissmedic covered the following areas:

- **44%** Pharmaceuticals
- **40%** Transplant products
- **14%** Blood transfusion services
- **2%** For-cause inspections

Number of inspections by foreign authorities in Switzerland (majority by distant assessment)

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:
Despite the continuing pandemic-related restrictions, inspections continued throughout the year. This was particularly important given the necessity of safeguarding the quality of COVID vaccine manufacturing and distribution. Swissmedic carried out a total of 564 (previous year: 472) GMP / GDP inspections of manufacturers and wholesale companies.

Once again, there was a sharp increase (+55%) in reports of major changes to installations, facilities and procedures that impacted GMP / GDP.

In view of pandemic-related restrictions, Swissmedic did not take part in 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:
Swissmedic's checks and inspections during 2021 focused primarily on testing activities associated with COVID testing. A total of 32 inspections were conducted in addition to a large number of investigations and checks of testing activities.

Inspections for third parties

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

Activities:
In the year under review, 12 inspections were carried out for the FOPH and one for the Principality of Liechtenstein.

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:
Once again, the number of inspections of pharmaceutical companies in Switzerland conducted by foreign authorities declined year-on-year owing to worldwide travel restrictions. Only 15 of the 21 scheduled inspections took place (USA: 1, Mexico 1: Russia: 13, 11 of which were distant assessments). Inspection report sharing increased, with Swiss inspectorates supplying 11 inspection reports to foreign authorities.

Swissmedic accompanied one GCP inspection by the EMA 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:
The effects of the pandemic dominated activities associated with blood transfusion service monitoring during 2021, specifically donor criteria in connection with vaccination status and the options presented by the therapeutic use of convalescent plasma in COVID-19 patients.

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 2021, Swissmedic had been notified of 22 institutions that work with cells and tissues for autologous transplantation. Two new institutions commenced relevant activities during the year.

Swissmedic conducted six inspections, some by distant assessment. 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 electronic submission of batch release applications via the Swissmedic Portal introduced in 2019 is now established and being used by applicants. Since July 2021, it has also been possible to submit information on plasma centres via the Portal for transfer to the laboratory database.

There was a slight year-on-year fall in the number of batch releases. This continues to be due to the COVID-related global plasma shortage, which resulted in reduced production and a smaller number of submissions to the OMCL.

Following the authorisation of COVID-19 vaccines, a total of 67 batches were notified for Switzerland in 2021, the batches in question having been released on the basis of an EU certificate.

Other OMCL activities

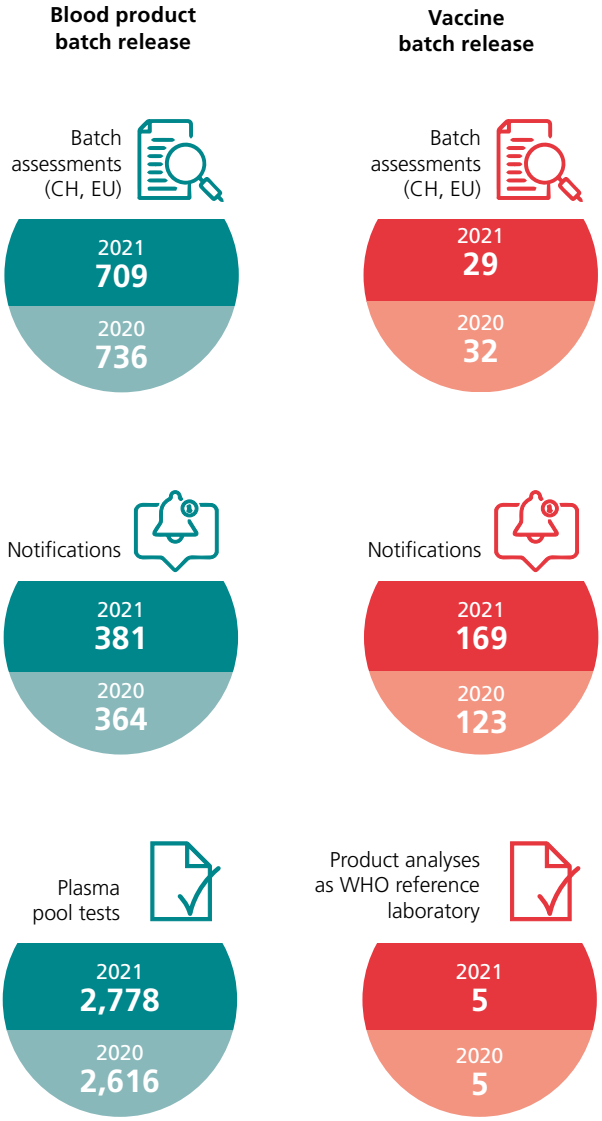
The OMCL supports all areas of Swissmedic by carrying out laboratory tests and developing and verifying test methods.

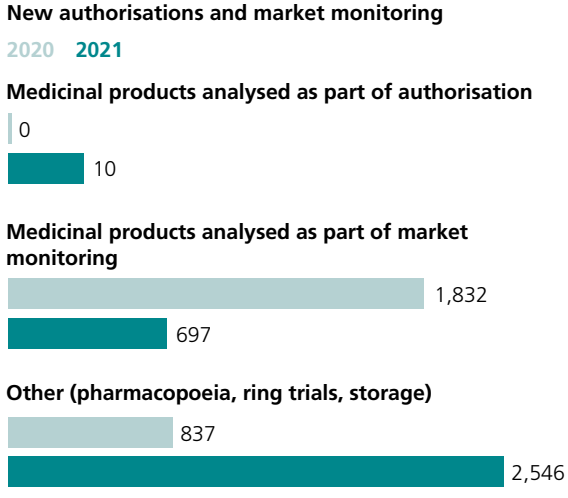
Activities:
Throughout the year, the OMCL tested nitrosamines that had been detected in further active pharmaceutical substances of various products worldwide. As a result, various product batches were recalled.

The OMCL also investigated a large number of products that had been imported illegally and forwarded the results of its tests to Market Surveillance.

Appeals procedure

Activities:
No official decision issued in connection with licences was contested. One case is still pending before the Federal Administrative Court, while two appeals are pending before the Federal Supreme Court.





Establishment licences in facts and figures

Manufacturing of medicinal products (under the old legislation)	**2021**	**2020**
Manufacturing of medicinal products (with a licence for distribution)	29	75
Manufacturing of medicinal products (without a licence for distribution)	24	41
Institutions with a Swissmedic licence for handling blood or labile blood products (blood transfusion activities)	12	19

Distribution of medicinal products (under the old legislation)	**2021**	**2020**
Import of medicinal products	69	159
Wholesale trading in medicinal products	136	288
Export of medicinal products	58	137
Trading in medicinal products abroad	46	106

Manufacturing of medicinal and transplant products (under the new legislation)	**2021**	**2020**
Manufacture of ready-to-use medicinal products and transplant products	361	283
Manufacture of active pharmaceutical ingredients	161	118
Handling of blood or labile blood products (blood transfusion activities)	59	35

Distribution of medicinal and transplant products (under the new legislation)	**2021**	**2020**
Import of medicinal products and transplant products	608	486
Wholesale trading in medicinal products and transplant products	879	698
Export of medicinal products and transplant products	479	393
Trading in medicinal products abroad and transplant products abroad	348	290
Brokerage or agency activities for medicinal products and transplant products	9	6

Microbiological laboratories	**2021**	**2020**
With a Swissmedic licence issued under the old procedure (1 January 2016 to 31 December 2018; activities A, B and/or C)	23	52
With a Swissmedic licence issued under the new procedure (from 1 January 2019; activities SE 1, SE 2 and/or SE 3)	101	63

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 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:
The dominant activity in 2021 was monitoring COVID-19 vaccines. The substantial year-on-year increase in reports of suspected ADRs is attributable to the large number of people who have been vaccinated as well as to public awareness of the importance of pharmacovigilance. Reports were submitted by medical professionals, while around half of COVID-19 vaccination-related reports came from the people affected.

The Vigilance One Ultimate database used to process ADR reports from Switzerland was upgraded to perform specialised analyses. The procedure for reporting side effects of COVID-19 vaccinations was simplified during 2021 and systems for processing these reports were optimised.

International collaboration with other countries' authorities and in multinational specialist organisations was stepped up significantly in the light of the COVID-19 vaccination campaign, for example as part of a regular dialogue on safety signals. Swissmedic regularly briefed the public and international partner authorities on reports connected with COVID vaccinations and the findings obtained. By the end of 2021, Swissmedic had published 20 COVID-19 reports.

Haemovigilance

Haemovigilance is the monitoring system employed for blood and 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:
The haemovigilance pages of Swissmedic's website and the reporting forms for transfusion reactions and errors were overhauled and a compilation of legal provisions governing haemovigilance was prepared.

The number of reports rose slightly year-on-year.

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 (218) and cats (85), followed

by cattle (22) and horses (4). Five reports of users experiencing reactions were also submitted.

Tox Info Suisse submitted 104 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 2021.

Swissmedic published a report on the evaluation of reports of ADRs to veterinary medicinal products on its website in October 2021.

International signals and safety reports

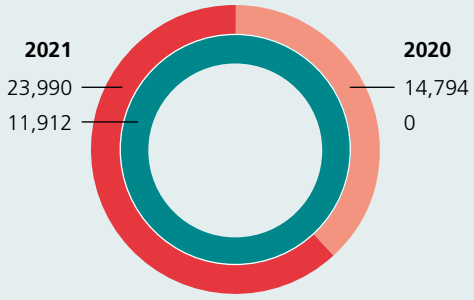
Assessment of pharmacovigilance plans and safety reports

As part of the procedure for authorising new medicinal products, companies must submit for assessment a pharmacovigilance plan (PVP) in accordance with ICH's international guidelines. In the PVP, the authorisation holder must comment on both the known and the potential risks associated with the new 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 2021, Swissmedic assessed 229 PVPs for medicinal products that had been submitted for authorisation plus 474 safety reports for medicinal products that had already been approved (including 147 PVP updates).

Pharmacovigilance

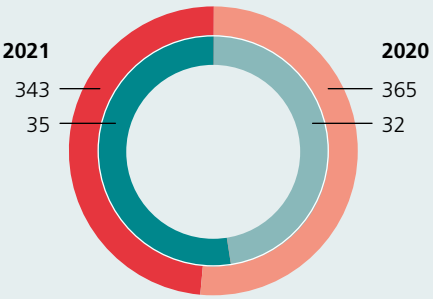
ADR reports incl. follow-up reports
Number of reports involving COVID-19 vaccines



Haemovigilance
Number of reports involving blood products

Vigilance for veterinary medicinal products

Number of ADR reports
Proportion of ADR reports from Tox Info Suisse



Assessment

2020 2021

Number of PVPs

Number of PSURs/PBRERs for human medicinal products

Number of PSURs for veterinary medicinal products

Risk mitigation measures

When new findings concerning the safety of a medicinal product come to light, companies are obliged to apply for a change to its product information. Swissmedic 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 relevant people within the companies. 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 2021. International pharmacovigilance activities during the year focused primarily on COVID-19 vaccines. Nineteen signals associated with COVID vaccines were validated and associated measures taken. 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 37 cases in the form of HPCs and DHPCs.

A total of 304 (previous year: 314) signals were completed.

Market Monitoring product

Quality defects and batch recalls

Swissmedic records reports on quality defects in medicinal products and takes the necessary corrective action. The reports are assessed, prioritised and, where a potentially major health risk is identified, a batch recall is initiated or information is sent to professionals or the public. When reports of quality defects are received from abroad, Swissmedic verifies whether the reports also affect medicinal products authorised in Switzerland.
At the same time, specific annual monitoring focal points are defined and implemented.

Activities:
The number of quality defects reported in 2021 rose dramatically, reaching the new record level of 866. A substantial number of these reports – approximately 80 – concerned COVID-19 vaccines. Investigations showed that the actual or suspected quality issues were attributable to the primary packaging (stoppers or vials) rather than to the vaccines themselves.

21 batches were recalled during 2021. 18 of these were batches of human medicinal products, the remaining three were veterinary medicinal products. Three recalls extended to patient or end-user level. In two cases, opioid analgesics were recalled. Both of these recalls were attributable to the product in question being contaminated with Burkholderia cepacia complex bacteria. B. cepacia group bacteria are a growing problem for medicinal product manufacturers and authorities because they form biofilms, are difficult to eliminate and are resistant to commonly used preservatives.

With synthetics being more closely monitored for genotoxic impurities – particularly nitrosamines – in recent years, there were further recalls during 2021. These involved sartan antihypertensives and a preparation used to help smokers quit.

One recurring cause of recalls is medicinal products getting mixed up with third-party products. One such case in 2021 concerned a Swiss contraceptive, which was found to contain blister packs of a different contraceptive, where the blister packs were printed in Spanish.

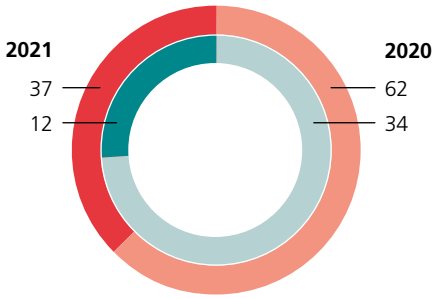
Out-of-stock products

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:
Once again, activities were impacted by the coronavirus pandemic. The number of applications fell compared with 2020 to something approximating the longstanding average. Many applications involved medicinal products for COVID patients. However, the general supply chain restrictions caused by the pandemic also led to shortages of other medicinal products, particularly oncologicals and parenteral nutrition products. Collaboration with the Federal Office for National Economic Supply, which operates a supply shortage reporting platform, resulted in specific improvements in supplies.

Quality defects and batch recalls

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



Measures against illegal medicinal products

2020 **2021**

Proceedings connected with illegal imports
6,733
8,790

Illegal distribution of medicinal products
51
77

Counterfeit medicinal products
111
165

Cases evaluated and forwarded to the responsible cantonal agencies
57
65

Enquiries
35
82

Other (notifications from abroad, theft abroad, etc.)
87
88

Control of advertising

Swissmedic controls and monitors the advertising of medicinal products and is responsible for the risk-based processing of infringements of advertising rules involving authorised medicinal products that are reported to it or which it identifies by screening advertising destined for the public. This includes checking printed, TV and other electronic advertising destined for the public with the specific aim of identifying and banning misleading advertising that could induce people to take excessive quantities of medicinal products or lead them to believe that medicinal products are safer than they are. Swissmedic responds to infringements that jeopardise patient safety by initiating 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 47 (previous year: 24) cases were dealt with as part of post-publication advertising inspection activities during 2021. Administrative proceedings had to be opened in 37 cases for the purpose of restoring legal compliance. 31 cases involved print advertising, while six involved advertising on electronic media, including TV commercials. In the remaining ten cases, Swissmedic found no infringements of advertising rules or was not responsible for enforcement and therefore forwarded the reports to the relevant agency.

Seven applications for advertising permits for laxatives were received.

Measures against illegal medicinal products

Swissmedic sensitises the public to the risks associated with using illegal medicinal products. It maintains dialogue with other authorities and promotes effective national and international networking. Swissmedic receives reports of counterfeit medicinal products, illegal activities and illegal distribution, 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 9,000 packages of illegally imported medicinal products impounded by customs offices were dealt with under the simplified procedure and destroyed. Only around 2 percent of the illegal imports that were seized resulted in ordinary administrative proceedings at the intended recipients' expense.

As the COVID-19 pandemic continued, the highly sought-after vaccines also became the targets of illegal activities. In more than a dozen cases, Swissmedic conducted administrative proceedings against parties who were offering to supply vaccines despite not having a permit to do so and without actually being in possession of the goods in question. These offerings involved advance payments of amounts reaching into the double-digit million range. Measures to prevent illegal trading in potentially counterfeit vaccines were vigorously pursued in the interests of protecting public health.

Appeals procedure

Activities:
During 2021, appeals were submitted to the Federal Administrative Court against four official decisions in connection with the market surveillance of medicinal products. Five cases are currently still pending before the Federal Administrative Court. No cases are still pending before the Federal Supreme Court after one appeal was upheld during 2021.

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.

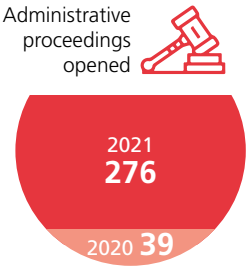
Activities:
Swissmedic received 300 new reports of offences in 2021, three-and-a-half times more than in the previous year. This increase is partly due to the fact that the Federal Customs Administration handed over more than 120 cases to Swissmedic and partly to more notifications of the general public illegally importing medicinal products. Many of these cases were dealt with in a short space of time using the abridged procedure, which is why the number of administrative penalties was 30 percent higher in 2021 than in 2020. At the end of 2021, 189 cases were still pending, of which around half were before the courts.

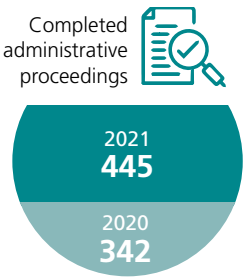
In addition to cases in which medicinal products were illegally imported, the administrative penal proceedings opened and conducted in 2021 concerned the illegal placing on the market or manufacturing of medicinal products, contraventions of advertising regulations and unlicensed trading abroad.

The Medicrime Convention celebrated its tenth anniversary on 21 October 2021. Switzerland was originally involved in drafting the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health and was subsequently one of the first countries to sign it. To date, 18 countries worldwide have implemented the Medicrime Convention and a further 18 have signed it. In mid-2021, the Committee of the Parties launched the monitoring process aimed at reviewing real-world implementation of the Convention. This process is likely to continue until mid-2023.

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 Administration and engages in dialogue on specific cases. Once again, various information events were held during 2021, including the Swiss Medicrime meeting on enforcement activities against illegal therapeutic products focusing on the COVID-19 pandemic.

Swissmedic was involved in several criminal cases during the year as a private claimant.





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 five house searches and 24 hearings, all of which were conducted in compliance with COVID-19 protection strategies. The number of cases unified with cantonal prosecution authorities rose to 40. Two of these cases were handled by Swissmedic.

Two appeals were lodged against Swissmedic. One concerned coercive measures the Agency had imposed, the second other investigative measures. In one case, the accused party withdrew its appeal, the second was dismissed.

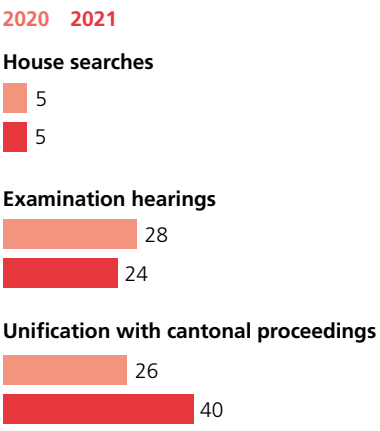
As part of international cooperation on criminal matters, Swissmedic requested legal assistance from foreign countries in ten cases. In turn, Swissmedic dealt with six requests for legal assistance from abroad: two from neighbouring countries and four from Eastern Europe.

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:
248 penalty decisions were issued during 2021, 180 of which were issued under the abridged procedure. The majority of these involved private individuals who had illegally imported medicinal products.

Proceedings were abandoned in eight cases, while three were tried before the cantonal courts. In one case, a private individual who had illegally imported a medicinal product requested a judicial assessment and subsequently received a final sentence from the cantonal criminal court. Two cases involved a medicinal products wholesaler who was accused of illegally importing medicinal products and failing to exercise their duty of care. Although Swissmedic prevailed on the question of guilt, the cantonal criminal court rejected its damages claim. The verdict is not yet legally enforceable.



MEDICAL DEVICES – **STANDARDS PRODUCT GROUP**

Legal Framework product

Technical Standards product

Medical Devices Regulation

The Swiss legal framework governing medical devices was updated to implement the safety and efficacy requirements enacted in the EU by the new, stricter Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR). The revised Medical Devices Ordinance (MedDO) and the new Ordinance on Clinical Trials with Medical Devices (CTO-MedD) came into force on 26 May 2021. Both Ordinances contain provisions equivalent to those in MDR. In addition, provisions were added to cushion the impact of the failure to update the Mutual Recognition Agreement between Switzerland and the EU (MRA, chapter 4, part of the Bilaterals I package of agreements) and to compensate for the loss of information exchange and enforcement cooperation with the EU.

At the same time, work continued on an In vitro Diagnostic Medical Devices Ordinance (IvDO) that will align Swiss legislation with IVDR. The Ordinance is scheduled to come into force on 26 May 2022.

MEDICAL DEVICES – **INFORMATION PRODUCT GROUP**

Informing the General Public product

Informing the Therapeutic Products Sector product

Informing the general public

Swissmedic provides information on various channels (website, newsletters, LinkedIn, Facebook, Twitter and its "Visible" magazine). During 2021, the subjects covered by "Visible" included the review process for clinical trials with medical devices and Swissmedic's new responsibilities in connection with combination products. An interview provided background information on the new medical devices regulation.

Press relations

Over 150 – around one eighth – of all media enquiries received by Swissmedic during 2021 involved medical devices. Questions were primarily about the legal framework for COVID-19 testing and the full revision of the Medical Devices Ordinance against the background of the failure to update the Mutual Recognition Agreement (MRA) with the EU.

Enquiries

Swissmedic answered around 4,000 enquiries about medical devices. The questions from laypeople and professionals were primarily about face masks and COVID-19 tests as well as implementation of the new medical devices regulation.

Transparency / FoIA

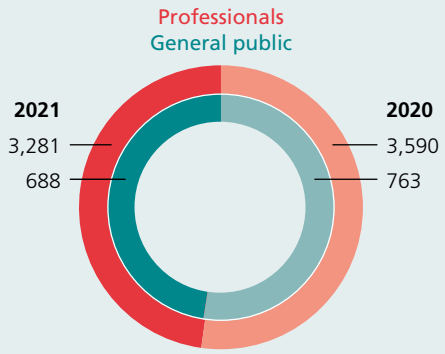
Fourteen requests to inspect official documents associated with medical devices were received during 2021. The average workload associated with processing one FoIA application was 33 hours.

No appeals are currently pending before the Federal Administrative or Federal Supreme Court regarding access to official documents connected with medical devices.

Parliamentary proposals

The number of parliamentary proposals concerning medical devices doubled year-on-year. The proposals dealt with medical face masks, COVID-19 tests and the situation facing medical devices following the termination of negotiations on the framework agreement between Switzerland and the EU. In particular,

Enquiries



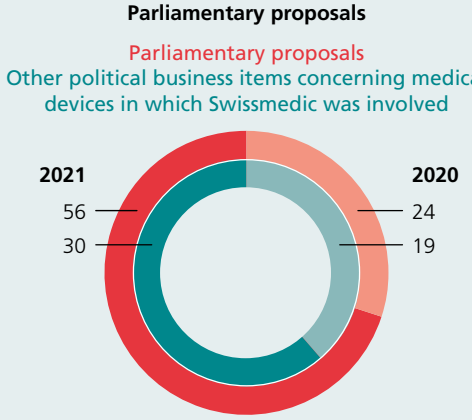
Transparency/FoIA

2020 **2021**

Requests under FoIA

Time requirement (in hours) for processing requests

Parliamentary proposals



supply shortages and the situation of Switzerland's medical devices industry were addressed. Swissmedic acted as lead agency on two proposals.

These included a motion discussed by the Social Security and Health Committee of the Council of States demanding Swiss authorisation for medical devices from outside European regulatory systems.

Information and publications for professionals

An important resource for providing information to professionals in the medical devices sector is the newsletter that is published four times a year and which draws attention to relevant publications. The focus in 2021 was on the extensive information associated with the introduction of the new regulation for medical devices (medical equipment, implants, surgical instruments, etc.)

Furthermore, Swissmedic regularly published answers to frequently asked questions associated with the new medical devices regulation as well as extensive enforcement aids. These included information sheets on the roles and obligations of the various economic operators and on the procurement of medical devices in health institutions.

In early September, Swissmedic held an online information event, which was very well attended, with around 1,600 participants. Information intended specifically for hospitals also attracted major interest.

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 increased by over 20 percent during 2021. 795 notifications concerning Class 1 medical devices (e.g. reusable surgical instruments, adhesive plasters or rolling walkers), custom-made classic or active implantable medical devices and systems and procedure packs were received. An additional 294 notifications concerned in vitro diagnostic medical devices (IVDs). One notification was submitted for classic and active implantable medical devices produced using or containing devitalised human tissue. In addition, five change notifications concerning devitalised human tissue were processed.

Placing on the market

2020 **2021**

Class I notifications

IVD notifications (Switzerland)

Notifications rejected

In 71 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. 17 applications were submitted and reviewed during 2021.

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.

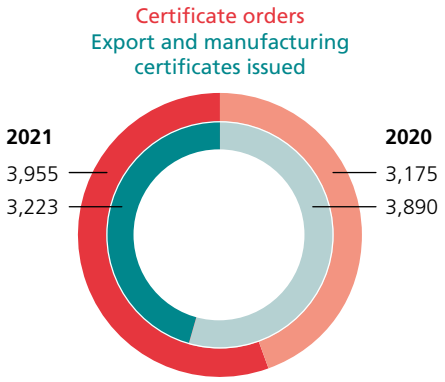
Activities:
Swissmedic approved 40 first-time applications for clinical trials and 54 variations requiring approval. A total of 108 variations to clinical trials were monitored, as were 87 annual safety reports and 23 safety reports from ongoing trials in Switzerland.

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 3,955 orders in 2021 and issued 3,223 export and manufacturing certificates. Since the change in legislation on 26 May 2021, it is no longer possible to submit collective orders for certificates. Timelines were respected in 99 percent of cases.

Export and manufacturing certificates



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.

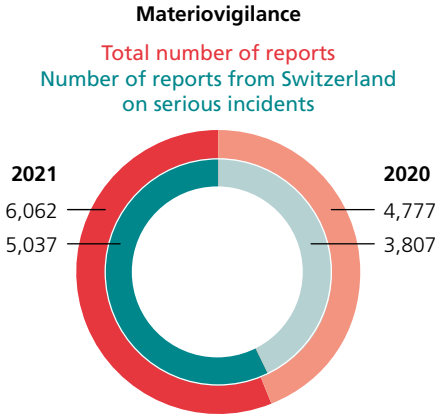
Activities:
From the time the revised Medical Devices Ordinance came into force on 26 May 2021, Swissmedic received 1,421 applications and issued 1,349 identification numbers. The timelines of 30 days were respected in 99 percent of cases.

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:
Over the past three years, the number of reports of serious incidents from Switzerland has more than doubled. 5,037 cases were reported during 2021, an increase of 32 percent on the previous year.

The implementation of safety measures in Switzerland was monitored in 642 cases. The number of reported Field Safety Corrective Actions has thus remained relatively stable over the past ten years (+/–10%).

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 49 National Competent Authority Reports (NCARs) on defective medical devices and received 782 reports from other authorities.

In 628 cases, Swissmedic published a safety report on its website to bring the matter to the attention of users.

In 2021, Swissmedic again discussed new suspected incidents and coordinated concrete action on pending cases during monthly telephone conferences with the other European surveillance authorities.

Market Monitoring product

Market monitoring procedures

Integration within the European monitoring system

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 system. In concrete terms, this means not only that Switzerland no longer benefits from simplified administrative assistance and participation in market monitoring activities, it has also lost access to EUDAMED, the new shared database and information system.

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 the cantonal authorities.

Activities:
Once again, the number of reports of suspected non-conforming medical devices declined year-on-year, although the number of reports received is still above the average for recent years. A large number of reports concerned masks and COVID-19 tests. Swissmedic ordered corrective action in 95 cases. It also carried out nine on-the-spot inspections of Swiss companies.

Notified bodies and inspections

Swissmedic monitors the notified bodies in Switzerland, designates and inspects them, collects their reports on certificates issued, and records them. Since 26 May 2021, Swissmedic has been excluded from quality assurance measures by the designating bodies in Europe.

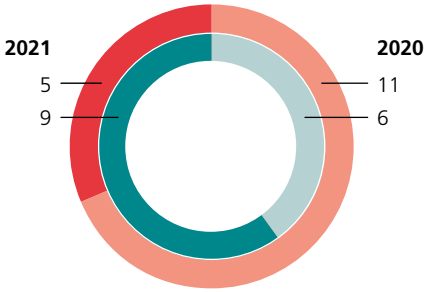
Activities:
As at the end of 2021, there was only one notified body to monitor in Switzerland. In addition, Swissmedic designated this body for conformity assessment procedures under MDR.

Despite coronavirus, Swissmedic was largely able to continue and even slightly increase its own inspection activities during 2021. However, inspections by foreign authorities of market players in Switzerland declined sharply.

Swissmedic conducted three inspections in Switzerland on behalf of the SAS.

Inspections

Inspections by foreign authorities (including accompanying inspectors on site if needed)
Inspections of market controls



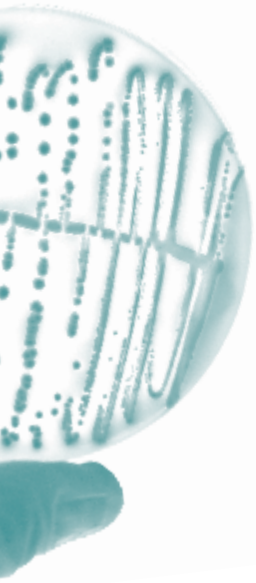
Hospital inspections

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 59 areas in 20 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.

In partnership with specialists from the Swiss society for sterile materials provision and the Swiss society for hospital hygiene, Swissmedic overhauled the guidelines for reprocessing sterile medical devices in hospitals and published the revised versions on 1 January 2022. This provides hospitals with an important framework for quality assurance activities in this area that takes account both of technical progress in recent years and the new medical devices regulation.



Borderline and classification issues

Under the Helsinki Process, decisions on borderline and classification issues affecting medical devices are made between the contracting states and published in the Manual on Borderline and Classification. Until 26 May 2021, Swissmedic was integrated into the decision process and was able to contribute its expert assessments to enquiries and take part in meetings of the European Commission working group responsible for the decision.

Activities:
In the period up to 26 May 2021, Swissmedic took part in six European enquiries on borderline questions regarding the classification of devices.

Appeals procedure

Activities:
During 2021, 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 Federal Administrative Court. The Federal Supreme Court dismissed one interim decision issued by the Federal Administrative Court.

MEDICAL DEVICES – **PENAL LAW PRODUCT GROUP**

Penal Law product

Criminal prosecution

Activities:
The majority of reports and criminal complaints concerning medical devices received in 2021 were associated with the COVID-19 pandemic. Preliminary investigations into COVID-19 rapid tests (IVD tests) were carried out and evaluated on a case-by-case basis as to whether administrative proceedings or additional administrative penalties were appropriate. Criminal proceedings were initiated against three suppliers of COVID-19 tests.

Investigative measures

Activities:
Five examination hearings were held in connection with medical devices.

In the case of one appeal against confiscation that the Federal Criminal Court had refused to admit on formal grounds in 2020, the accused applied to the Federal Supreme Court, which in turn dismissed the appeal.

Decisions / verdicts by Swissmedic and the courts

Activities:
Four penalties were imposed for medical devices. In one case, criminal proceedings were abandoned once investigations were complete. Financial penalties were imposed in three cases of criminal proceedings against suppliers of COVID-19 rapid tests (IVD tests) and fines combined with financial penalties were issued in a fourth. The sale of IVD tests to medical laypeople is prohibited. The suppliers in question had actively advertised the tests and sold them to members of the public without further investigation or enquiry – in one case even continuing to do so after Swissmedic had intervened as part of its market supervision activities. Swissmedic was also able to prove that this latter actor was operating for commercial gain and skimming off the illegal profits.

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. A verdict was not reached during 2021.

Criminal prosecution

2020 2021

New complaints
7 4

Administrative proceedings opened
2 5

Completed administrative proceedings
8 9

Investigative measures

2020 2021

House searches
0 0

Examination hearings
1 5

Unification with cantonal proceedings
0 0

Decisions/verdicts by Swissmedic and the courts

2020 2021

Criminal judgments
5 5

Cantonal judgements
1 1

CORPORATE GOVERNANCE

Organisation and compliance

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 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 direct to the Executive Director.

There were no organisational modifications at either sector or division level curing 2021.

As part of its comprehensive risk management activities, Swissmedic operates an internal control system (ICS). 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.

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.

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 period of office ended on 31 December 2021. With the exception of Vincenza Trivigno, all members stood for re-election. All were re-elected by the Federal Council. Monika Rüegg Bless, regional governor (Statthalter) and Chair of the Department of Health and Social Affairs of the Canton of Appenzell Innerrhoden, was elected as a new member.

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 containing the Agency's annual accounts, auditors' report and business report; 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.

In accordance with its normal practice, the first Agency Council meeting of the year dealt with the disclosure of members' vested interests and the Management Board's secondary occupations. In addition, the Agency Council decided to undertake a comprehensive appraisal of its activities during 2022. It commenced the preparatory work for this appraisal, which will be conducted in conjunction with an external facilitator.

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

Remuneration for the Agency Council in 2021 totalled CHF 213,000 (including expenses (previous year: CHF 183,083), of which CHF 58,000 (previous year: CHF 56,000) was paid to the Chair.

www.swissmedic.ch

President, Lukas Bruhin
(from 1 August 2020)

Vice President, Vincenza Trivigno
(1 January 2016–31 December 2021)

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

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

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

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

Giovan Maria Zanini
(from 1 January 2015)

Management Board

The Management Board is Swissmedic's executive body and is responsible for operational aspects. It is led by the Executive Director and is responsible for the tasks and responsibilities set out in 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. Daniel Leuenberger has been head of the Infrastructure section since 1 January 2021.

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 Code of Conduct is also available to the public.

The remuneration paid to the Management Board is subject to the Ordinance on the Personnel of the Swiss Agency for Therapeutic Products. The total amount paid to the Management Board in remuneration was CHF 1,980,815 (previous year: CHF 1,898,632) of which CHF 307,812 (previous year: CHF 305,520) was paid to the Executive Director.

www.swissmedic.ch

Raimund Bruhin, Dr. med.
Executive Director

Philippe Girard, Dr.
Deputy Executive Director
Head of Licensing

Claus Bolte, Dr. med.
Vice Director, Head of Authorisation

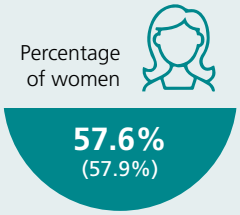
Helga Horisberger
Head of Legal Affairs

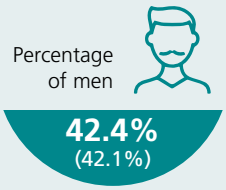
Daniel Leuenberger
Head of Infrastructure

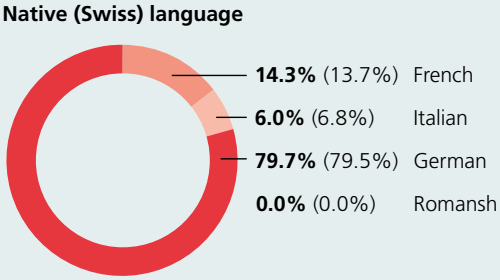
Karoline Mathys Badertscher, Dr. pharm.
Head of Market Surveillance

Jörg Schläpfer, Dr. med. vet., PhD
Head of Management Services and International Affairs

Barbara Schütz Baumgartner
Head of Human Resources and Finance







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.

At the end of 2021, the following people were employed by Swissmedic (by surname, in alphabetical order):

Abegglen Julia, Aeberhard Jacqueline, Aebischer Kathrin, Aeschbacher Monique, Aeschlimann Evelyn Kate, Affolter Julian, Aguirre Anouk, Albayrak Mehmet, Allemann Claudia, Althammer Andreas, Althaus-Steiner Esther, Amar Rajeev, Amstutz Yann, Andrejic Milan, Arnheiter Larissa, Atiek Eiman, Bachmann Beat, Bachmann Vanessa, Baeriswyl Gerda, Baresic Mario, Bärtsch Martin, Baumann Marianne, Baumann Yvonne, Beckert Ingo, Bellac Caroline, Bellwald Patricia, Berger Christoph, Beroud Isabelle, Besinovic Zeljko, Bigler Weber Cornelia, Bill Helena, Binggeli Gabriela, Bischof Ilana, Bizzini Alain, Blanco Philippe, Blankenbach Kira, Blaser Beatrice, Blind Eberhard, Blum Markus, Bögli Katja, Bögli-Schlüchter Franziska, Böhlen-Walther Caroline, Bolli Richard, Bolte Claus, Borissov Petya, Boschung Andrea, Bossi Martina, Breisinger André, Briggeler Nadine, Brügger-von Schierstaedt Caroline, Bruhin Raimund, Brunner Stefan, Brunschwiler Elija Simon David, Büchi Jacqueline, Büchler Monika, Buchs Renato, Buchter-Denkinger Linda, Bühler Tim, Bulter René, Buntschu Samuel, Bur Kathrin, Burgener Roger, Burgunder Estelle, Bürk Katrin, Burkhalter Gabriele, Camenisch Corina, Carrel Nadja, Carulli Amico Sabina, Catucci Corina, Cavaliero Tania Cecilia, Cernoch Patrick, Chatelain Barbara, Christen Tobias, Cimini Federico, Cokoja Adisa, Colangelo Elena, Colangelo Stefania, Conde Janine, Conti Massimiliano, Coso Marija, Crottet Pascal, Cudré-Mauroux Fanny, Curat Cyrile-Anne, Dalla Torre Simon, Damke Beat, Dannacher Philipp, De Matteis Isabella, Degand Julie, Déverin Olivier, Dexheimer Petra, Diethelm Markus, Ditesheim Véronique, Djonova Julia, Dollinger Silke, Drapela Aurélie, Drechsel-Weiss Bettina, Dürr-Kammer Eva, Eggel Christian, Eggenschwyler Doris, Egger Franziska, Ehmann Richard, Ehrensperger Edmund, Ehrensperger Murri Eva, Endress Eva-Maria, Endrich Michael, Engel Marie-Helene, Engels Julia, Escandari Markus, Essen Renate, Eugster Urs, Eyal Eva, Eyquem Jeanne, Fabritius Martin, Fahrni Ursula, Farré Viviane, Federer-Oetliker Martina, Feldmann Danila, Feller Selina, Ferbitz-Scheurer Simone, Filgueira David, Fischer Bernt, Flechtner Olivier, Flückiger Patrick, Fotinos Nicolas, Frank Simone, Friedli Stefan, Fritz Olaf, Fritzsche Constanze, Fuchs Sebastian, Fuhrer Therese, Fürer Andreas, Gafner Verena, Gamma-Lauber Madeleine, Gassner Beat, Gaudesius Giedrius, Gautschi Jonas, Gautschi Matthias, Geissbühler Lucien, Geluk Charlotte, Gerber Martina, Gerlach Markus, Gertsch Rolf, Gilgen Bernadette, Gilgen Michael, Girard Philippe, Girčys Arūnas, Glauser Daniel, Gobet Magali, Gosdschan Tobias, Graber Angelika, Graber Stefan, Griesser Nadine, Grüter Eric, Grütter Daniela, Guggisberg Joël, Guggisberg Stefan, Gugler Claudia, Gulkowska Anna, Gürtler Rolf, Gut Silvan, Gysin René, Häberli-Airoldi Isabelle, Haenggeli Christine, Hafner Roger, Hahn Spielmann Véronique, Haldemann Silvia, Hammel Mario, Häni Brigitte, Hartmann Ulrike, Haslebacher Angela, Hatibovic Maja, Haueter Monika, Häuptli Daniel, Häuptli Michelle, Häuptli Thomas, Hausammann Georg, Häusermann Monika, Hediger Ronald, Heneka Bilkis, Hernandez Perni Maria Engracia, Herrli Stefan, Herzog Barbara Suzanne, Hess Lorenzo, Hess Michelle, Hetzenecker Stefanie, Hock Andreas, Hofer Micheline Larissa, Hofmann Alexander, Hofmann Linda, Hofstetter Christiane, Hör Michaela, Horisberger Helga, Horn-Lohrens Ottmar, Horst Alexander, Hottiger Thomas, Hotz Rolf, Huber Cornelia, Huber Elisabeth, Huber Jasmina, Hunkeler Thomas, Hürlimann Daniel, Hutz Levin, Iannaccone Reto, Iovino Mario, Jaggi Lukas, Jäggli Christoph, Jahn Katrin, Janitsary Anna, Jankovic Sandra, Jankowski Eva, Järmann Stephan, Jentzsch Christoph, Jéquier Martine, Jermann Ronald, Johner Regula, Joos Monika, Josty Alexander, Joye Laetitia, Jungo Jacqueline, Junker Christian, Juritz Stephanie,

409 Full-time equivalents (382)

Percentage of women in executive positions (40%) **40.3%**

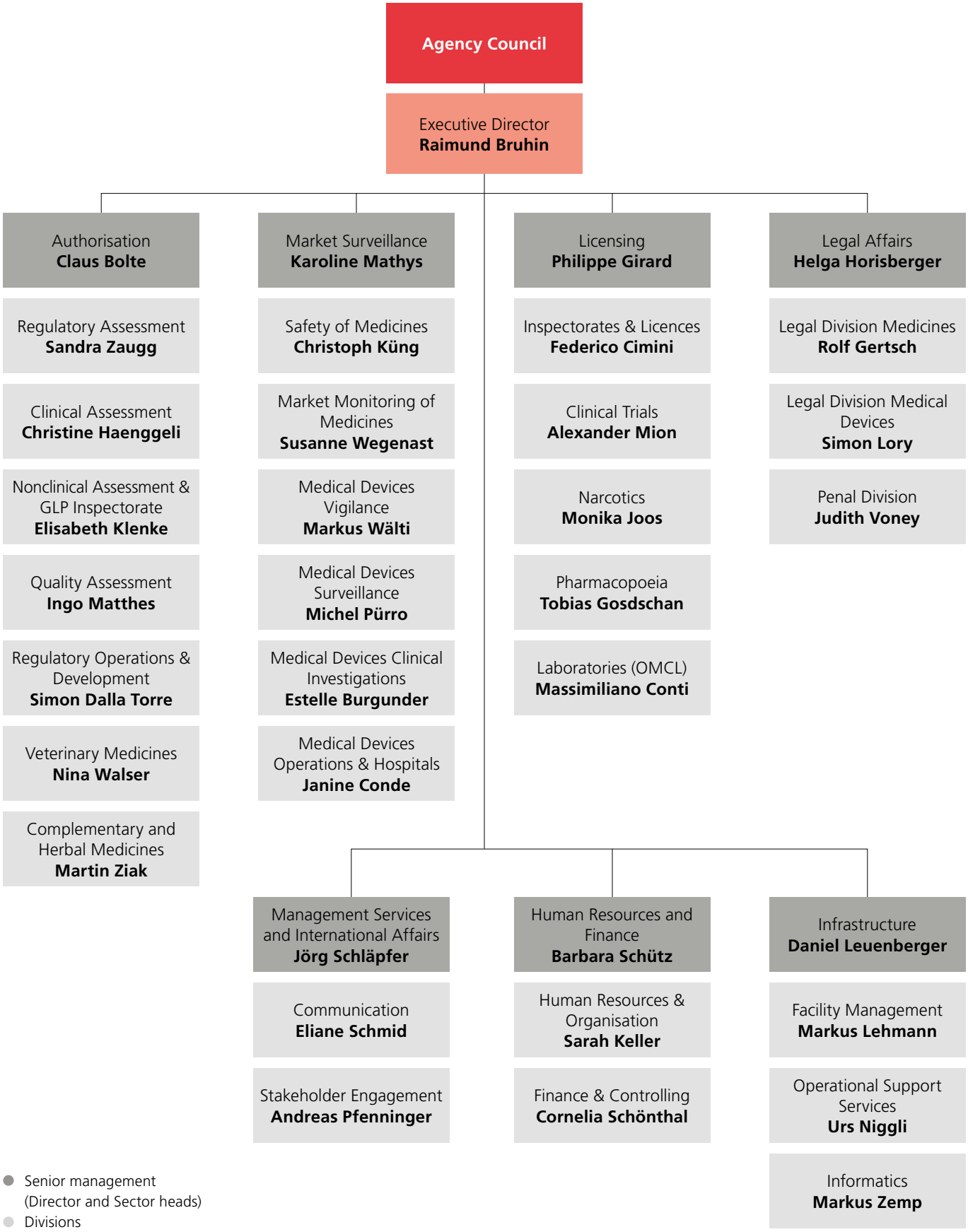
47.6 Average age (47.8)

Percentage of staff working part time (up to 89%) (50%) **49.2%**

5.5% Fluctuation rate (5.4%)

Käser Sandra, Keller Michael, Keller Sarah, Kempná Bukovac Petra, Keusen-Weyermann Katrin, Kindler Adrian, Kläy Barbara, Klenke Elisabeth, Kleppisch Thomas, Koeninger Franziska, Köhli Michael, Kottmann Helena, Krebs Franziska, Kühni Martin, Kummer Robert, Küng Christoph, Kunz-Greub Marianne, Kuster André, Langenkamp Anja, Lany Catharina, Lapke Conwitha, Latorre Martinez Mayra, Lavanchy Vincent, Le Stanc Pascale, Lehmann Markus, Lehmann Thomas, Leidreiter Kirsten, Leist Roman, Lerch Sébastian, Leu Martin, Leuenberger Beat, Leuenberger Daniel, Li Qiyu, Linder Ursula, Liniger-Thommen Andrea, Liu Fong-Yei, Lochmatter Cecchetto Priska, Löffel Werner Patrik, Löhr Kottmann Ingrid, Lory Simon, Lottaz Daniel, Ludwig Ljubica, Luginbühl-Weber Karin, Lüthi-Wyss Nicole, Lütolf Natalie, Lyzwinski Krzysztof, Maier Ralph, Manolio Silvana, Manzoni Isabella, Marazzi Céline, Marti Andreas, Mathys Badertscher Karoline, Matthes Ingo, Maurer Jessica Maria, Meier Ulf, Meincke Ricarda, Meseguer Georges, Messerli Nicole, Messi Mara, Meusburger Madeleine, Meyer Simon, Meyer Ulrike, Meyer Urs, Michel Dominic, Miletzki Barbara, Mion Alexander, Mohajeri Hasan, Morancy Meister Anne-Catherine, Morand Fabien, Morciano Julie, Moreno Rafael, Mosimann Ruth, Müller Jessica, Müller Marie, Müller Matthias, Müller Petra, Müller-Mook Renate, Münger Laura, Müntener Cedric, Mutti Sven, Näf Myrtha, Nava Gabriela, Neeser Zaugg Rosmarie, Netsch Marco, Neukamp Michal, Neziri Lavdije, Nick André, Niggli Urs, Nikolic Danijela, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Nyffeler Chiara, Op den Camp Roeland, Osswald Tschan Marco, Paganini Lodovico, Paniga Nicoletta, Pavelic Ferretti Danijela, Pavic Matea, Pecaric Petkovic Tatjana, Peitrequin Aurélie, Pereira Claudia, Perera Iliana, Perez Eugenio, Pérez González Nicolás, Pernusch Jenny, Perrenoud Florence, Petkovic Vibor, Pfenninger Andreas, Pinsard François, Plattner Patricia, Polatti Daniela, Poma Giorgio, Ponti Lorenzo, Porporini Lucio, Prisching Andrea, Prost Francine, Puliafito Anita, Pürro Michel, Rached Eva, Rätz Katerina, Reich Anne-Isabelle, Reiter Damaris, Renaudin Michael, Renftle Wolfgang, Reusser Daniel, Rickenbacher Nadja, Rieder Barbara, Riesen Sabine, Robbiani-Meier Corinne, Roduit Sandra, Rogl Schmid Jeannette, Rohr Ulrich-Peter, Roost Matthias, Roth Daniel, Roux Catherine, Ruch Claudia, Rudofsky Leonie, Ruppen Christine, Sandrowski-Ramseyer Alice, Sänger Michael, Santhirasegarar Luxshana, Sautter Caroline, Schärer Christian, Schärer Tiina, Scheidegger Michelle, Scheidegger René, Schenkel Robin, Scherrer Frédérique, Schilli David, Schläpfer Jörg, Schlechtinger Tobias, Schlegel Andreas, Schmid Eliane, Schmid Peter, Schmid Susanne, Schmidkunz Eggler Dorit, Schmitt Iris, Schmitt-Koopmann Irmgard, Schmutz Einat, Schnyder Benno, Schochat Thomas, Scholz Irene, Schöni Damian, Schönthal Cornelia, Schorer Georg, Schüpbach Miro, Schütz Baumgartner Barbara, Schwab-Stampfli Rebekka, Schwander Simone, Schwartz Thomas, Schwyter Andrea, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Sen Jenifer, Senessie Charles, Senn Claudia, Siegrist Kerstin Sara, Sommer Andrea, Sorg Regula, Spicher Jennifer, Spohn Margot, Spörri Bernhard, Spring Andrea, Stach-Rüefli Michaela, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stammschulte Thomas, Stämpfli Ursula, Staudenmann Jasmin, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Storre Stephanie, Strack Guido, Straub Andrea Katharina, Stüdle Nicolas, Sulser Mario, Süptitz Sven, Sutter Claudia, Tanner Soland Eveline, Tanner Yvonne, Terkovics Attila Leo, Teuscher Françoise, Thiess Maria, Thomet Rahel, Thürig Soltermann Eva, Toma Valeriu, Török Michael, Traglia Marco, Tromp Jan, Tschirren Markus, Tschui Janie, Unger Matthias, Urwyler Stefan André, Vattoru Thantrige Sandya, Vela Kaja, Vihertola Mari, Vilei Edy, Vogel Lukas, Voney Judith, Vonlanthen Bianca, Vuilleumier Julienne, Wacker Christoph, Wagner Jan, Wälchli Sabine, Walser Nina, Walter Katharina, Walther Barbara, Walther Chantal, Wälti Markus, Wälti Rudolf, Waser Isabelle, Weber Heidi, Wegenast Susanne, Wegmann Barbara, Weissmahr Richard, Weix Janine, Weller Katja, Werder Carine, Werner Hanna, Weyermann Andrea, Weyermann Philipp, Whitehead Frances, Wieland Christa, Wildner Oliver, Wings Susanne, Winkler Lorenz, Wittke Bärbel, Wittwer Aurélie, Wolfer Anita, Würstlin Oliver Djun, Wüthrich Karin, Wyss Brigitte, Wyss Kaspar, Wyss Martin, Wyss-Romanello Sabine, Zaninotto Elisa, Zaugg Kunz Sandra, Zberg Jasmin, Zbinden Raphael, Zeilfelder Nora, Zemp Markus, Zenger Daniel, Zenhäusern Gabriela, Ziak Martin, Ziehli Salvisberg Mariette, Zurbuchen Andreas, Zurkinden Tanja, Zysset Stefan

Organisational chart



- Senior management (Director and Sector heads)
- Divisions

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 can issue recommendations for authorisation documentation reviews, the market surveillance of medicinal products and medical devices and other procedures. However, decisions are always made by Swissmedic.

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 are their vested interests.

The HMEC held 15 meetings and issued 64 recommendations on applications. The majority concerned new authorisations or additional indications for medicinal products. In addition, HMEC experts carried out 25 assessments of parts of dossiers and 45 individual expert opinions were obtained.

The VMEC experts were consulted on an ad hoc basis during 2021 when issues connected with veterinary medicinal products arose.

www.swissmedic.ch

Members of the Human Medicines Expert Committee (HMEC)

Current as at December 2021

President
Krähenbühl Stephan, Prof. Dr. med. et pharm.

Ordinary members
Arand Michael, Prof. Dr. phil. nat.
Bauer Matthias, PD Dr. med.
Bodmer Michael, Prof. Dr. med.
Cerny Andreas, Prof. Dr. med.
Cerny Thomas, Prof. Dr. med.
Hullin Roger, Prof. Dr. med.
Schild Laurent, Prof. Dr. med.
Wicki Andreas, Prof. Dr. med. et phil.

Extraordinary members
Aicher Lothar, Dr. rer. nat.
Bonkat Gernot, PD Dr. med.
Buser Katharina, Dr. med.
Caldelari Reto, Dr. phil. nat.
Cavin Frédy, phil. nat.
Driessen Christoph, Prof. Dr. med.
Duwe Frank, Dipl. med.
FitzGerald Reginald Edward, Dr. phil. nat.
Fussenegger Martin Prof. Dr. phil. nat.
Giannopoulou-Politakis Catherine, PD Dr. med. dent.
Günthard, Huldrych, Prof. Dr. med.
Hayoz Stefanie, Dr. phil. nat.
Hess Urs, Dr. med.
Klenke Frank, PD Dr. med. et Dr. phil. nat.
Leuppi Jörg, Prof. Dr. med.
Luciani Paola, Prof. Dr.
Möller Burkhard, Prof. Dr. med.
Müller Antonia Maria, PD Dr. med.
Nägeli Hanspeter, Prof. Dr. med. vet.
Pfeifer Dina, Dr. med.
Ritscher Daniel Dr. med.
Rodondi Pierre-Yves, Dr. med.
Rothen-Rutishauser Barbara Prof Dr. med.
Schmid Christoph, Prof. Dr. med.
Sonderegger-Stalder Emanuel, Dr. med.
Steveling Esther, Dr. med.
Strik Werner, Prof. Dr. med.
Thumann Gabriele, Prof. Dr. med.

Tramèr Martin, Prof. Dr. med.
Vernazza Pietro, Prof. Dr. med.
Vock Michael Dr. phil. nat.
von Mandach Ursula Prof. Dr. pharm.
von Wolff Michael, Prof. Dr. med.
Weiler Stefan PD Dr. med. et phil.
Wildhaber-Brooks Johannes Prof. Dr. med.
Wilks Martin F., Prof. Dr. med.
Wolf Ursula, Prof. Dr. med.
Yerly Daniel, Dr. phil. nat.
Zimlich Klaus-Heinrich, Dr. rer. nat.
Zwahlen Marcel Prof. Dr. phil.

Advisory members
Hafezi Farhad, Prof. Dr. med.
Heininger Ulrich, Prof. Dr. med.
Heinrich Michael, Prof. Dr. rer. nat.
Hunger Robert Emil, Prof. Dr. med.
Kiesel Ludwig, Prof. Dr. med.
Özsahin Hülya, Prof. Dr. med.
Thumm Dietmar, Dr. med.

Members of the Veterinary Medicines Expert Committee (VMEC)

Current as at December 2021

President
Knutti Barbara Katharina, Dr. med. vet.

Ordinary members
Brunner Katharina, Dr. med. vet.
Glaus Tony, Prof. Dr. med. vet.
Hemphill Andrew, Prof. Dr. phil. nat.
Meylan Mireille, Prof. Dr. med. vet.
Nägeli Hanspeter, Prof. Dr. med. vet.
Perreten Vincent, Prof. Dr. sc. tech.

Extraordinary members
Charrière Jean-Daniel, MSc., Dipl. Ing. Agr.
Iff Isabelle, Dr. med. vet.
Kümmerlen Dolf, Dr. med. vet.
Loretz Bölsterli Claudia, Dr. Med. vet.
Schmid-Posthaus Heike, PD Dr. med. vet.
Zinsstag Jakob, Prof. PhD DVM

Pharmacopoeia experts

Around 120 Swiss specialists from industry, the universities, community and hospital pharmacies and authorities contribute to the preparation of the Pharmacopoeia. The experts work firstly in the Swiss pharmacopoeia expert groups organised by Swissmedic and secondly in the specialist committees coordinated by the EDQM in Strasbourg for the European Pharmacopoeia (Ph. Eur.).

The Swiss Pharmacopoeia (Ph. Helv.) is prepared by five specialist committees 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 issuing the Ph. Helv. A total of 77 mandates are currently held across all Swiss pharmacopoeia committees.

Swiss experts currently hold 91 of the 800-plus mandates in the active Ph. Eur. expert and working groups, of which there are around 60. The relevant tasks are overseen by the European Pharmacopoeia Commission, which is made up of delegations from the Ph. Eur. member states.

Sustainability

Environmentally compatible building technology

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. This is an area where Swissmedic pursues a holistic approach. In addition to generating its own energy, the Agency has extensively optimised the shells and technical installation control systems of its buildings. The buildings and technical installations form an integral system and therefore have to be attuned to each other as effectively as possible in order to ensure energy-efficient operation. The building control system is state-of-the-art, with a modern control centre that monitors buildings 24 hours a day. This ensures a prompt response in the event of any major technical component failing.

A second photovoltaic installation went into service during 2021, allowing Swissmedic to increase self-generated electricity output by 13 percent and further reduce the amount of electricity it has to buy in. A borehole heat exchanger is also due to be installed at the Agency's headquarters building to utilise geothermal energy, and associated planning work started in 2021. Once completed, this project will fulfil 90 percent of cooling requirements and 70 percent of heating requirements.

Planning is also in progress for a further photovoltaic installation at the listed property in Erlachstrasse. The office and laboratory building in Freiburgstrasse already obtains 90 percent of its heating and cooling energy from groundwater.

Swissmedic has an energy requirement of 1,880,000 kWh a year, divided between electricity and district heat. The measures already in place and the projects due to be implemented in 2022 will increase the amount of energy obtained from renewable sources to 42 percent of the total requirement.

BALANCE SHEET

(in KCHF)	Annex	31.12.21	31.12.20
Cash and cash equivalents	1	41,978	21,088
Receivables from sales and services	2	64,759	61,364
Uninvoiced procedural fees	3	5,809	5,630
Prepaid expenses	4	265	103
Current assets		**112,811**	**88,185**
Fixed assets	5	2,294	2,731
Real estate	6	64,772	66,304
Intangible assets	7	1,342	1,084
Right of use	8	2,714	2,895
Capital assets		**71,122**	**73,014**
Total assets		**183,933**	**161,199**
Commitments on sales and services	9	6,147	5,350
Other commitments	8+10	1,517	884
Short-term financial commitments	12	5,000	0
Deferred income	11	4,179	4,496
Short-term commitments		**16,843**	**10,730**
Long-term financial commitments	12	0	5,000
Lease liabilities	8+10	2,551	2,722
Liability for loyalty bonuses		2,855	2,811
Pension obligations (net)	13	46,374	82,090
Long-term commitments		**51,780**	**92,623**
Annual gain		21,852	28,936
Reserves		79,508	50,572
Endowment capital		14,500	14,500
Accumulated actuarial losses		–550	–36,162
Own capital		**115,310**	**57,846**
Total liabilities		**183,933**	**161,199**

INCOME STATEMENT

(in KCHF)	Annex	2021	2020
Procedural fees and income pursuant to Art. 69 TPA (net)	14	43,335	46,079
Supervisory levies		62,547	58,085
Other income		307	365
Federal contribution		16,728	16,698
Other operating income		68	63
Net income		**122,985**	**121,290**
Services for third parties	15	–3,070	–1,298
Personnel	16	–76,138	–70,000
Rental, maintenance, energy, transport and insurance		–2,391	–2,340
Administration		–3,790	–3,542
IT	17	–10,504	–9,951
Other expenses		–595	–584
Amortisation	5–8	–4,076	–4,245
Total operating expenditure		**–100,564**	**–91,960**
Operating income		**22,421**	**29,330**
Financial income	18	7	10
Financial expense	19	–576	–404
Financial result		**–569**	**–394**
Annual gain		**21,852**	**28,936**

STATEMENT OF COMPREHENSIVE INCOME

(in KCHF)	Annex	2021	2020
Annual gain		21,852	28,936
Actuarial gains / losses	13	35,612	–10,351
Total		**57,464**	**18,585**

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

CASH FLOW STATEMENT

(in KCHF)	Annex	2021	2020
Income / (expenditure) from business activities			
Annual gain		21,852	28,936
Depreciation of tangible fixed assets	5	922	958
Writedowns on real estate	6	2,402	2,348
Amortisation of intangible assets	7	571	758
Writedowns on right of use	8	181	181
Reversal (–) / recognition (+) of liability for loyalty bonuses		44	366
Reversal (–) / recognition (+) of pension obligations, excl. actuarial (losses) gains	13	–105	2,899
Interest expense (+) / interest income (–)		567	398
Cash flow before change in net current assets		**26,434**	**36,844**
Increase (–) / decrease (+) in receivables from sales and services	2	–3,395	–29,090
Increase (–) / decrease (+) in uninvoiced procedural fees	3	–179	–25
Increase (+) / decrease (–) in prepaid expenses	4	–162	–60
Increase (+) / decrease (–) in commitments from sales and services	9	797	785
Increase (+) / decrease (–) in other current, non-interest-bearing commitments	10	633	–339
Increase (+) / decrease (–) in deferred income	11	–317	997
Cash flow from business activities		**23,811**	**9,112**
Income / (expenditure) from investing activities			
Investments in tangible fixed assets	5	–485	–1,374
Disposals of tangible fixed assets	5	1	0
Investments in real estate	6	–870	–351
Investments in intangible assets	7	–829	–116
Cash flow from investing activities		**–2,183**	**–1,841**
Income / (expenditure) from financing activities			
Repayment of interest-bearing commitments	12	0	–5,000
Interest paid		–567	–398
Repayment of lease liabilities	8	–171	–169
Cash flow from financing activities		**–738**	**–5,567**
Net increase / (decrease) in cash and cash equivalents		**20,890**	**1,704**
Cash and cash equivalents at start of year	1	21,088	19,384
Cash and cash equivalents at year end	1	41,978	21,088

STATEMENT OF CHANGES IN EQUITY

(in KCHF)	Annual gain	Reserves	Endow-ment capital	Accum. actuarial gains / losses	Total equity
Opening balance on 1 January 2020	**26,030**	**24,542**	**14,500**	**–26,103**	**38,969**
Correction of actuarial assumptions for loyalty bonuses	0	0	0	292	292
Annual gain	28,936	0	0	0	28,936
Other income	0	0	0	–10,351	–10,351
Total	**28,936**	**0**	**0**	**–10,059**	**18,877**
Appropriation of gain	**–26,030**	**26,030**	**0**	**0**	**0**
Closing balance on 31 December 2020	**28,936**	**50,572**	**14,500**	**–36,162**	**57,846**
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**

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, TPA) 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 2021 to 31 December 2021. The balance sheet date is 31 December 2021. 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 22 April 2022.

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 2021.

– Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16: Interest Rate Benchmark Reform (Phase 2)
– Amendments to IFRS 16: COVID-19-related rent concessions after 30 June 2021

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. 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, 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.

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 depreciation method of each asset is reviewed at the end of each financial year 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 depreciation 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 provisions for loyalty bonuses are 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	31.12.21	31.12.20
Euro	1.06750	1.08590
US dollar	0.92920	0.92070
British pound	1.25950	1.20840
Swedish kronor	0.1071	0.1061

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. 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 FOPH).

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 0.8 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. There are no unrealised gains or losses. 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 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
Since Swissmedic does not have any significant interest-earning assets, cash flow is essentially unaffected by changes in market rates. The effect of changes in market interest rates on Swissmedic's mortgages 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. 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 Agency Council discusses the ICS with the Management Board at each of its March meetings. The person responsible for the ICS and the auditor review the ICS annually to review its effectiveness and existence.

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 fixing 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)	31.12.21	31.12.20
Current accounts at banks	41,978	21,088
Total cash and cash equivalents	**41,978**	**21,088**

Cash and cash equivalents virtually doubled on the previous year. This is primarily attributable to the gain achieved in 2021.

2 Receivables from sales and services

Trade receivables from third parties

(in KCHF)	31.12.21	31.12.20
Not overdue	64,652	61,268
1–30 days overdue	59	23
More than 30 days overdue	85	94
Total receivables from sales and services (gross)	64,796	61,385
Individual value adjustments	–35	–18
Flat-rate value adjustment	–2	–3
Total receivables from sales and services (net)	**64,759**	**61,364**

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 (99.7%), Confederation and Cantons (0.04%) and private individuals (0.26%).

Payment schedules

(in KCHF)	31.12.21	31.12.20
Non-overdue receivables for which the payment deadline was subsequently extended (payment schedules)	63	20
Total payment schedules	**63**	**20**

As at the end of 2021, there were 18 payment schedules (previous year: 9) for an unpaid amount of KCHF 63. There are no foreign currency receivables.

Value adjustments on receivables

(in KCHF)	31.12.21	31.12.20
Total value adjustments on receivables 1 January	–21	–29
Recognition	16	0
Reversal	0	8
Use	0	0
Total value adjustments on receivables as at 31 December (total of individual and flat-rate adjustments)	**–37**	**–21**

3 Uninvoiced procedural fees

(in KCHF)	31.12.21	31.12.20
Uninvoiced procedural fees	5,809	5,630
Total uninvoiced procedural fees	**5,809**	**5,630**

4 Prepaid expenses

(in KCHF)	31.12.21	31.12.20
Prepaid expenses	265	103
Total prepaid expenses	**265**	**103**

The following items are recorded as prepaid expenses:
- Individual invoices for services due for delivery in 2022 but which had to be paid for in 2021.
- One outstanding service charge invoice for 2021.
- Individual invoices for contracts dating from 2022.

5 Fixed assets

Statement of changes (in KCHF)	Furnishing and off. equip.	Archive equipment	Laboratory equipment	Computer systems	Total fixed assets
Acquisition cost					
1 January 2020	**2,723**	**1,963**	**5,023**	**87**	**9,796**
Additions	133	0	1,241	0	1,374
Disposals	0	0	–541	0	–541
31 December 2020	**2,856**	**1,963**	**5,723**	**87**	**10,629**
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**
Accumulated depreciation					
1 January 2020	**–1,675**	**–1,894**	**–3,825**	**–87**	**–7,481**
Additions	–523	–37	–398	0	–958
Disposals	0	0	541	0	541
31 December 2020	**–2,198**	**–1,931**	**–3,682**	**–87**	**–7,898**
Net carrying amounts as at 31 December 2020	**658**	**32**	**2,041**	**0**	**2,731**
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**

Various fixed assets, such as videoconferencing systems and laboratory equipment, were acquired and capitalised during 2021. As at the balance sheet date, there were no indications of any unanticipated impairments.

6 Real estate

Statement of changes (in KCHF)	Renovation account	Property	Land	Total real estate
Acquisition cost				
1 January 2020	**45**	**83,634**	**11,730**	**95,409**
Additions	351	0	0	351
Reclassifications	–184	184	0	0
31 December 2020	**212**	**83,818**	**11,730**	**95,760**
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**
Accumulated depreciation				
1 January 2020	**0**	**–27,108**	**0**	**–27,108**
Additions	0	–2,348	0	–2,348
31 December 2020	**0**	**–29,456**	**0**	**–29,456**
Net carrying amounts as at 31 December 2020	**212**	**54,362**	**11,730**	**66,304**
1 Janury 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**

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. Investments in renewing wooden decking and fitting out a project room were made and capitalised during 2021. 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.

7 Intangible assets

Statement of changes (in KCHF)	Software in development	Software developed by Swissmedic	Total intangible assets
Acquisition cost			
1 January 2020	**0**	**16,147**	**16,147**
Additions	116	0	116
31 December 2020	**116**	**16,147**	**16,263**
1 January 2021	**116**	**16,147**	**16,263**
Additions	829	0	829
Reclassifications	–634	634	0
31 December 2021	**311**	**16,781**	**17,092**
Accumulated amortisation			
1 January 2020	**0**	**–14,421**	**–14,421**
Additions	0	–758	–758
31 December 2020	**0**	**–15,179**	**–15,179**
Net carrying amounts as at 31 December 2020	**116**	**968**	**1,084**
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**

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. Two intangible assets – SAP SuccessFactors and the LISA literature search system – were capitalised during 2021. As at the balance sheet date, there were no indications of any unanticipated impairments.

8 Right of use

Statement of changes (in KCHF)	Right of use	Total right of use
Acquisition cost		
1 January 2020	**3,257**	**3,257**
Additions/disposals	0	0
31 December 2020	**3,257**	**3,257**
1 January 2021	**3,257**	**3,257**
Additions/disposals	0	0
31 December 2021	**3,257**	**3,257**
Accumulated writedowns		
1 January 2020	**–181**	**–181**
Additions/disposals	–181	–181
31 December 2020	**–362**	**–362**
Net carrying amounts as at 31 December 2020	**2,895**	**2,895**
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**

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)	31.12.21	31.12.20
Starting balance as at 1 January	**2,917**	**3,086**
Redemption	–195	–195
Accrued interest	24	26
Final balance as at 31 December	**2,746**	**2,917**
of which short-term	195	195
of which long-term	2,551	2,722

There are no further lease liabilities (IFRS 16.53 c to e and g).

9 Commitments on sales and services towards third parties

(in KCHF)	31.12.21	31.12.20
In CHF	6,110	5,333
In foreign currencies	37	17
Total commitments on sales and services towards third parties	**6,147**	**5,350**

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

10 Other commitments

(in KCHF)	31.12.21	31.12.20
Short-term lease liabilities	195	195
Other short-term commitments towards third parties	1,322	689
Total other short-term commitments	**1,517**	**884**

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.

11 Deferred income

(in KCHF)	31.12.21	31.12.20
Deferred income	231	138
Amount deferred for leave and flexitime	3,948	4,358
Total deferred income	**4,179**	**4,496**

Deferred income comprises individual outstanding invoices from 2021.

12 Financial commitments

(in KCHF)	31.12.21	31.12.20
Short-term commitments	5,000	0
Long-term commitments	0	5,000
Total financial commitments	**5,000**	**5,000**

The properties owned by Swissmedic are financed by fixed-rate mortgages. Swissmedic still has one CHF 5 million mortgage. This mortgage has an interest rate of 0.9% and matures on 24 November 2022. The fixed-rate mortgage is valued at updated acquisition cost. Its fair value is materially the same as the carrying amount.

13 Pension provision

Description of pension plans and pension institution

Under Article 76 of the Therapeutic Products Act, Swissmedic employees are insured against the economic consequences of 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)	2021	2020
Change in commitments and assets		
Dynamic present value of benefit obligations at start of year	**–390,472**	**–357,450**
Actuarial pension benefit expenses	–11,283	–9,593
Employee contributions	–4,148	–3,828
Past benefit expenses	0	0
Interest expense	–589	–899
Curtailment, settlement	0	0
Benefits paid	4,125	3,788
Actuarial gain (+)/loss (–) on commitments	21,282	–22,490
Dynamic present value of benefit obligations at year-end	**–381,085**	**–390,472**
Plan assets at market value at start of year	**308,381**	**288,609**
Interest income	466	727
Employer contributions	11,625	6,972
Employee contributions	4,148	3,828
Benefits paid	–4,125	–3,788
Administrative expenses	–114	–106
Actuarial gain (+)/loss (–) on assets	14,330	12,139
Plan assets at market value at year-end	**334,711**	**308,381**
Balance sheet	**31.12.21**	**31.12.20**
Plan assets at fair value	334,711	308,381
Dynamic present value of benefit obligations (DBO)	–381,085	–390,472
Liability on balance sheet	**–46,374**	**–82,091**
Duration	18.10	18.70

Income statement (in KCHF)	2021	2020
Actuarial pension benefit expenses	–11,283	–9,593
Interest expense	–589	–899
Interest income	466	727
Past service cost	0	0
Gain (loss) from curtailment, settlement	0	0
Administrative expenses	–114	–106
Net expenses for benefit obligations	**–11,520**	**–9,871**
Change in the balance sheet	**31.12.21**	**31.12.20**
Liability on the balance sheet at start of year	**–82,091**	**–68,841**
Net benefit expenses (employer)	–11,520	–9,871
Employer contributions	11,625	6,972
Actuarial gains / losses	35,612	–10,351
Liability on the balance sheet at year-end	**–46,374**	**–82,091**
Anticipated employer contribution payment in following year	7,762	7,296
Effective return on plan assets	14,796	12,866
Key actuarial assumptions as at balance sheet date	**31.12.21**	**31.12.20**
Discount rate	0.35%	0.15%
Future payroll increases	1.25%	1.25%
Future pension increases	0.00%	0.00%
Projected interest rate	1.00%	1.00%
Actuarial bases	OPA 2020 GT	OPA 2015 GT
Probable rate of turnover	High	High
Retirement age	63.5	63.5
Life expectancy at retirement age	24.17 / 25.99	24.25 / 26.36
Asset allocation	**31.12.21**	**31.12.20**
Cash and cash equivalents	3.30%	3.50%
Bonds	51.90%	54.70%
Equities	26.80%	28.20%
Real estate	15.80%	11.40%
Other	2.20%	2.20%
Total	**100.00%**	**100.00%**
Of which stock exchange-traded	82.10%	86.50%

Defined benefit pension plans	31.12.21	31.12.20
Revaluation of actuarial gain (+) / loss (–) from obligations	**21,282**	**–22,490**
Owing to changes in holdings	–6,943	–4,428
Owing to demographic assumptions	14,009	0
Owing to financial assumptions	14,216	–18,062
Revaluation of actuarial gain (+) / loss (–) from investments	**14,330**	**12,139**
Total amount recognised in equity	**35,612**	**–10,351**

Sensitivities – impact on DBO (in KCHF)	2021	2020
Discount rate +0.25%	–16,716	–17,830
Discount rate –0.25%	17,914	19,127
Payroll increase +0.25%	1,211	1,234
Payroll increase –0.25%	–1,182	–1,205
Pension increase +0.25%	–12,444	–13,373
Pension increase –0.25% (not lower than 0%)	0	0
1-year increase in life expectancy	15,426	15,772

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

Notes on the income statement

14 Procedural fees and income pursuant to Art. 69 TPA

(in KCHF)	2021	2020
Authorisation (with no fee rebates)	35,957	38,611
Licensing	12,805	12,686
Therapeutic products information	10	37
Informing the general public	3	1
Market supervision	3,270	2,923
Penal law	308	–37
Fee surcharges	490	1,180
Earnings from conferences (Art. 69 TPA)	17	14
Earnings from publications (Art. 69 TPA)	4	1
Earnings from services for third parties (Art. 69 TPA)	110	218
Fee reductions	–9,639	–9,555
Total procedural fees and income pursuant to Art. 69 TPA	**43,335**	**46,079**

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.

15 Services for third parties

(in KCHF)	2021	2020
Medical and pharmaceutical services	–2,343	–785
Laboratory services	–69	–32
Other services for third parties	–658	–481
Total expenditure on services for third parties	**–3,070**	**–1,298**

The increase in medical and pharmaceutical services under services for third parties is attributable to the dramatic increase in adverse reaction reports associated with coronavirus vaccines.

16 Personnel

(in KCHF)	2021	2020
Wages and salaries	–57,845	–54,115
Net expenses for benefit obligations	–11,520	–9,871
Social security	–5,242	–4,725
Other personnel expenses	–1,370	–1,252
Work by third parties	–161	–37
Total personnel expenses	**–76,138**	**–70,000**

Personnel expenses roses by some CHF 6 million in 2021. This is primarily due to the planned headcount increases that have been implemented, particularly in connection with the additional duties associated with medical devices.

17 IT

(in KCHF)	2021	2020
Operating and support services	–6,118	–5,984
Hardware	–272	–182
Software licences	–614	–480
Development services	–2,445	–2,633
Maintenance services	–1,055	–672
Total IT	**–10,504**	**–9,951**

18 Financial income

(in KCHF)	2021	2020
Interest income from receivables	3	1
Exchange rate gains	4	9
Total financial income	**7**	**10**

19 Financial expense

(in KCHF)	2021	2020
Interest expense, banks	–543	–372
Interest expense, leases	–24	–25
Exchange rate losses	–9	–7
Total financial expense	**–576**	**–404**

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 commitments towards third parties	11	34	5,041	0	5,086
Commitments on sales and services towards third parties	2,907	0	0	0	2,907
Commitments on sales and services towards related parties	2,443	0	0	0	2,443
Lease obligations toward third parties	49	146	780	2,145	3,120
Total contractual cash flows from financial commitments 2020	**5,410**	**180**	**5,821**	**2,145**	**13,556**
Financial commitments 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**

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 50,000 per year.

Transactions with related parties

Related parties are individuals and companies 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, Federal Office of Information Technology, Systems and Telecommunication (FOITT)
- The Federal Office for Buildings and Logistics (FOBL), the Federal Compensation Office (CFC), the Federal Office of Public Health (FOPH)
- Members of the Agency Council
- Members of the Management Board

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

Transactions with related parties

All transactions with related parties take place at arm's length, i.e. at market value. 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)	31.12.21	31.12.20
PUBLICA, social insurance contributions	1,009	950
FOITT, IT expenses	1,394	1,202
CFC, social insurance contributions	0	291
Total commitments towards related parties	**2,403**	**2,443**

(in KCHF)	2021	2020
GS FDHA, federal contribution	16,727	16,698
Total net income involving related parties	**16,727**	**16,698**
PUBLICA, social insurance contributions	15,773	10,790
FOITT, IT expenses	5,421	5,315
CFC, social insurance contributions	6,640	6,724
Total operating expenses involving related parties	**27,834**	**22,829**

Remuneration of individuals in key positions

The following fees and salaries were paid:

(in KCHF)	2021	2020
Short-term benefits due to the Management Board	1,980	1,898
Benefits following termination of employment contract	339	316
Benefits occasioned by termination of employment contract	0	0
Share-based compensation	0	0
Total remuneration of individuals in key positions	**2,319**	**2,214**

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 68 18
www.ey.com/ch

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

Berne, 22 April 2022

Statutory auditor's 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, which comprise the statement of financial position as at 31 December 2021 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, International Standards on Auditing (ISAs) and Swiss Auditing Standards. 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 in the annual report. The other information comprises all information included in the annual report, but does not include the financial statements, the stand-alone financial statements and our auditor's reports thereon.

Our opinion on the financial statements does not cover the other information in the annual report 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 in the annual report 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, ISAs and Swiss Auditing Standards 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 at the website of EXPERTsuisse: http://www.expertsuisse.ch/en/audit-report-for-public-companies. This description forms part of our auditor's report.

Report on other legal and regulatory requirements
We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 728 CO) and that there are no circumstances incompatible with our independence.

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

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

Ernst & Young Ltd

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

Stefan Schmid
Licensed audit expert

swissmedic

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

Hallerstrasse 7
3012 Bern
Tel. +41 58 462 02 11
Fax +41 58 462 02 12
www.swissmedic.ch