swissmedic

ANNUAL REPORT 2019

Mission:

Our competence –
for therapeutic products you can trust.

Guiding principles of Swissmedic

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FOREWORDS

Major challenges for the healthcare system

Stéphane Rossini, President of the Agency Council

Health is one of the public's biggest concerns. Access to treatments and medicines, quality of services and solidarity-based financing are complex issues that impact on personal factors and social justice. Cost efficiency and efficacy are the authorities' main priority in their efforts to organise and regulate the healthcare system. The media are adept at leveraging the issue to their advantage. By reporting on individual misfortunes, they often paint a critical, black and white picture of the system that unfortunately sows the seeds of mistrust in the institutions within that system.

Swissmedic responds to this complex environment and the contradictory interests within it by exercising its supervisory powers professionally and dynamically. The legal framework coupled with the expertise and diligence of the people responsible for implementation guarantee extremely safe access to medicines. The international networking that is an essential part of the globalised economy is a further guarantor of quality and efficacy.

In the past year, the Agency Council systematically pressed ahead with implementation of the strategic goals for 2019–2022. The following points are noteworthy: Swissmedic's good financial results help safeguard its independence. They are a positive sign in the light of the challenges that the future will bring. The Agency Council attaches great significance to internal governance. Various tools guarantee efficient management of financial aspects, operational processes or risk management. In addition, the Agency Council initiated measures to ensure compliance with the new Corporate Governance provisions issued by the Federal Council.

Brexit and relations with the European Union are a challenge. They will impact access to medicinal products and medical devices. The Agency Council and Management Board have worked closely with the relevant authorities in an attempt to analyse the situation and its possible consequences carefully and rationally. There is also regular liaison with the federal parliament. The National Council's Finance and Control Committees and its Social Security and Health Committee follow our activities attentively. The Agency Council regards this dialogue as an important and essential foundation for mutual trust.

There were two changes in the membership of the Agency Council at the end of 2019. Reto Obrist stood down after many years of service to Swissmedic. His foresight and vision for the healthcare system and Swissmedic's role were particularly valuable and correspondingly valued. I also stepped down as President of the Agency Council, but will remain in federal service as Head of the Federal Social Insurance Office. I would like to offer my sincere gratitude to everyone who has supported me during my time in this exciting role at Swissmedic.

Start of the 2019–22 strategy period – a year of renewal and operational highlights

Raimund T. Bruhin, Executive Director

New governance, a new Therapeutic Products Act (de facto a complete revision), a new vision, management with strategic goals covering a period of four years and based on the strategy for 2019–2022, a new business and IT roadmap, and new challenges for Swissmedic as the regulator of a system-relevant sector, an organisation with a safety and economic oversight rule, partner to a broad and heterogeneous national and international stakeholder environment and an agile learning organisation – all these topics were covered at the staff event that took place in January 2019 to mark the start of the new strategy period. The event was about a shared understanding of these topics, transparent leadership and the personal individual contribution that each individual can make to achieving Swissmedic's vision and strategic goals.

The new vision enables Swissmedic to align its current strategy with future needs. It also provides a beacon and landmark for a worthwhile future development status that puts us at eye level with our stakeholder environment and extends into the next strategy period. The vision addresses key issues such as safety and public access to therapeutic products, transparent information and communication, leadership, high professional standards and quality, competitiveness and agility, and scientific, political and organisational autonomy. Developed in a structured bottom-up, top-down process, this vision was one of the operational highlights of 2019.

Other innovations and operational highlights are also noteworthy. The medical technology sector now has institutionalised stakeholder involvement in the form of a MedTech round table. Swissmedic also set up an innovation round table, which met for the first time in October 2019, the aim of which is to use anticipation to improve regulatory preparedness and thus accelerate access to innovative medicines. The introduction of a simplified processing procedure for packages from abroad enhanced the efficiency of illegal medicinal product confiscations very significantly. In 2019, Swissmedic's laboratory once again played a world-leading role in uncovering carcinogenic impurities in different medicine categories. Midyear the Swiss Medical Association's postgraduate medical training institute awarded the Agency the status of a category A training institution for its consultant-level qualification in pharmaceutical medicine. In December 2019, Swissmedic signed a Good Manufacturing Practice agreement with South Korea.

Last but not least, this restructured, more compact report is also an innovation. I hope you enjoy reading it.

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.

Swissmedic's 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
- Medicinal products vigilance (P)
- Market monitoring of medicinal products (P)
- Medical devices vigilance (P)
- Market monitoring of medical devices (P)

Penal law PG

Key issues in 2019

Revised Therapeutic Products Act in force

The revised Therapeutic Products Act (TPA) entered into force on 1 January 2019. It had been preceded by parliamentary approval of two legislative changes (ordinary revision in 2016 and amendments arising from the approval and implementation of the Medicrime Convention in 2017) as well as extensive amendments to the implementing legislation (2017 and 2018). The overall result was that four Federal Council ordinances and five Agency Council ordinances entered into force alongside the legislative changes at the beginning of 2019.

The main goals of revision were to simplify market access, improve drug safety and promote transparency. Pursuit of these goals meant extensively amending not only the legal framework, but also operational processes and IT systems. The transition from the old system to the new went smoothly and with no significant impact on stakeholders.

New governance in place

The revised TPA also enshrines in law Swissmedic's obligation to comply with the Confederation's Corporate Governance principles. In particular, Chapter 5 of the law contains provisions on the Agency's governing bodies and their tasks, competencies and responsibilities, Swissmedic's autonomy and supervision by the Federal Council. The Corporate Governance section of this report contains details on the composition of the governing bodies and vested interest disclosures.

At operational level, the management regulations were revised: Swissmedic's organisational rules, the Agency Council's business regulations (including the code on dealing with conflicts of interest), the Management Board rules and the Code of Conduct for Swissmedic employees were brought into alignment with current governance standards. As of the 2019 business year, reporting also complies with the new governance standards.

New vision implemented, 2019–2022 strategy period underway

Swissmedic's new vision was developed in a participatory top-down, bottom-up process and approved by the Management Board and Agency Council:

"Impartial, networked and highly professional at all times, intelligible and in tune with events – Swissmedic, the key authority for safe therapeutic products in Switzerland."

The Federal Council approved the strategic goals for the 2019–2022 period in October 2018. The key tenets of the new strategy are employee skills, capacity expansion in the medical devices sector, speeding up time-critical processes and digital transformation.

Milestones, measures and metrics for implementing and achieving the strategic goals are set annually; the Management Board and Agency Council review goal attainment levels using a balanced score card. At the end of the first year of the four-year strategy period, the Agency is on course to achieve its goals.

Medical devices: regulatory alignment and resource expansion in progress

Switzerland is integrated into the European medical devices regulatory and surveillance system through its Bilateral Agreements with the EU. CE-marked medical devices are considered to be compliant and may be distributed in all contracting states.

In April 2017, after various scandals involving medical devices, the European Parliament tightened up its regulation very significantly and to the benefit of patient safety. The new regulations for medical devices will apply from spring 2020, those for in vitro diagnostics from spring 2022.

To ensure equivalence is maintained, the Swiss legal framework is currently being revised. Swissmedic was heavily involved in work on this legislative project through-out 2019 and will continue to contribute to it.

Parallel to this, Swissmedic is preparing to implement the new regulation as of May 2020. In addition to expanding skills and resources in all fields of activity, a lot of processes have to be networked with EUDAMED 3, the new central European database, and its functions. EUDAMED 3 will become the new entry point and hub for a large number of application and reporting processes and will also improve transparency.

Swissmedic as national point of contact for counterfeit medicinal product issues

With the entry into force of the revised TPA (the part that implements the Medicrime Convention), Swissmedic officially became the national single point of contact (SPOC) for issues relating to counterfeit medicinal products. In this context, Swissmedic further expanded its existing partnership with the Directorate General of Customs, the Federal Office of Police (fedpol), the Cantons and other stakeholders. To sensitise healthcare professionals and the public to the subject of therapeutic products crime and products that are dangerous to health, Swissmedic added a new microsite to its website (www.medicrime.ch). The platform also provides information on national-level cooperation with the key partner authorities and the international network for combating therapeutic product crime. In addition, the site gives people the option of directly reporting their own findings concerning suspicious products.

As the national point of contact for illegal trading in medicinal products, Swissmedic worked in several international bodies. These provide a forum for experience-sharing and evaluating focal campaigns. Suspicions of illegal medicinal products that may be harmful to health are shared in the SPOC network and between national authorities.

Nitrosamines still a headache for authorities

Analytical testing for nitrosamines kept Swissmedic's Official Medicines Control Laboratory (OMCL) busy again in 2019. Following on from the sartans, other active substances were suspected of being contaminated with nitrosamines. Effective information-sharing with various international authorities and close collaboration within Swissmedic made it possible to identify further suspicious products.

In summer 2019 the OMCL was concerned with ranitidine. The molecules in this preparation contain the two constituents of N nitrosodimethylamine (NDMA), which generate a relatively high concentration of NDMA during production or in the course of their shelf life. Since the impurity was above the safe limit in the three products sold in Switzerland, Swissmedic had all batches recalled.

In October 2019, the focus turned to medicines containing metformin. Nitrosamine contamination was detected in a number of products. However, levels were in most cases within the safe limit. Only products from one manufacturer had to be withdrawn owing to an excessive NDMA content.

Report on Depakine scandal published

In response to a postulate submitted by Councillor of States Maury Pasquier, Swissmedic produced a report on medicines containing valproate and the situation in Switzerland. The Federal Council published the report in December. Swissmedic presents its evaluation on how to ensure that healthcare professionals are made aware of this issue in future.

Joint assessment in the ACSS Consortium and Project Orbis

As part of the New Active Substance Work Sharing Initiative (NASWSI) set up by the Australia, Canada, Singapore and Switzerland (ACSS) consortium, Swissmedic took part in its first trilateral worksplit with Australia's Therapeutic Goods Administration (TGA) and Health Canada (HC). This involves dividing up the assessment and peer review for the authorisation of a new active substance (NAS), and is followed by a joint communication to the applicant. However, each regulatory authority makes its own authorisation decision independently of the others. Further applications that may be suitable for a worksplit assessment are being processed or are at the preliminary investigation stage. Up to now the initiative has been restricted to applications involving NAS; however, it is now being extended to applications for indication extensions.

In addition to its involvement in the ACSS consortium, Swissmedic also received an enquiry from the US Food and Drug Administration (FDA) asking whether it would be interested in participating in Project Orbis.

This initiative by the FDA Oncology Center of Excellence provides a framework for concurrent submission and review of oncology products among international partners. The project aims to give patients in different countries the fastest possible access to oncologicals. After an internal assessment, Swissmedic decided to take part in a pilot in the first quarter of 2020.

Continued engagement in development cooperation

Swissmedic has been involved in development cooperation since 2015 on the basis of the Memorandum of Understanding with the Bill and Melinda Gates Foundation, the Federal Department of Home Affairs and the Federal Department of Foreign Affairs. With the Federal Council's consent, this involvement will continue during the 2019–2022 strategy period. Support focuses on improving access to therapeutic products by strengthening regulatory systems, primarily in low- and middle-income countries in sub-Saharan Africa.

The first of three development cooperation projects focuses on supporting the African Medicines Regulatory Harmonisation (AMRH) initiative in collaboration with the World Health Organization (WHO). Swissmedic attends working group and steering committee meetings as an observer and advisor, and provides various expert reports.

The second project enables African regulatory authorities and the WHO to be included in an assessment process carried out by Swissmedic for medicinal products intended to treat diseases that disproportionately affect people in southern Africa. This Marketing Authorisation Procedure for Global Health Products (MAGHP) is currently in the pilot phase and initial experience has been gathered.

In the third project, Swissmedic provides training opportunities for regulatory authorities in low- and middle-income countries. Swissmedic conducted regulatory training for regulatory authorities twice during 2019. The Agency also invited experts from African authorities to its Good Manufacturing Practice (GMP) training course, giving four African inspectors from the Intergovernmental Authority on Development region the opportunity to attend two GMP inspections in Switzerland.

Swissmedic and its national stakeholder groups

Overview of the national network

National-level cooperation is important for guaranteeing therapeutic product safety. The different stakeholder groups have diverse, heterogeneous and often contradictory demands. Swissmedic's national network includes:

- Patients/consumers and their associations/organisations
- Healthcare professionals and their associations/organisations
- The therapeutic products industry and its associations/organisations
- Service providers from the therapeutic products industry
- Cantonal and federal authorities and the Swiss parliament

Activities in 2019

The patient and consumer organisations working group met three times. The core subjects were the changes arising from the revision of the TPA, the tightening of medical devices regulations and the working group's contribution to the drafting of patient information (pilot project).

The annual meeting between Swissmedic and the Association of Cantonal Pharmacists took place in March 2019. Swissmedic briefed the Association on the Federal Supreme Court's decision of 15 March 2019, which ruled that preparations from a clinic in eastern Switzerland that had been made with cell extracts were not subject to an authorisation requirement. Other subjects were: the revision of medical devices legislation, focusing on the effects on the Cantons, current market

surveillance cases (including needle-free Hyaluron Pens for injecting hyaluronic acid and the current situation as regards nitrosamines in sartans), progress on reallocating medicinal products to new dispensing categories and enforcement issues (including pharmacists' duty of documentation).

In August 2019, experts from Swiss customs, fedpol, Antidoping, the cantonal public prosecutors and enforcement agencies met at Swissmedic for the first national Medicrime meeting. The main subjects were information flow and networking between the participating organisations to ensure concerted action against therapeutic products crime.

In October 2019, Swissmedic organised the first innovation round table on the subject of "Innovative methods and technologies in clinical trials". Representatives of ETH Zurich, University Hospital Zurich, the pharmaceutical industry and the authorities discussed trends, technical options and operational issues.

Representatives of industry associations met with Swissmedic for two Regulatory Affairs round tables during 2019. The round tables provide a forum for sharing information and experience on regulatory, process-related and technical issues associated with medicinal product authorisation. The topics discussed included: positioning Swissmedic as a first-wave agency, experience with implementing the revised TPA, defining the scope of the innovative temporary and fast-track authorisation procedures, the regulatory framework for tissue-agnostic applications and joint appraisal by the ACSS consortium.

June saw the annual meeting between Swissmedic and stakeholders from the complementary and herbal medicines sector. In addition to questions on implementing the revised TPA, the meeting discussed advertising guidelines for medicinal products without indication and requirements for inspections.

A meeting between Swissmedic and a delegation from veterinary medicinal product distributors led by Scienceindustries discussed the differences between the new EU veterinary medicinal products regulation and Swiss regulations (gap analysis, need for action).

Three MedTech round tables involving representatives of the medtech industry and Swissmedic took place during 2019. The discussions focused on the European Union's new Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), the resulting regulatory changes in Switzerland, and ongoing preparations for implementation. The concerns of medical technology associations were also addressed.

Swissmedic in international bodies

International collaboration and international network

Cooperation between authorisation and supervisory authorities and with international organisations active in the medicinal products and medical devices field is extremely important for stakeholders, for Switzerland as a location, and for Swissmedic. Efforts focus on exchanging information throughout the medicinal product authorisation process, market surveillance, and preparing new draft legislation related to therapeutic products.

In accordance with its strategy, Swissmedic has consistently networked with partner authorities in recent years, and has now concluded information-sharing agreements with virtually all internationally recognised therapeutic products authorities that work to comparable standards. Bilateral technical collaboration with partner authorities has been stepped up and a system of benefits-driven information sharing has been established.

Bilateral collaboration

In December 2019, the Ministry of Food and Drug Safety of the Republic of Korea and Swissmedic signed their first agreement on Good Manufacturing Practice (GMP). Under the terms of the agreement, each authority will recognise and accept the other's GMP certificates and inspection reports.

Multilateral collaboration

International Council for Harmonisation (ICH):
The ICH held two Assembly meetings during 2019 – the first in Amsterdam in June and the second in Singapore in November. A delegation of experts represented Swissmedic at both events, contributing to the Management Committee and Assembly, as well as to the working groups that prepare harmonised guidelines for human medicinal products.

International Pharmaceutical Regulators Programme (IPRP):
The members of the IPRP and representatives of authorities, regional harmonisation initiatives, the WHO and the European Directorate for the Quality of Medicines (EDQM) met twice in 2019. In addition to inter-authority dialogue and working group updates, the 2019 meeting focused among other things on reliance and real-world evidence in drug safety.

Heads of agencies in the Australia-Canada-Singapore-Switzerland (ACSS) consortium:
The agency heads met in May and October. The main subjects of the 2019 meetings were the strategic direction and further development of the ACSS working groups (new active substances, generic medicines, biosimilars, complementary health products, ACSS work sharing, information technology, ICH working group) and communication with the industry going forward.

International Coalition of Medicines Regulatory Authorities (ICMRA)
The plenary meeting in June discussed vaccines, the latest developments in the project supply chain, pharmacovigilance, innovation and communications. The overarching subject of the summit, which was held in October, was evolving global science and regulatory challenges.

Drug Information Association (DIA):
The DIA Council of Regulators met in June. The Council is a strategic body that works within the DIA Governance Framework and has members from seven regulatory authorities and the WHO.

Competent Authorities for Medical Devices (CAMD):
Swissmedic took part in the semi-annual meetings of the member states' umbrella group and contributed to several working groups. In addition, a Swissmedic representative sat on the organisation's steering committee, the CAMD Executive Group (CEG). The focal issues of the regular meetings and telephone conferences were the authorities' preparations for implementing the new regulation and the possible impacts of Brexit.

Medical Device Coordination Groups (MDCGs):
The EU Commission's MDCGs are the steering committees for implementation of the new medical devices regulations MDR and IVDR. Swissmedic is an observer in both groups and contributes to 13 working groups that are preparing for implementation. Particular mention should be made of the expert groups that address the various modules in EUDAMED, the EU's new central database. The database will register all economic operators and medical devices, provide a central information resource containing all relevant findings from the market and make certain data transparent to the general public. The Clinical Investigation expert group addressed the stricter requirements for clinical trials of medical devices.

STANDARDS PRODUCT GROUP

Legal Framework product

Technical Standards product

Medical Devices Regulation

In April 2017, the EU Commission adopted two regulations on medical devices (MDR) and in vitro diagnostics (IVDR). These Regulations supersede the existing guidelines and entered into force on 25 May 2017. Once various transition periods have expired (up to three years for the MDR, up to five for the IVDR), all member states are required to apply the regulations in full.

In Switzerland, medical devices are governed by the following legislation: TPA, Medical Devices Ordinance, Human Research Act, and Ordinance on Clinical Trials in Human Research. The aim of aligning Swiss medical device legislation with the new EU Regulations is to improve the safety and quality of medical devices in Switzerland. To avoid trade barriers between the two parties, it is essential to safeguard the equivalence of Swiss and EU legislation, as confirmed in the agreement between Switzerland and the EU on the mutual recognition of conformity assessments (MRA, chapter 4, part of the Bilateral Agreements I).

Switzerland intends to update its legal framework for medical devices simultaneously with the EU. The revised Medical Devices Ordinance and the new Ordinance on clinical trials of medical devices are scheduled to enter into force in May 2020.

Cannabis control

Trading in cannabis is forbidden under the current Narcotics Act (NarcA). Medical use is permissible only with an exemption, which the Federal Office of Public Health (FOPH) can issue under certain circumstances.

However, cannabis is increasingly being used in medical settings that do not fit the definition of exceptional circumstances to which restricted medical use in accordance with NarcA is subject. To resolve this contradiction, the current status of cannabis as an illegal narcotic is to be removed.

On 4 July 2018, the Federal Council fulfilled the Kessler motion (14.4164) by mandating the Federal Department of Home Affairs to prepare a bill to be submitted for consultation by mid-2019. The primary goal of revising NarcA is to lift the ban on cannabis trading for medical purposes. It should become possible to treat cannabis-based medicinal products in a similar way to other narcotic medicinal products such as opioid-based painkillers. Swissmedic is involved in the legislative work as the competent enforcement authority. Consultation took place during 2019.

New EU veterinary medicinal products legislation and Switzerland

On 27 January 2019, two new Regulations entered into force in the EU. These cover all regulatory aspects of veterinary medicinal products, such as placing on the market, manufacturing, dispensing, market surveillance, etc. (Regulation on veterinary medicinal products and Regulation on the manufacture, placing on the market and use of medicated feed). Both Regulations will apply in all EU countries from January 2022 following a three-year transition period.

In Switzerland, veterinary medicinal products, like human medicinal products, are governed by the Therapeutic Products Act and associated implementing ordinances.

The vast majority of Switzerland's veterinary medicinal products are sourced from the EU's veterinary pharmaceuticals industry. To continue to safeguard this supply, the legal framework governing the Swiss veterinary medicinal products market (authorisation procedures, dispensing and use requirements) will be harmonised with EU requirements as far as necessary and possibly also as far as politically expedient.

Various options were drafted on the basis of a study report that Swissmedic prepared in conjunction with the Federal Food Safety and Veterinary Office (FSVO), and which used a gap analysis to investigate the need for alignment. To avoid trade barriers, Swiss legislation will have to be amended and implemented with effect from 28 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. Swissmedic participates in the drafting of the Ph. Eur. under the terms of a treaty and issues supplementary regulations of national importance in the Ph. Helv.

In 2019, supplements 9.6, 9.7 and 9.8 entered into force and the 10th edition of the Ph. Eur. summary report was published.

By publishing a free online version of the Ph. Helv., Swissmedic drove forward the process of digitalising its business activities and contributed to the paradigm shift for national legislation. The electronic version has now superseded the printed version as the legally binding form of the pharmacopoeia. Since 1 July 2019, users have therefore had free access to both the main text and to supplement 11.3, which entered into force on the same date.

www.phhelv.ch

INFORMATION PRODUCT GROUP

Informing the General Public product

Informing the Therapeutic Products Sector product

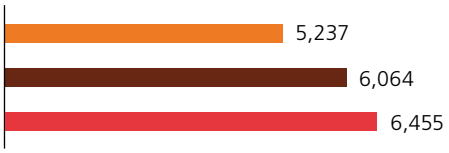
Enquiries and publications

The majority of questions in 2019 related to the revised TPA and its implementation in practice. The impending introduction of the new Medical Devices Regulation also gave rise to a lot of questions.

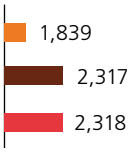
The Swissmedic website (www.swissmedic.ch) recorded growing visitor numbers in 2019. Demand for updated documents resulting from the revision of therapeutic products legislation was particularly strong. The number of visitors accessing the site from mobile devices rose once more, and now accounts for nearly one third of the total. In addition to medicinal product lists and safety advice, the electronic version of the Swissmedic Journal was one of the most-consulted items on the site.

In addition to the publications generally issued in the course of the year (Annual Report, Swissmedic Journal, Vigilance News and annual reports on market surveillance of human and veterinary medicinal products), Swissmedic issued 29 Direct Health Care Professional Communications (DHPCs) and Healthcare Professional Communications (HPCs). This important safety information is directed primarily at medical professionals and is distributed through various channels, including the Internet, a newsletter and a specialist journal. 722 publications on safety measures and recalls relating to medical devices were published.

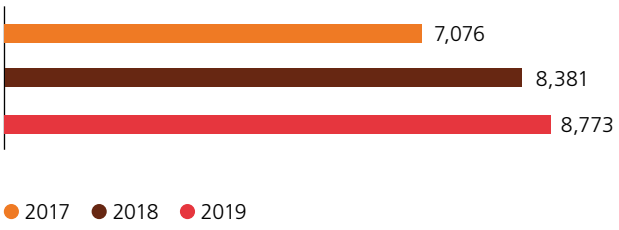
General enquiries (specialists/general public)



Medical device-related enquiries (specialists/general public)



Total

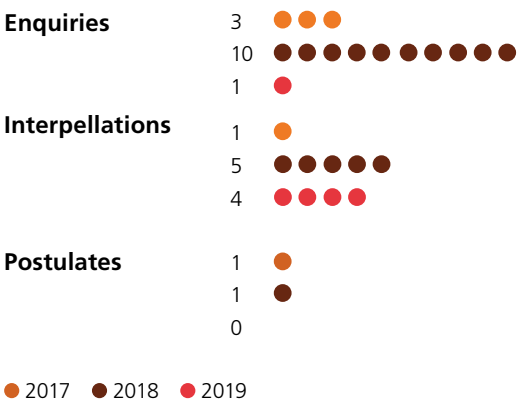


Parliamentary proposals

The number of parliamentary proposals for which Swissmedic was lead agency declined significantly on 2018.

The parliamentary proposals covered various topics, including pharmacovigilance, checking advertising prior to publication, paediatric medicinal products and safeguarding the neutrality of Swissmedic experts.

Parliamentary proposals



Press relations

The Media Unit dealt with around 550 enquiries from media representatives, slightly more than in the preceding year. In January Swissmedic hosted a media event on the key changes in therapeutic products legislation. The topics included the changes in dispensing categories, the problems presented by global trade in illegal medicines and questions about authorisation practice.

In the drug safety area of its work, the Agency regularly receives questions about the risks associated with individual medicines. Swissmedic specialists gave over 20 interviews on the topic. The business practices of CryoSave, a company that moved stem cells from umbilical cord blood that it had collected to a location abroad, made headlines in summer.

The international consortium of investigative journalists working on the "Implant Files" continued their reporting, focusing on medical device safety and the amendments to Swiss medical devices legislation.

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 in 2019 primarily related to official documents associated with the authorisation of medicinal products. There was a year-on-year rise in the number of requests to inspect official documents associated with medical devices.

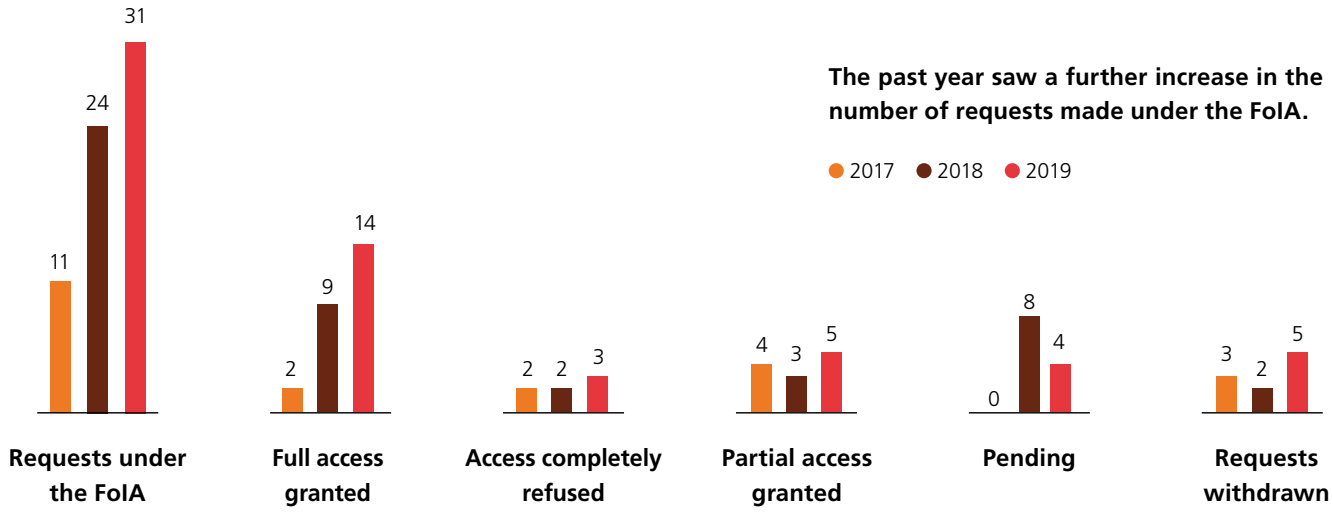
Appeals against Swissmedic decisions on access to official documents may be lodged with the Federal Administrative Court within 30 days. One decision was contested in 2019, proceedings before the Federal Administrative Court are pending.

Events

In addition to the meetings mentioned in the Swissmedic and its national stakeholder groups section of this report, the Agency conducted the following events in 2019:

- Haemovigilance workshop for hospital haemovigilance officers
  Subject: training on adverse events involving blood products
- Swissmedic inspector training for inspectors from health authorities in Switzerland and abroad
  Subject: inspecting API manufacturers and distributors
- Clinical trial symposium for people working on clinical trials
  Subject: safety, quality and GCP inspections in clinical trials
- Swissmedic Regulatory News for people working in regulatory affairs
  Subject: current regulatory issues
- Information and news on narcotics for people who work with controlled substances and preparations
  Subject: current regulatory issues
- Quality defects meeting for regulatory agency staff
  Subject: information- and experience-sharing on quality defects in medicinal products

The past year saw a further increase in the number of requests made under the FoIA.



MARKET ACCESS PRODUCT GROUP

Authorisation product

Overview

Application statistics

In total, 14,200 authorisation and other applications were completed in 2019. This figure does not include applications for variations and major variations under the old legislation (i.e. those submitted before 1 January 2019).

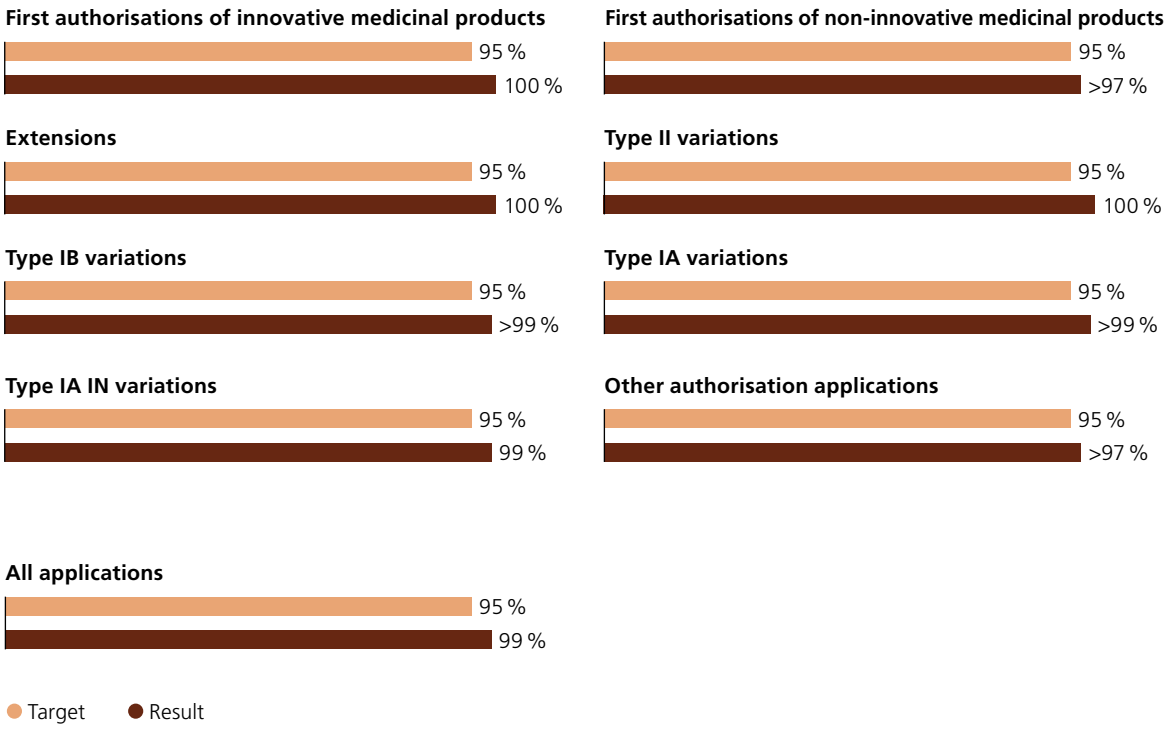
1,781 applications were submitted as multiple applications. While the majority of these consisted of two applications, the largest number was 52.

Of the 19 scientific advice meetings, 22 presubmission meetings and 11 clarification meetings requested during the year, 40 were answered in writing, while meetings took place in 12 cases.

Time limits

In 2019, 99% of all applications dealt with under the new legislation were processed and completed on schedule. For innovative medicinal products, the time limits were respected in 100% of cases; the figure for non-innovative medicinal products was 97.4%.

Performance indicator



Lead times

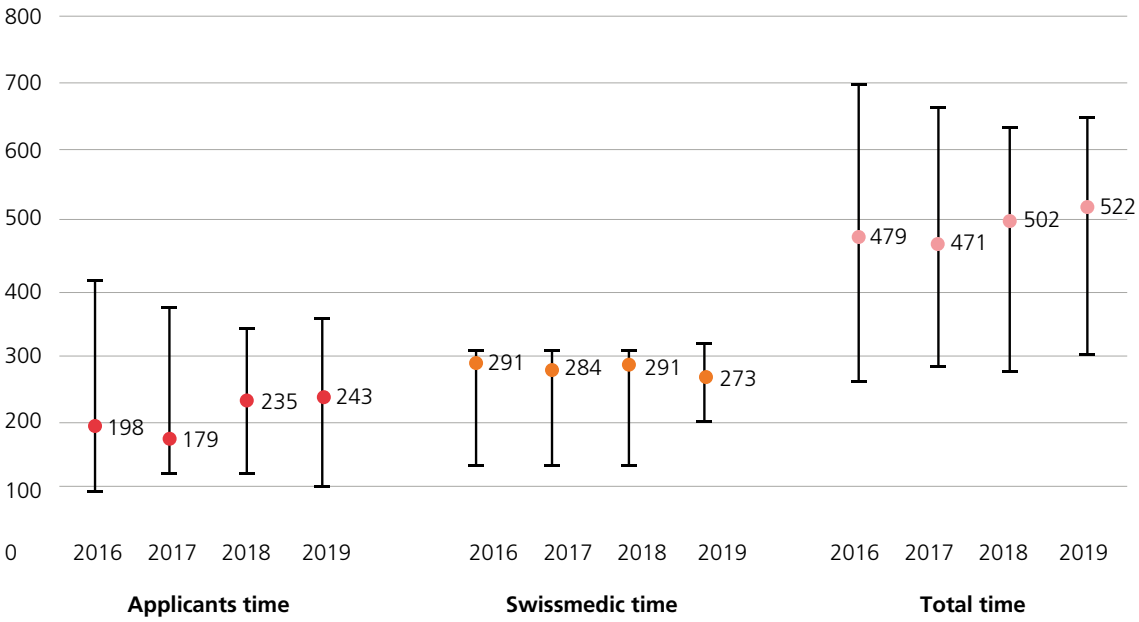
The table below shows total processing time divided between Swissmedic and applicants for new active substances authorised between 2016 and 2019. It covers all authorisation procedures (fast-track procedure, procedure with prior notification and procedure under Art. 13 TPA). The median lead time for each is shown (in calendar days), as are the 90th and 10th percentiles.

Biosimilars

Since the beginning of 2019, it has been possible to authorise biosimilars under Article 13 TPA if the European Commission (at the EMA's recommendation) or FDA has already authorised the biosimilar in question. Applicants made active use of this option, with nine out of ten biosimilar applications being submitted under Article 13 TPA.

Lead times
New active substances authorized (all authorisation procedures)

Number of applications per year
2016: 39 2017: 29 2018: 26 2019: 28



Human medicinal products

New authorisations

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) and non-innovative medicinal products (medicinal products with known active substances and co-marketing medicinal products). Extensions (e.g. a new pharmaceutical form of a medicinal product) require a new authorisation procedure.

The following were completed during 2019:
- 70 applications for new authorisations and extensions for innovative medicinal products
- 16 applications for extensions under the new legislation
- 140 applications for first authorisation of non-innovative medicinal products, including 30 applications for co-marketing products.
- 17 applications to parallel-import a medicinal product

Of the 30 medicinal products with new active substances that were authorised for the first time, two were authorised under the fast-track procedure.

Variations

An application must be made for any variation to a medicinal product authorised by Swissmedic. A distinction is made between minor variations that can be reported after the fact (type IA/IA IN), variations that have to be notified prior to implementation (type IB) and major variations (type II).

The following were completed in the year under review:

5,253
type IA/IA IN variations

4,402
type IB variations

784
type II variations

These figures include all applications for variations, regardless of whether these were single or multiple applications. However, collective applications are only counted as one application.

Fast-track authorisation procedure

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

Once Swissmedic is satisfied that these conditions have been met, the request for the fast-track procedure is approved and the relevant application may be submitted. Swissmedic's time limit for processing the application is reduced from 330 to 140 days.

The following were completed in the year under review:
- 20 requests for fast-track authorisation
- 2 applications for first-time authorisation
- 8 extensions

All applications were completed within the prescribed time limits.

Procedure with Prior Notification (PPN)

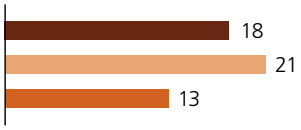
If applicants provide three to six months' advance notification of submission, Swissmedic will review their application 20% faster provided certain prerequisites are met (e.g. the product is a human medicinal product with a new active substance, the application is for an extension, preclinical and clinical trials will have been completed at the time of submission and Swissmedic has sufficient staffing capacity). If they are, the PPN request is approved and the application can then be submitted under the "procedure with prior notification". Swissmedic's time limit for processing the authorisation application is reduced from 330 to 264 days.

The following were completed in the year under review:
- 13 applications for PPN, all of which were approved
- 4 applications for new authorisation
- 10 extensions
- 1 authorisation of a new pharmaceutical form

All PPNs were completed within the prescribed time limits.

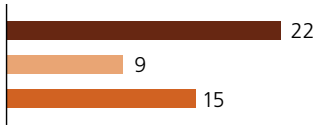
Growth in requests for PPNs over the last three years:

PPN requests received



PPN requests approved

PPN requests withdrawn



Authorisation applications approved using PPN

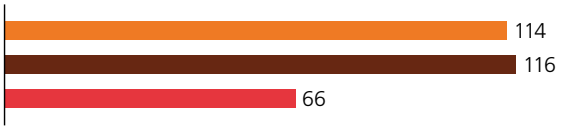
* Excludes major variations under the old legislation.

Applications under Article 13 TPA

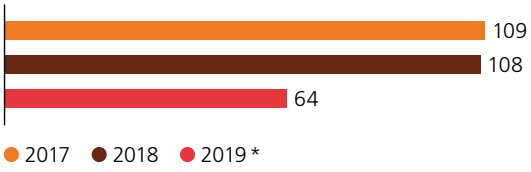
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose provided various requirements are satisfied (e.g. the submitted documents from the foreign procedure are not more than five years old and correspond to the authorisation status in the other country; full final assessment reports exist).

The following were completed in the year under review:
- A total of 66 applications, of which 64 (97%) were approved
- 3 new notifications of a new active substance
- 12 known active substances with innovation
- 2 biosimilars
- 35 known active substances without innovation
- 1 authorisation extension
- 1 indication extension
- 12 variations

Completed applications under Art. 13 TPA



Approved applications under Art. 13 TPA



* Excludes major variations under the old legislation Factoring these in, completed applications under Art. 13 TPA increased 70% year-on-year.

Applications under Article 14 TPA

The revised TPA now includes the option of requesting simplified authorisation procedures for new and known active substances that have been authorised abroad for many years or with which practical experience has been acquired over a period of many years.

The new procedure was actively used during 2019. 23 applications for human and veterinary medicinal products were received, the vast majority of which cited 10 years' authorisation in the EU/EFTA.

Orphan drugs

Swissmedic may, upon application, recognise orphan drug status for medicinal products used to treat rare diseases. Applicants must prove that the medicinal product is 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 a country with comparable medicinal product control. Most applications are based on recognition of orphan drug status in another country with comparable medicinal product control, and in particular by the European Medicines Agency (EMA) or the US Food and Drug Administration (FDA). Medicinal products can be authorised as orphan drugs either while the recognition process is in progress or once the status has been recognised (usual case).

The following were completed in the year under review:

- 48 applications for recognition of orphan drug status
- 48 status grants spread over 41 preparations
- 15 preparations approved as new orphan drugs
- Additional orphan indications approved for one preparation
- Status discontinued for five products

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.

In 2019, the submission of PIPs once again proved helpful in the notification of paediatric clinical trials. A total of 25 paediatric trials was authorised.

Novel processes

Swissmedic also authorises special manufacturing processes. This is necessary 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. This process is typically used for labile blood products and transplant products.

The following were processed in 2019:

- 1 extension of the authorisation for a pathogen inactivation process for platelets
- 1 change in the quality documentation for this process
- 1 application for authorisation of a transplant product process based on autologous fat stem cells and destined for a cosmetic indication

Note: The Transplantation Act does not distinguish between medical and cosmetic indications; the Therapeutic Products Act (TPA) is also applicable to cosmetic indications.

Transplant products

Under the Transplantation Act, products from somatic cell therapy, tissue cultures and ex vivo gene therapy are equivalent to medicinal products and thus also subject to the TPA. Compliance with legal provisions is verified, and products are also assessed for safety and efficacy using a risk-based approach.

The following were processed in 2019:
- 3 authorisation applications for products with new active substances (NAS), specifically 1 regular authorisation of a chondrocyte product, 1 authorisation of an oligonucleotide product under Art. 13 TPA and 1 CAR T-cell product under a fast-track procedure
- 2 other authorisation applications, including 1 fast-track procedure and 1 Art. 13 TPA (reviews still in progress)
- 3 new applications for fast-track procedures (approved)
- 6 applications for recognition of orphan drug status (approved)
- 33 applications for a quality variation requiring approval (23 official decisions issued)
- 6 applications for a variation in clinical documents (4 official decisions issued)
- 3 answers to quality conditions (2 official decisions issued)
- 8 answers to clinical document conditions plus 2 from 2018 (10 official decisions issued)
- 8 Periodic Safety Update Reports (5 official decisions issued)

Initial experience of issuing a temporary licence for a vaccine that had been modified using gene therapy (also known as compassionate use) was acquired.

Vaccines

Vaccines are an extremely important medicinal product category from a public health perspective because of their essential role in protecting the public. Since 2019, an internal, interdisciplinary Vaccine Focus Team have been providing an additional peer review that puts decisions on vaccines by the Authorisation sector on a broader, more transparent footing. Specifically, the focus team tracks every new application, extension application and new dosage recommendation for vaccines, ensuring a standardised, high-quality assessment that takes account of public health and supply considerations.

Complementary and herbal medicines

Complementary and herbal medicines (CHMs) enjoy a high level of acceptance in Switzerland. Swissmedic ensures that the main authorisation requirements for these product groups are respected. All CHMs are essentially eligible for simplified authorisation under the general provisions of the Complementary and Phytotherapeutic Products Ordinance (CPTPO). Quality, safety and tolerability must be guaranteed in each case.

92% of CHM applications were completed within the time limits in 2019.

Complementary medicinal products

Complementary medicinal products comprise homeopathic, anthroposophic and Asian (Chinese, Tibetan or Ayurvedic) medicinal products. In addition to medicinal products with a specified area of use (indication), a wide range of medicinal products with no indication is authorised in these product groups. Medicinal products without an indication are generally authorised using a greatly simplified authorisation or notification procedure.

The following were completed in the year under review:

- 6 applications for the new authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication.
- 9 applications for simplified authorisation with a reduced dossier; of these, 4 preparations were authorised, and 5 applications were rejected or withdrawn.
- 2 applications for simplified authorisation of veterinary medicinal products with a reduced dossier (approved)
- 86 products without an indication using the notification procedure; 39 of these were single products, 47 were combined products.
- 25 single products for use in gemmotherapy without an indication using the notification procedure

Herbal medicinal products

Herbal medicinal products contain only herbal substances or preparations. 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. It is possible to apply for conventional authorisation of herbal medicinal products that have been used for medicinal purposes for at least 30 years, of which at least 15 must have been in an EU or EFTA state.

The following were completed in the year under review:

- 6 applications for non-innovative new authorisations (all co-marketing products)

Veterinary medicinal products

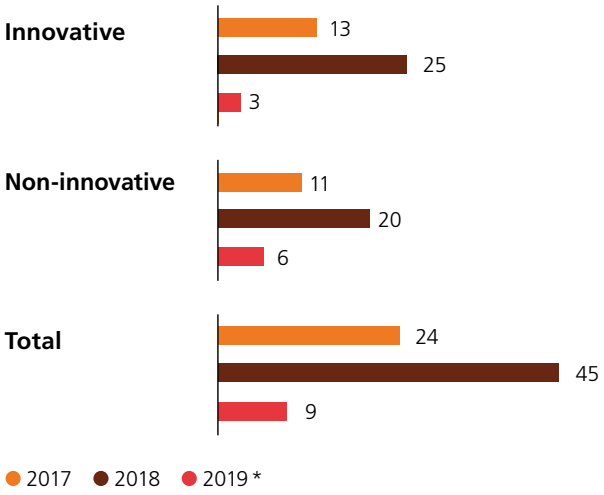
New authorisations

New authorisation of veterinary 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) and non-innovative medicinal products (medicinal products with known active substances and co-marketing medicinal products). Extensions (e.g. a new pharmaceutical form of a medicinal product) require a new authorisation procedure. One important aspect of the safety assessment of products that are used in livestock is their effect on the safety of foodstuffs. The current standards defined in foodstuffs legislation are used within the authorisation procedure to specify the medicinal product residue levels that can be tolerated in foodstuffs such as meat, milk, eggs or honey when a product has been administered to cattle, poultry or bees.

The following were completed in the year under review:

- 3 applications for new authorisations and extensions for innovative medicinal products
- 6 applications for new authorisations of non-innovative medicinal products

Number of completed first-time applications for authorisation



* Excludes major variations under the old legislation.

All of these applications were processed within the prescribed time limits.

Variations

A request must be submitted to Swissmedic for any change to a veterinary medicinal product that has already been authorised. A distinction is made between minor variations that can be reported after the fact (type IA/IAIN), variations that have to be notified prior to implementation (type IB) and major variations (type II).

The following were completed in the year under review:

272
type IA and IA IN variations

249
type IB variations

41
type II variations

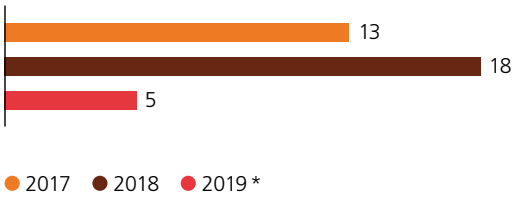
These figures include all applications for variations, regardless of whether these were single or multiple applications. However, collective applications are only counted as one application.

Applications under Article 13 TPA

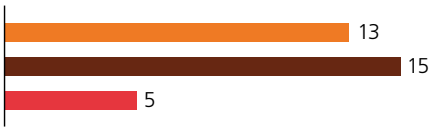
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose provided various requirements are satisfied (e.g. the submitted documents from the foreign procedure are not more than five years old and correspond to the authorisation status in the other country; full final assessment reports exist).

The following were completed in the year under review:
- A total of 5 applications, all of which were approved (100%)
- 1 new notification of a new active substance
- 4 variations

Completed applications under Art. 13 TPA



Approved applications under Art. 13 TPA



* Excludes major variations under the old legislation.

Appeals procedure for authorisation of medicinal products

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

15 appeals against official decisions were lodged with the FAC during 2019.

The FAC and FSC ruled on one case each. The FAC cancelled one appeal, the FSC rejected another.

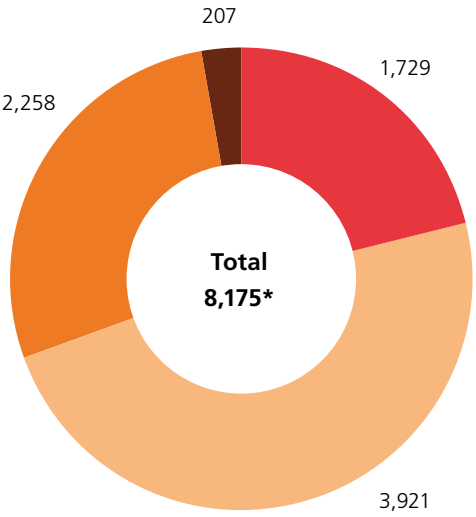
Medicinal products: facts and figures

Medicinal products: facts and figures

Therapeutic products code	Number of authorised medicinal products
Human medicinal products	
Synthetics	4,920
Biotechnologicals	357
Vaccines	62
Blood products	63
Radiopharmaceuticals	58
Allergen preparations	291
Bacterial and yeast products	23
Antidotes/antivenins	41
Transplant products	8
Phytopharmaceuticals	538
Lozenges	49
Homeopathics	643
Anthroposophics	385
Ayurvedic medicinal products	1
Tibetan medicinal products	6
Homeopathic and anthroposophic medicinal products authorised under the notification procedure and medicinal products for gemmotherapy without indication	11,570
Veterinary medicinal products	704

Number of authorisations by dispensing category as at end-2019

Dispensing category/Authorised medicinal products with number of authorised medicinal products



- Dispensed once only on medical or veterinary prescription
- Dispensed on medical or veterinary prescription
- Dispensed after expert advice
- Dispensed without expert advice

* 60 medicinal products are still assigned to dispensing category C (in pharmacies without a medical prescription) because the reassignment process could not be completed.

Overview of authorisation applications completed in 2019

	HAM	KPA	TAM	Total
New applications, new active substances (NAS)	34	–	1	**35**
New applications, biosimilars	9	–	–	**9**
New applications, known active substances (KAS) with innovation	23	10	2	**35**
New applications, known active substances (KAS) without innovation	83	–	6	**89**
Authorisation of co-marketing medicinal products	23	7	–	**30**
Indication extension (IE) (under new legislation)	16	–	–	**16**
Authorisation extension (under new legislation)	3	–	–	**3**
Type II variations (without IE) (under new legislation)	771	13	41	**825**
Type IB variations (under new legislation)	4,120	282	249	**4,651**
Type IA/IAIN variations (under new legislation)	5,035	218	272	**5,525**
Scientific advice, presubmission or clarification meetings	42	8	2	**52**

HAM Human medicinal products
KPA Complementary and herbal medicines
TAM Veterinary medicinal products

Trends for applications under Art. 13 TPA

	2017		2018		2019 *	
	Appr.	Rej.	Appr.	Rej.	Appr.	Rej.
Human medicinal products						
New active substances	0	2	3	0	3	0
Known active substances with innovation	10	2	9	2	11	1
Biosimilars	0	0	0	0	2	0
Known active substances without innovation	38	1	50	4	35	0
Known active substances of complementary and herbal medicines	0	0	0	0	0	0
Additional indications	3	0	4	0	0	1
Extensions	2	0	3	0	1	0
Variation applications	56	0	39	2	12	0
Total	**109**	**5**	**108**	**8**	**64**	**2**
Veterinary medicinal products						
New active substances	0	0	0	0	1	0
Known active substances with innovation	2	0	0	0	0	0
Known active substances without innovation	5	0	9	1	0	0
Additional indications	0	0	1	1	0	0
Extensions	2	0	1	1	0	0
Variation applications	4	0	4	0	4	0
Total	**13**	**0**	**15**	**3**	**5**	**0**

* Excludes major variations and applications for variations under the old legislation
Appr. = Approval
Rej. = Rejection/application withdrawn

Human medicinal products with a new active substance authorised in 2019

Therapeutic area (ATC)	Active substances	Name of medicinal product	Application
Alimentary tract and metabolism	Mercaptamine bitartrate	Procysbi, gastroresistant capsules	Nephropatic cystinosis
Blood and blood-forming organs	Caplacizumab	Cablivi, powder and solvent for solution for injection	Acquired thrombotic thrombocytopenic purpura (aTTP)
	Damoctocog alfa pegol	Jivi, powder and solvent for solution for injection	Haemophilia A
	Turoctocog alfa pegol	Esperoct, powder and solvent for solution for injection	Haemophilia A
	Iron(III) as iron isomaltoside	Monofer, solution for intravenous injection/infusion	Iron deficiency
	Lanadelumab	Takhzyro, solution for injection	Prophylaxis of attacks of hereditary angioedema
Dermatologicals	Dupilumab	Dupixent, pre-filled syringe with safety system	Moderate to severe atopic dermatitis
Anti-infectives for systemic use	Avibactam sodium, ceftazidime pentahydrate	Zavicefta, powder for concentrate for solution for infusion	Infectious diseases
	Doravirine	Pifeltro, film-coated tablets	HIV infection
	Bictegravir sodium, emtricitabine, tenofovir alafenamide hemifumarate	Biktarvy, film-coated tablets	HIV infection
	Haemophilus influenzae type b polysaccharide, Neisseria meningitidis B outer membrane protein complex, hepatitis B viral antigen, pertussis toxoid, filamentous haemagglutinin, pertactin, type 2 and 3 fimbriae, diphtheria toxoid, tetanus toxoid, inactivated type 1 poliovirus (Mahoney), inactivated type 2 poliovirus (MEF-1), inactivated type 2 poliovirus (Saukett)	Vaxelis, suspension for injection	Primary and booster vaccination in infants and toddlers between the ages of 6 weeks and 4 years (before 5th birthday) against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b (Hib)
Antineoplastic and immunomodulating agents	Gemtuzumab ozogamicin	Mylotarg, powder for concentrate for solution for infusion	Acute myeloid leukaemia
	Binimetinib	Mektovi, film-coated tablets	Melanoma with a BRAF V600 mutation
	Encorafenib	Braftovi, hard capsules	Melanoma with a BRAF V600 mutation
	Dacomitinib monohydrate	Vizimpro, film-coated tablets	Advanced or metastatic non-small cell lung cancer (NSCLC)
	Abemaciclib	Verzenio, film-coated tablets	Locally advanced or metastatic HER2-negative breast cancer
	Talazoparib tosylate	Talzenna, hard capsules	Germline BRCA-mutated, HER2-negative, locally advanced or metastatic breast cancer
	Apalutamide	Erleada, film-coated tablets	Non-metastatic castration-resistant prostate cancer (nmCRPC)

	Risankizumab	Skyrizi, solution for injection	Moderate to severe plaque psoriasis
	Tildrakizumab	Ilumetri, solution for injection	Moderate to severe plaque psoriasis
	Axicabtagene ciloleucel	Yescarta	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Primary mediastinal B-cell lymphoma (PMBCL)
Musculoskeletal system	Autologous cultured chondrocytes	Spherox, suspension for implantation	Symptomatic articular cartilage defects of the femoral condyle and the patella of the knee
Nervous system	Fremanezumab	Ajovy, solution for injection in prefilled syringe	Migraine prophylaxis
	Galcanezumab	Emgality, solution for injection in prefilled pen	Migraine prophylaxis
	Fampridine	Fampyra, prolonged-release tablets	Multiple sclerosis
	Patisiran sodium	Onpattro, concentrate for solution for infusion	Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)
	Edaravone	Radicava, solution for infusion	Amyotrophic lateral sclerosis (ALS)
Respiratory system	Ivacaftor, tezacaftor	Symdeko, film-coated tablets	Cystic fibrosis
Miscellaneous	Lutetium (177Lu) oxodotreotide	Lutathera, solution for infusion	Metastatic or unresectable progressive, well differentiated (G1 and G2) somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours (GEP-Nets)

Veterinary medicinal products with a new active substance authorised in 2019

Therapeutic area (ATC)	Active substances	Name of medicinal product	Application
Cardiovascular system / calcium channel blocker	Amlodipine	1.25 mg ad ad us. vet	For the treatment of systemic hypertension in cats

Licensing product

Licensing of medicinal and transplant products

Establishment licences for medicinal and transplant products

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 require an establishment licence. Swissmedic issues this licence on the basis of a successful inspection or other evaluation.

Activities:
Swissmedic has been issuing establishment licences under the revised therapeutic products legislation (TPA and Medicinal Products Licensing Ordinance) since January 2019. The format of licences has changed, and licences are valid for an indefinite period.

More than a third of companies applied to have their establishment licence modified or extended during 2019 and now hold a licence issued under the new legislation.

Overall, fewer establishment licences were issued, extended, modified or revoked than in the previous year. The total was 688, compared with 844 in 2018.

Manufacturers of medicinal products and transplant products who hold an establishment licence issued under the new legislation are registered in the Eudra-GMDP database operated by the European Medicines Agency (EMA) on the basis of the agreement between Switzerland and the European Union on the mutual recognition of conformity assessments.

Performance indicator

Establishment licences: proportion of procedures that were completed within six months

● Target ● Result

Special licences for medicinal products

On application, Swissmedic issues medical professionals with a special licence to import small quantities of medicinal products that are not authorised in Switzerland, but which are essential for the treatment of certain animals or animal populations. Responsibility for importing, using or dispensing these products lies solely with the medical professional in question.

Activities:
Since 1 January 2019, and in accordance with the revised therapeutic products legislation, Swissmedic has only been issuing special licences for the import of veterinary medicinal products. The number of special licences has therefore declined substantially on the previous year.

Total number of special licences issued

1,152
2017

1,401
2018

636
2019

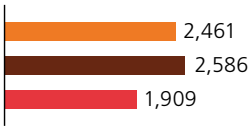
Certificates for medicinal and transplant products

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 their current authorisation status in Switzerland in French, English or Spanish.

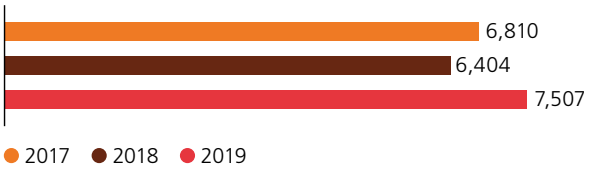
Activities:
Following the introduction of the new establishment licence format, manufacturers of medicinal products, their trading partners and medicinal product regulatory authorities can search for certificates in the Eudra-GMDP database. As a result, the number of GMP/GDP certificates issued has fallen.

Since 2019 it has also been possible to order GMP/GDP certificates via the online portal. This form of ordering, which was introduced for product certificates in 2018, is efficient and simplifies oversight.

GMP/GDP certificates issued



Product-specific certificates issued



Performance indicator

GMP/GDP certificates: percentage of procedures completed within 14 days

Product-specific certificates: percentage of procedures completed within 28 days

Target Result

Control of the flow of narcotics

Swissmedic issues establishment licences to companies and individuals that handle controlled substances. Every import and export of controlled substances must be licensed in advance by Swissmedic. Swissmedic must be notified of domestic deliveries of narcotics in Lists A, B and D. Licence holders must keep records of all transactions involving controlled substances. These records must be used to prepare annual accounts for submission to Swissmedic. The Agency examines these accounts and forwards a consolidated report to the International Narcotics Control Board (INCB, UN, Vienna) in accordance with international agreements.

Import and export permits granted for controlled substances

Performance indicator

Import and export permits for controlled substances: percentage of procedures completed within 10 days

Target Result

Activities:
In the year under review, 370 companies held an establishment licence for handling controlled substances. More applications for modifications, renewals or the start of operations were processed than in the previous year, with the figure totalling 175.

For the purpose of reporting to the International Narcotics Control Board (INCB) in accordance with international agreements, Swissmedic examined the annual accounts submitted by 464 company sites.

The Agency reviewed the group listing of lysergic acid and nitazene derivatives, plus 11 new psychoactive substances, and applied to the Federal Department of Home Affairs for their inclusion in NarcLO-FDHA.

Clinical trials of medicinal products and transplant 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 180 applications for clinical trials of medicinal products during the year under review. Of these, it processed 176 and returned the remainder because they were incomplete.

A total of 163 clinical trials was approved. Five were for first-in-human trials. One clinical trial was withdrawn by its sponsor while it was under review. The other applications are currently being processed. The increase in product complexity – and thus in application dossier complexity – that has been observed since 2016 continued in 2019.

In addition, Swissmedic processed 3,048 other requests or notifications relating to clinical trials of medicinal products (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, end-of-trial reports) as well as 105 reports of suspected unexpected serious adverse reactions (SUSARs).

New clinical trial submissions

Approved clinical trials

Submitted trials, rejected

2017 2018 2019

Clinical trials of transplant products, medicinal products for gene therapy and genetically modified organisms (TpP/GT/GMO)

Activities:
Swissmedic received six applications for clinical trials of transplant products. While the majority were for cancer therapies, some were for first use in humans.

Swissmedic processed 84 clinical trial amendments. In several cases, these affected the quality-related part of the documentation submitted.

Performance indicator

First submissions of clinical trials: percentage of applications reviewed within 30 days

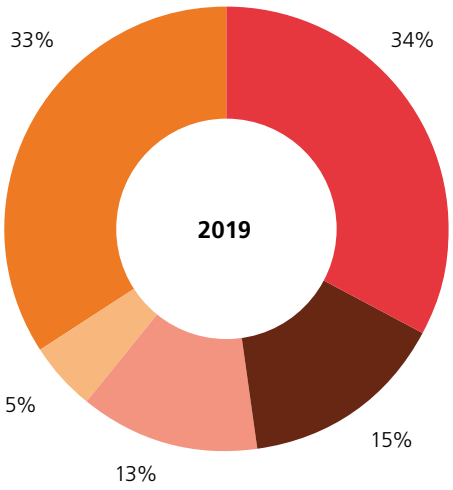
Target Result

Inspections

GMP and GDP inspections

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

Activities:
During the year under review, a total of 571 GMP/GDP inspections of manufacturers and wholesale companies was carried out. 511 were carried out by the regional inspectorates, 60 by Swissmedic. Swissmedic inspected the following areas:



- 33% transplant products
- 15% blood transfusion activities
- 13% preapproval inspections
- 5% for-cause inspections
- 34% pharmaceuticals

Performance indicator

Licensing inspections: percentage fulfilment of annual planning

Target Result

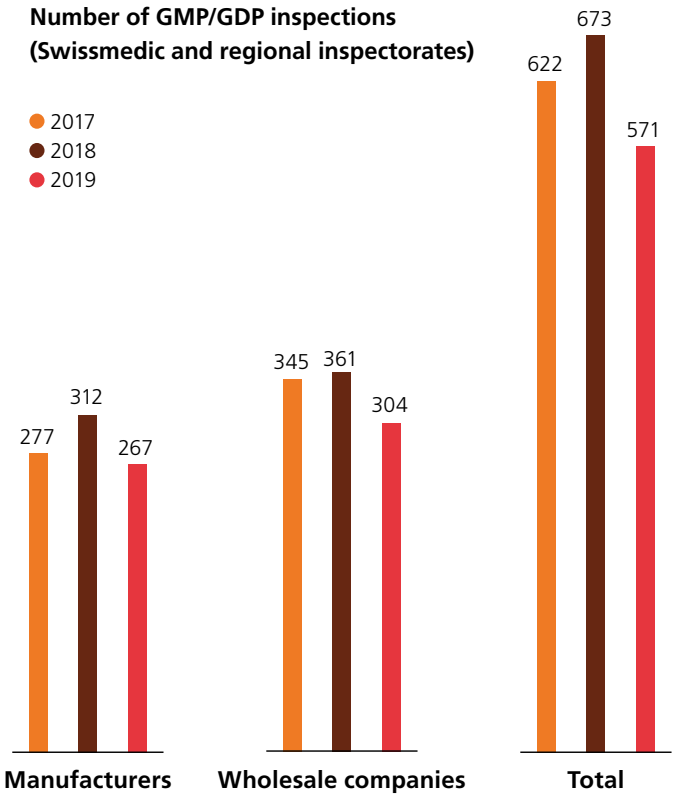
In 2019, Swissmedic once again took part in international inspection programmes run by partner authorities outside Switzerland. Three active substance manufacturers in India were inspected with the EDQM. In addition, Swissmedic took part in evaluations of partner authorities under the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and participated in the reassessment of Health Canada's GMP surveillance system under the existing Mutual Recognition Agreement between Switzerland and Canada.

In light of the new requirements that entered into force in January 2019, the implementation of mandatory licensing for brokers and agents was addressed and a standard procedure for inspecting such institutions was defined. As a result, several companies decided to stop working with brokers or agents for their medicinal products.

Drawing on the knowledge acquired from global investigations of impurities in certain active substances, inspections focused increasingly on solvent preparation and the reprocessing of non-conforming active substances.

Once again, there was a sharp increase (+37%) in reports of major changes to installations, facilities and procedures that impacted GMP/GDP. Swissmedic subsequently drew up a technical interpretation document specifying the relevant changes introduced by the ordinances.

Swissmedic expanded its monitoring of institutions that work with tissues and cells for autologous transplantation. During the year under review, 19 institutions notified the Agency that they had commenced relevant activities. This takes the total number of institutions registered with Swissmedic as conducting such activities to 53. In the course of six inspections, the Agency carried out random checks of compliance with legal quality assurance requirements relating to cells and tissues. The inspections focused primarily on umbilical cord blood banks, which store autologous cells from the umbilical cord and institutions that collect autologous blood stem cells. In one case, Swissmedic was obliged to open administrative proceedings and stop the institution in question from continuing activities involving tissues and cells for autologous transplantation.



GCP and GVP inspections

Clinical trials carried out in Switzerland by sponsors and contract research organisations are inspected by Swissmedic on a random basis according to defined risk criteria with regard to compliance with the rules of Good Clinical Practice (GCP). The same applies to trial locations, facilities and laboratories. In doing so, Swissmedic also verifies whether the safety and personal rights of the study participants are guaranteed. Checks are also carried out to establish whether trial implementation satisfies 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 the year under review, Swissmedic inspected a total of 21 clinical trials of medicinal products in Switzerland and accompanied 52 GCP inspections by the EMA in Switzerland.
Swissmedic also conducted ten GVP inspections in Switzerland and accompanied three GVP inspections under PIC/S inspection programmes in Portugal, Spain and Slovenia.

Performance indicator

GCP / GVP inspections: percentage fulfilment of annual planning

Target Result

GLP inspections

With the exception of pharmacodynamic testing, non-clinical trials associated with notification or authorisation procedures in Switzerland have to be conducted in accordance with Good Laboratory Practice (GLP). Swissmedic's GLP unit 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. Additional requirements imposed by other authorities, such as those for medical devices imposed by the FDA, are also taken into account.

Activities:
In 2019, Swissmedic inspected GLP compliance at a total of eight assessment facilities and two service providers in partnership with the FOPH and FOEN. Four of these inspections were conducted entirely by Swissmedic GLP inspectors; three more were carried out in partnership with the FOPH and FOEN.

The three GLP units held quarterly meetings for the purpose of sharing information from important OECD and EU international working groups. Inspector training was a further focus area, as was consultation on technical issues.

Performance indicator

GLP inspections; degree to which the annual plan was fulfilled

● Target ● Result

Inspections for third parties

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

Activities:
In the year under review, 28 inspections were carried out for the FOPH and two 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:
Foreign authorities carried out a total of 67 inspections at pharmaceutical companies in Switzerland, a fall of around 20% compared with the previous year. The inspecting authorities concerned were from the USA (30 inspections), Russia (24), Belarus (4), Turkey, Brazil and Libya (two each), Saudi Arabia, Yemen and Mexico (one each).

In addition, Swissmedic accompanied two GCP inspections by the EMA during 2019.

Inspections by foreign authorities in Switzerland

94
2017

83
2018

69
2019

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:
Changes in the blood transfusion service necessitated by the revised Medicinal Products Licensing Ordinance were implemented smoothly since the key changes had been implemented in Switzerland even before the Ordinance was amended.

The effects of the blood donation criteria for men who have sex with men (MSM) that were introduced in mid-2017 are regularly evaluated. As yet, the changed rules have not brought about any significant growth in the overall donor population. At the same time, no increase in the number of donors with positive infection markers was observed. A number of donors who had been diagnosed with an infectious disease had not completed the questionnaire properly.

As is the case every year, it was necessary to adapt donor suitability criteria in order to stave off the risks to blood product safety posed by the specific epidemiological situations, such as the – in some cases seasonal – spread of transmissible diseases like dengue fever and Chagas disease, or cases of West Nile virus (WNV) and Chikungunya disease in nearby countries.

Licensing of microbiological laboratories

Establishment licences for microbiological laboratories

The Federal Act on Combating Communicable Human Diseases (Epidemics Act, EpidA) requires laboratories that conduct, or intend to start conducting, microbiological testing for the identification of communicable diseases to obtain an establishment licence from Swissmedic. This requirement applies to microbiological laboratories that carry out diagnostic and epidemiological tests (patient diagnosis), microbiological tests to rule out a disease transmitted by blood, blood products or transplants (screening) or microbiological tests on environmental samples (environmental analytics).

Activities:
At the end of 2019, 104 microbiological laboratories held a licence issued by Swissmedic under the revised Epidemics Act. This leaves nine laboratories which, as a result of the transitional provisions, still possess a licence issued under the old legislation. These transitional provisions will expire at the end of 2020.

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 the statutory provisions and periodically carries out inspections.

Activities:
Swissmedic inspected 26 licensed laboratories. These inspections took account of whether or not laboratories have been accredited by the Swiss Accreditation Service (SAS).

Inspections of microbiological laboratories

26
2017

33
2018

26
2019

Official Medicines Control Laboratory

Swissmedic's accredited Official Medicines Control Laboratory (OMCL) is responsible for the official batch release of stable blood products and vaccines, and supports the various sectors of Swissmedic by carrying out laboratory analyses and developing and assessing methods.

Activities:
Electronic submission of batch release applications via the Swissmedic Portal was successfully implemented. The number of plasma pools tested rose once more.

Testing for nitrosamines in sartans, ranitidine and metformin was carried out extensively throughout the year. The results prompted several product batch recalls.

The OMCL was successfully accredited to the new ISO/IEC 17025:2017 standard in the year under review.

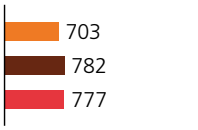
Performance indicator

Batch release: percentage of assessments completed within the prescribed time limits

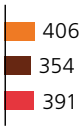
● Target ● Result

Blood products

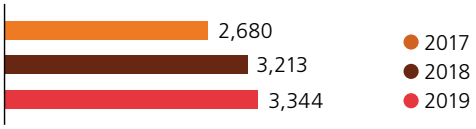
Batch assessments (CH, EU and WHO)



Notifications

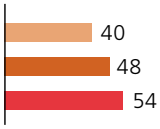


Plasma pool tests

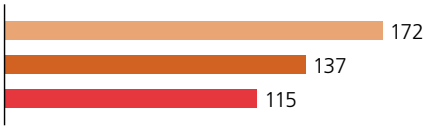


Vaccines

Batch assessments (CH, EU and WHO)

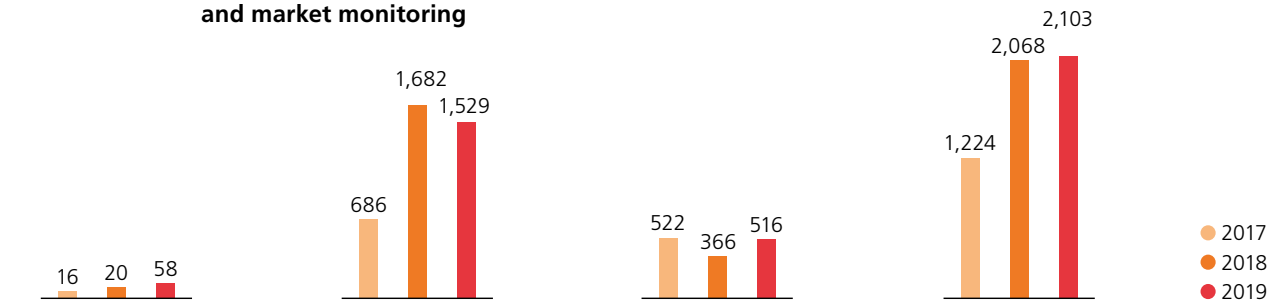


Notifications



Product analyses as WHO reference laboratory

Analyses completed for new marketing authorisations and market monitoring



Medicinal products analysed as part of authorisation

Medicinal products analysed as part of market monitoring

Other (pharmacopoeia, round robin tests)

Total

Appeals procedure regarding licensing for medicinal products and transplant products

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

Three appeals against official decisions were lodged with the FAC during 2019.

The FAC ruled on two cases, rejecting both appeals. The FSC also ruled on two cases, upholding one, and partially upholding the other.

Establishment licences in facts and figures

Companies with Swissmedic licences issued under the old legislation (the licences are distributed across 690 companies)

Manufacturing of medicinal products (under old legislation)	
Manufacturing of medicinal products (with a licence for distribution)	139
Manufacturing of medicinal products (without a licence for distribution)	69
Institutions with a Swissmedic licence for handling blood or labile blood products (blood transfusion activities)	23

Distribution of medicinal products (under old legislation)	
Import of medicinal products	315
Wholesale trade of medicinal products	509
Export of medicinal products	247
Trading in medicinal products abroad	197

Microbiological laboratories	
Microbiological laboratories with a Swissmedic licence issued under the old procedure (1 January 2016 to 31 December 2018; activities A, B and/or C)	79
Laboratories with FOPH recognition (issued before 1 January 2016)	9

Controlled substances	
Establishment licences for handling controlled substances	370

Companies with Swissmedic licences issued under the new legislation (the licences are distributed across 556 sites)

Manufacturing of medicinal products (under new legislation)	
Manufacture of ready-to-use medicinal products and transplant products	174
Manufacture of active pharmaceutical ingredients	77
Handling of blood or labile blood products (blood transfusion activities)	20

Distribution of medicinal products (under new legislation)	
Import of medicinal products and transplant products	279
Wholesale trading of medicinal products and transplant products	418
Export of medicinal products and transplant products	249
Trading in medicinal products abroad and transplant products abroad	187
Brokerage or agency activities for medicinal products and transplant products	3

Microbiological laboratories	
Microbiological laboratories with a Swissmedic licence issued under the new procedure (from 1 January 2016; activities SE 1, SE 2 and/or SE 3)	29

Licensing of medical devices

Placing on the market

Manufacturers of medical devices that entail an elevated level of risk must have the conformity assessment of their products carried out by an officially accredited notified body. Certain medical devices are subject to mandatory notification. Swissmedic receives the notifications for such products, checks them at random to ensure the products have been correctly classified, issues instructions to make corrections where necessary, and records the notifications in the European EUDAMED database.

Activities:
576 notifications under Art. 6 para.1 MedDO were received. The notifications concerned classic Class 1 medical devices, custom-made classic or active implantable medical devices, systems and treatment units. Class 1 products include devices such as reusable surgical instruments, adhesive plasters and rolling walkers.

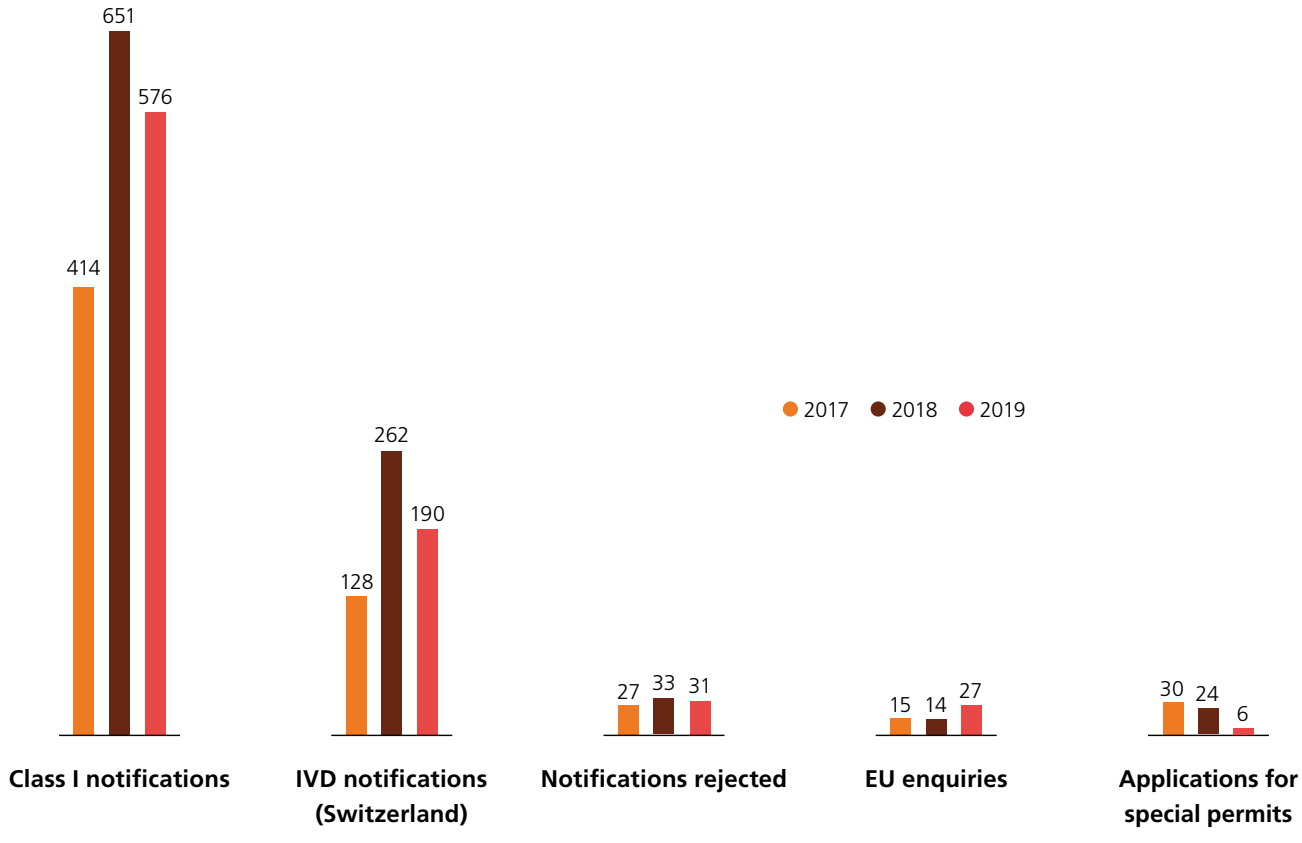
A total of 190 notifications under Art. 6 para. 2 and para. 2bis MedDO were submitted for in vitro diagnostic (IVD) devices.

Eight notifications in accordance with Art. 6 para. 3 MedDO were received for classic and active implantable medical devices made using or containing devitalised human tissue. In addition, 16 change notifications concerning devitalised human tissue were processed.

In 31 cases, Swissmedic rejected companies' notifications of medical devices because the products had been incorrectly categorised or classified, or because they did not fall within its area of responsibility.

In 2019, Swissmedic took part in 27 EU enquiries on delimitation questions regarding the classification of devices.

Swissmedic can issue special permits to import non-compliant medical devices if such devices could resolve a life-threatening situation faced by a patient. Six applications were submitted and reviewed during 2019.



Clinical trials of medical devices

Swissmedic approves and monitors clinical trials of medical devices for human use if the products or intended uses 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. Swissmedic can inspect investigators, sponsors and contract research organisations throughout Switzerland.

Activities:
Switzerland issued 44 licences in response to first-time applications for clinical trials.

96 modifications to clinical trials were monitored, 21 of which required approval, were reviewed and approved.

92 Annual Safety Reports and 36 safety reports from ongoing trials in Switzerland were monitored.

Performance indicator

Clinical trial approvals: percentage of applications that were reviewed within 30 or 60 days

● Target ● Result

Export certificates

Swiss companies can order export and manufacturing certificates for medical devices from Swissmedic. The certificates issued by Swissmedic confirm that the products in question are lawfully marketed in Switzerland. Foreign authorities may require export certificates as a precondition for importing devices into their country.

Activities:
As part of the process of digitalisation, electronic ordering of export and manufacturing certificates via the Swissmedic Portal was introduced. This process both simplified and speeded up processing.

Despite the major – 46% – increase on 2018, 95% of orders were completed within the time limits during 2019.

Export and manufacturing certificates

MARKET SURVEILLANCE PRODUCT GROUP

Medicinal Products Vigilance product

Medicinal products vigilance

Pharmacovigilance

Swissmedic records safety signals associated with medicinal products on the basis of reports of adverse drug reactions (ADRs) from within Switzerland. If investigation confirms a new risk, Swissmedic initiates the necessary actions following international consultation.
As part of the pharmacovigilance network, six regional pharmacovigilance centres (RPvCs) assess ADR reports submitted by professionals and patients on Swissmedic's behalf and record them in the national database. Pharmaceutical companies also submit reports on adverse reactions from within Switzerland to Swissmedic.

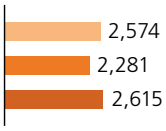
Activities:
The new Vigilance One Ultimate database for adverse drug reactions from within Switzerland was upgraded so that it is now possible to carry out specialised data analyses.

International collaboration with other countries' authorities and in multinational specialist organisations was further intensified, for example as part of regular dialogue on safety signals or as part of ICH or WHO activities.

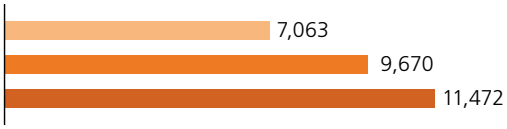
Swissmedic made contributions on drug safety-relevant aspects to the Swiss National Report on Quality and Safety in Healthcare.

New service agreements were drawn up for cooperation with the RPvCs during 2021 and 2022. The new agreements focus on reports containing safety-relevant aspects.

ADR reports from RPvCs



ADR reports from pharmaceutical companies



Total ADR reports

2017 2018 2019*

* The 2019 figures now also include follow-up reports and are therefore not directly comparable with previous years' figures.

Performance indicator

Serious ADRs: percentage of assessments carried out and transmitted to companies within 15 calendar days

Target Result

Haemovigilance

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

Activities:
Swissmedic received a total of 4,160 reports of transfusion reactions and transfusion errors (16% more than in the previous year). This increase is attributable to a greater awareness of the reporting obligation.

A working group comprising various stakeholders in the transfusion chain was initiated during 2019 to improve the efficacy of the look-back procedure in accordance with the Medicinal Products Licensing Ordinance.

Swissmedic used the 2018 haemovigilance statistics to publish information and various prevention measures, for example for transfusion-associated circulatory overload.

Number of reports involving blood products

3,076
2017

3,567
2018

4,160
2019

Vigilance for veterinary medicinal products

Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich to collect and assess reports on adverse reactions to veterinary medicinal products. Reports on vaccines for animals are recorded by the Institute for Virology and Immunology (IVI) of the Federal Food Safety and Veterinary Office (FSVO). Swissmedic does not have evaluations of these reports.

Activities:
371 reports of ADRs involving veterinary medicinal products were received, an increase of almost 13% on the previous year. 43 of the reports submitted to Swissmedic by Tox Info Suisse were also recorded.

Once again, the ADR reports primarily involved dogs (215) and cats (108), followed by cattle (25) and horses (4). The medicinal product categories most frequently involved were antiparasitics (201 reports), products containing hormonally active substances (37), antibiotics (34) and anaesthetics (18). This distribution is virtually unchanged from previous years.

For the first time, Tox Info Suisse submitted 108 cases of humans being exposed to veterinary medicinal products. Mix-ups, consumption by children and accidental contact with the veterinary medicinal product in question each account for about one third of these reports.

Three signals were generated from the 371 reports and from the analysis of the periodic safety update reports (PSURs). Two concerned preparations for use in small animals, the third a preparation for use in chickens.

Number of ADR reports

Percentage of ADR reports from Tox Info Suisse

Risk management

Risk management

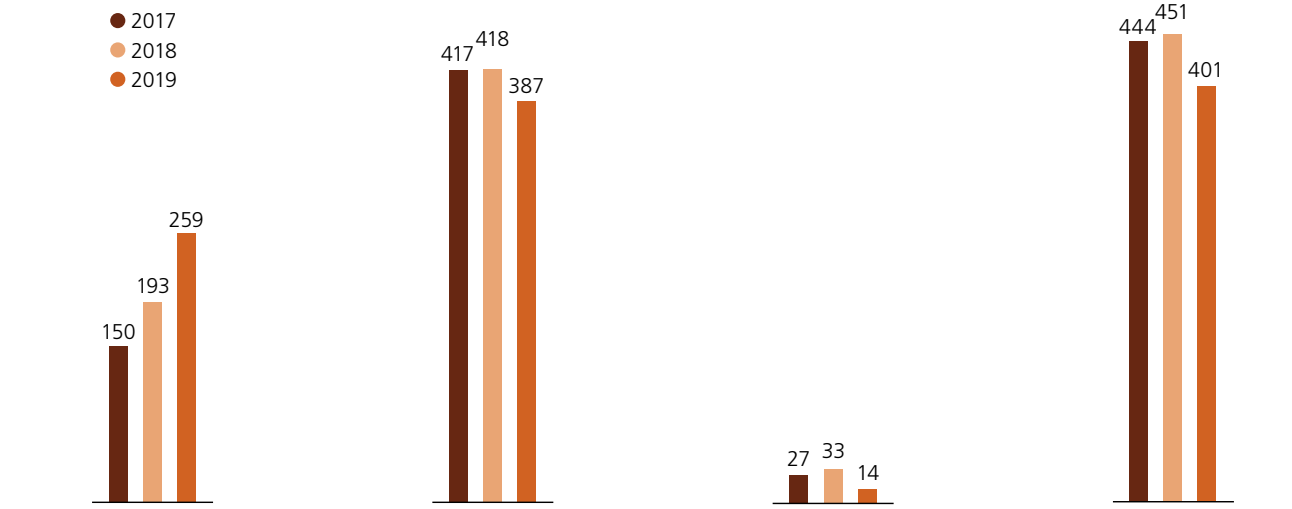
As part of the procedure for authorising new medicinal products, companies must submit for assessment a pharmacovigilance plan (PVP) in accordance with ICH guidelines. In the PVP, the authorisation holder must comment on both the known and the potential risks associated with the new medicinal product 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, the Agency evaluates international drug safety data and identifies and evaluates safety signals from national and international sources.

Activities:
In 2019, 259 PVPs for medicinal products submitted for authorisation and 401 safety reports for authorised medicinal products were assessed (including 117 PVP updates).

Risk mitigation measures

Even after a medicinal product has been authorised, companies are obliged to apply for a change to its product information if new findings come to light, and particularly if those findings affect its safety. If Swissmedic becomes aware of new risks and the firm responsible has not spontaneously applied for risk mitigation measures, the Agency initiates corrective measures ex officio. Swissmedic examines and approves the texts of the circulars to healthcare professionals (Direct Healthcare Professional Communications, DHPCs) and the list of intended recipients. These DHPCs and information on medicinal product risks issued by Swissmedic are also published on the Swissmedic website, in the Swiss medical journal Schweizerische Ärztezeitung and in the pharmaJournal.

Activities:
The number of international signals rose in the year under review. Efficient signal processing management ensured that risk mitigation measures were implemented in Switzerland contemporaneously with the international environment.
Warnings to healthcare professionals were published in 29 cases in the form of (DHPCs).
A total of 242 signals were completed.



Number of PVPs assessed

Number of PSURs/PBRERs for human medicinal products

Number of PSURs/PBRERs for veterinary medicinal products

Total PSURs/PBRERs

Market Monitoring of Medicinal Products product

Market monitoring of medicines

Quality defects and batch recalls

Swissmedic records reports of quality defects in medicinal products and takes the necessary 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 and/or the public. When reports of quality defects are received from abroad, Swissmedic verifies whether the reports affect preparations authorised in Switzerland. On request, Swissmedic authorises the distribution of medicinal products produced for other countries in order to avoid supply shortages.

Activities:
In total, 705 reports of quality defects were received during 2019. There was a year-on-year rise in batch recalls, three of which extended as far as patient level.

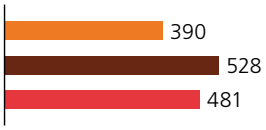
Although no further cases of nitrosamine contamination in sartans were found in 2019, all ranitidine preparations authorised in Switzerland had to be withdrawn from the market in autumn. Shortly afterwards, metformin (used to treat diabetes) supplied by a particular manufacturer also had to be withdrawn owing to nitrosamine contamination.

Given the possibility of further products being affected by the nitrosamine issue, manufacturers were called on to carry out their own comprehensive risk investigations.

As yet, parallel importing of medicinal products is not widespread in Switzerland. However, the first parallel-imported preparation had to be recalled during 2019 owing to a possible mix-up of the two dosages in which the preparation is sold. The investigations proved particularly challenging because the entire manufacturing and supply chain – starting with the (original) packer abroad and continuing through the repacker and wholesaler in Switzerland as far as the patient – had to be examined to see if there were any points where the two dosage strengths may possibly have been muddled.

Number of reports of quality defects

Number of reports relating to Switzerland



Number of batch recalls

Measures against illegal medicinal products

Swissmedic increases public awareness of the dangers associated with the use of illegal medicinal products. Professionals and the public are warned of the risks in media releases, interviews and publications. The Agency consults regularly with authorities and private-sector bodies in the course of this task, and promotes effective national and international networking. Swissmedic receives reports on illegal products, activities and distribution, examines them and initiates corrective action where necessary. Swissmedic works closely with the customs authorities to control medicine imports, ordering the return or destruction of illegal packages.

Activities:
Activities in 2019 focused on the roll-out and implementation of the Medicrime Convention. The relevant legislative amendments entered into force in January 2019, and, in addition to creating the new single point of contact at Swissmedic, provided various other partnership-based options for ensuring safer medicinal products. For example, it is now possible to exchange

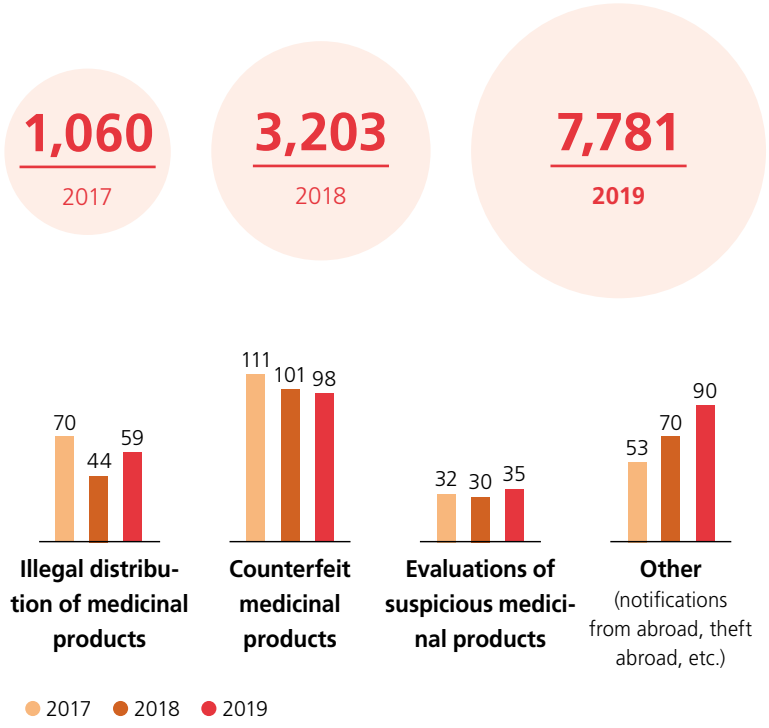
information directly with the industry in certain cases for the purpose of combating medicinal product crime.

The first Medicrime meeting was held as part of national-level cooperation with partners from the Cantons, customs, police and prosecution agencies. Swissmedic explained its role as the single point of contact (SPOC) and a joint procedure was defined for information flow when activities that are illegal under therapeutic products legislation come to light.

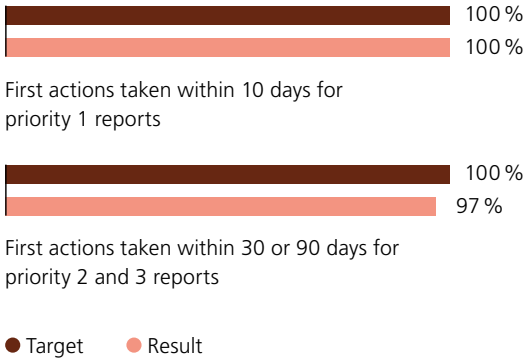
In October 2019, a workshop on the subject on delimitation issues was held in Uppsala. Swissmedic was involved in organising the event, which was attended by participants from 30 countries. The target audience was experts from the member states of the Council of Europe whose work involves classifying potentially illegal products. The aim of the workshop was to address issues associated with borderline products and provide an information-sharing platform.

At the start of 2019, Swissmedic and the Federal Customs Administration officially introduced a simplified procedure that they had previously trialled and which is capable of significantly increasing the number of seizures.

Number of seized packages



Performance indicator



Control of advertising

Swissmedic controls and monitors the advertising of medicinal products. Following the entry into force of the revised TPA, mandatory prior control of advertising destined for the public, regardless of medium, has been restricted to "sensitive" medicinal products (such as laxatives or sleeping aids) that are known to be dependence-forming or susceptible to abuse. Swissmedic also follows up information regarding infringements of advertising legislation and decides whether administrative proceedings need to be initiated, or whether legal compliance can be reestablished by means of an official objection. Swissmedic issues publications and information sheets and gives presentations to inform interested parties about the current legal situation regarding advertising for medicinal products.

Activities:

25 cases were dealt with as part of post-publication advertising inspection activities. Twelve cases involved print advertising, thirteen involved advertising on electronic media. Administrative proceedings were initiated in ten cases.

It was often necessary to object to claims of guaranteed efficacy or the fact that advertising did not comply with the most recently approved version of medicinal product information. In several cases, objections were raised against indications or applications being claimed for complementary medicinal products that had not been authorised for the indication in question.

No applications for advertising permits were received during 2019

Appeals procedures regarding medicinal products market monitoring

Recipients of official decisions issued during market monitoring have a period of 30 days in which to lodge appeals with the Federal Administrative Court (FAC). FAC verdicts can be contested before the Federal Supreme Court (FSC).

Three appeals against official decisions were lodged with the FAC during 2019. The FAC refused to admit one appeal.

Medical Devices Vigilance product

Market Monitoring of Medical Devices product

Integration within the European system and European market surveillance activities

Switzerland has concluded agreements on the mutual recognition of conformity assessments for medical devices with EU Member States, EFTA states and Turkey. This European system provides the authorities of the contracting states with a shared database (EUDAMED) that acts as an information system for market monitoring. CE-marked medical devices are considered to be compliant and may be distributed in all contracting states.
Since Swissmedic is integrated into the European medical devices system, it carries out market surveillance activities in consultation with partner authorities from contracting states in addition to its national market surveillance activities.

Activities:
At 114, the number of requests for mutual assistance from European partner authorities was below the previous year's level.

The number of requests made by Swissmedic to European partners remained stable at 32.

As part of efforts to step up surveillance of conformity assessment bodies (CABs) and accredit them under the new European Regulations (MDR/IVDR), Swissmedic once again took part in internationally accompanied audits of CABs during 2019.

Materiovigilance

Manufacturers and users are obliged to report to Swissmedic incidents involving medical devices that are deemed to be serious, and which have taken place in Switzerland. Companies must also inform Swissmedic of safety measures they have taken, such as product recalls, which the Agency then monitors. Swissmedic is integrated into the European reporting system and also informs affected contracting states about incidents in Switzerland and the safety precautions taken.

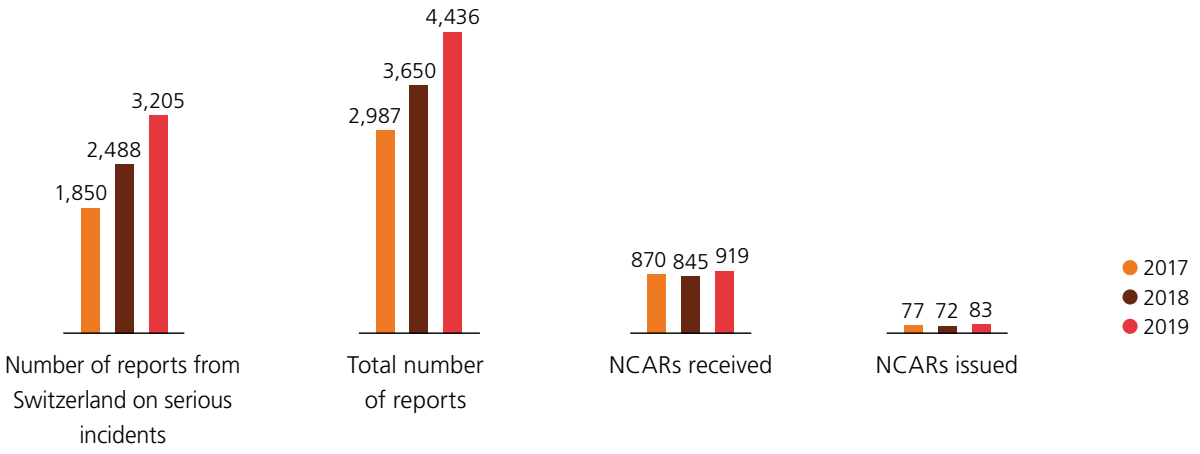
Activities:
A total of 3,205 serious incidents were reported in Switzerland. This represents a further sharp increase compared with the previous year (+ 29%).

The implementation of safety measures in Switzerland was monitored in 731 cases.

A total of 83 reports on defective medical devices (National Competent Authority Reports, NCARs) were drawn up for the attention of foreign authorities, and Swissmedic received 919 NCARs from the European partner authorities.

In 722 cases, a public safety report was published on the Swissmedic website for the information of users.

In 2019, Swissmedic again discussed new suspected incidents and concrete action on pending cases during monthly telephone conferences with the other European surveillance authorities.



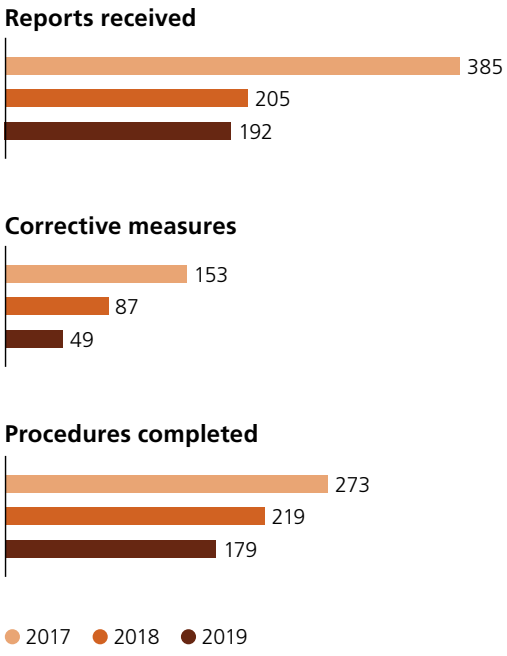
Market supervision

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:

Swissmedic received a total of 192 reports of suspected non-compliant medical devices. Since the number remains high, reports are processed strictly according to risk-based criteria.

Swissmedic imposed corrective measures on market participants in Switzerland in 49 cases. It also carried out eleven on-the-spot inspections of Swiss companies.

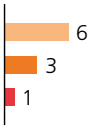


Monitoring of conformity assessment bodies (CABs) and inspections

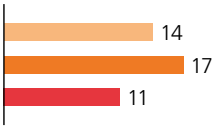
Swissmedic monitors the Swiss CABs in collaboration with the Swiss Accreditation Service (SAS), awards them notified body designation, inspects them, collects their reports on certificates issued, and records these in EUDAMED. Swissmedic takes part in quality assurance measures carried out by the European authorities that appoint notified bodies, and carries out other inspections in connection with medical devices.

Activities:
One Swiss CAB ceased medical device-related activities at the end of October. Swissmedic was actively involved in the wind-down process so it could use the options provided by legislation to minimise the impact on affected companies. As at the end of 2019, there was only one CAB in Switzerland.

CAB inspections (excluding ISO 13485)

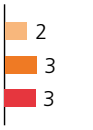


Inspections of market controls

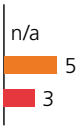


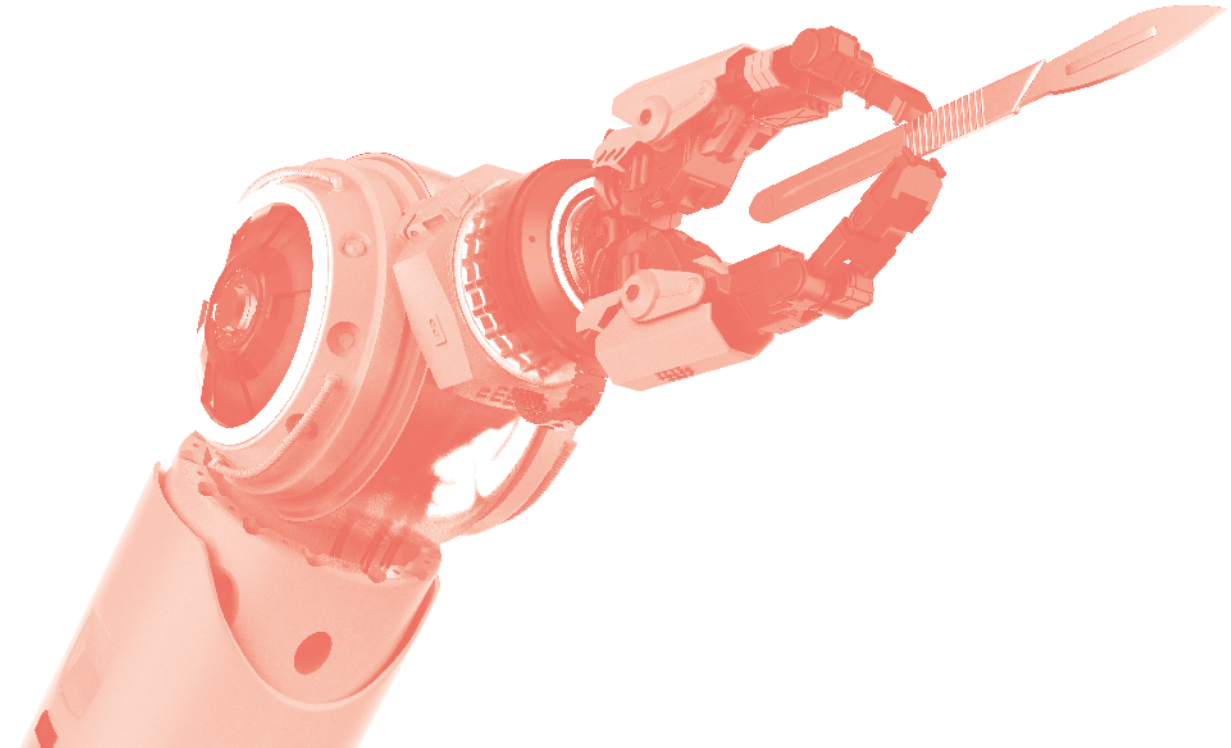
Inspections by foreign authorities (co-ordination with SECO, including accompanying inspectors on site if needed)

Joint assessments



Inspections on behalf of SAS





Hospital inspections

Market monitoring also extends to inspecting hospitals' reporting systems for serious incidents. While the Cantons are responsible for inspecting the reprocessing of sterile medical devices such as surgical instruments and endoscopes and ensuring that equipment such as X-ray machines is maintained correctly in doctors' practices and other healthcare institutions such as nursing homes, Swissmedic conducts the relevant inspections in hospitals.

Activities:
In 2019, Swissmedic continued its focus campaign of inspecting hospitals' reprocessing of endoscopes, which it started in 2019. A checklist setting out the key compliance aspects was published to improve reprocessing and enable hospitals to prepare for inspections. Swissmedic conducted a total of 25 inspections (reprocessing, maintenance or reporting systems) during 2019.

Hospital audits (reprocessing, maintenance and reporting system)

Appeals procedure regarding the market surveillance of medical devices

Recipients of official decisions issued during market monitoring have a period of 30 days in which to lodge appeals with the Federal Administrative Court (FAC). FAC verdicts can be contested before the Federal Supreme Court (FSC).

Six appeals against official decisions were lodged with the FAC during 2019.

Five of these were dismissed. Three were still pending at the end of 2019.

PENAL LAW PRODUCT GROUP

Criminal prosecution by Swissmedic

Swissmedic is responsible for part of the process of prosecuting offences against Therapeutic Products legislation. The Agency can carry out penal investigations and impose fines and financial penalties, and impose measures such as confiscations. If a custodial sentence is an option, sentencing is the responsibility of the cantonal court from the outset. In cases that come to court, Swissmedic represents the prosecution. Offences associated with the use and dispensing of therapeutic products fall under the remit of the cantonal criminal justice authorities. Since the beginning of 2019, Swissmedic has been able to exercise the rights of a private claimant.
The revised TPA provides new powers to prosecute therapeutic products crime, under which Swissmedic, the Federal Customs Administration and cantonal public prosecutors share the task of punishing contraventions of the TPA.

Activities:
Swissmedic received 117 new reports of offences during 2019 (34 from within the organisation, 83 from outside), an increase of 65% on the the previous year. This increase is attributable to the fact that many reports were on the same subject, namely the procurement abroad of veterinary medicinal products for livestock in a way that did not comply with the relevant requirements. In individual cases, mandatory accounting requirements had also not been observed, something that would normally be the responsibility of the cantonal public prosecutors. To guarantee that the same standards were applied in all cases, it was agreed that Swissmedic would manage all proceedings. The option of assuming responsibility for cantonal proceedings has been available to Swissmedic since 1 January 2019, and was used here to increase efficiency and ensure a standardised approach. This series of proceedings more than doubled the number of administrative penal procedures opened during 2019, and increased procedural unification with cantonal criminal proceedings almost tenfold.

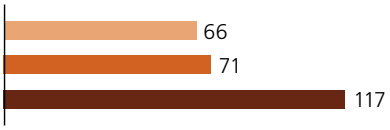
The new proceedings opened and conducted in 2019 concerned cases of illegal importing, placing on the market and manufacturing of medicinal products, failure to comply with reporting requirements, and violations of the duty of care or maintenance obligations for medical devices.

The Medicrime Convention is the first international criminal law agreement that obliges contracting states to criminalise the counterfeiting of therapeutic products and similar activities. The Convention entered into force in Switzerland on 1 February 2019. It includes provisions on substantive and formal criminal law, protection and prevention measures and international collaboration.

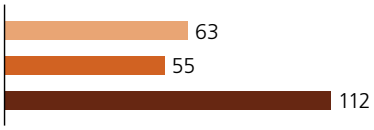
The new powers to prosecute therapeutic products crime require collaboration on the part of all participating agencies. Swissmedic is in close contact with all prosecution authorities and the Customs Administration and engages in dialogue on specific cases, including for the purposes of establishing processes. Various information events were held during 2019.

Swissmedic was involved in five criminal cases as a private claimant during the year under review.

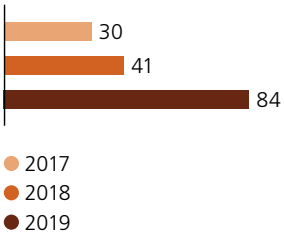
New complaints



Procedures closed



Administrative penal procedures opened



Investigative measures

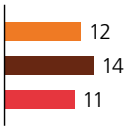
The Federal Act on Administrative Criminal Law gives Swissmedic's investigators-in-charge powers that are comparable to those of a cantonal or Federal prosecutor. In particular, they can conduct examination hearings, carry out coercive measures such as seizures and house searches, demand the handover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

Activities:
Swissmedic carried out 11 house searches and 21 examination hearings in 2019. There were no complaints against coercive measures ordered by Swissmedic. In one case, the Federal Criminal Court approved the majority of Swissmedic's application to remove the seals from information that was secured during a house search in 2018.

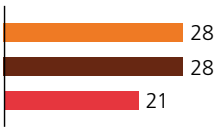
International cooperation in criminal matters primarily involved neighbouring countries. Swissmedic made three requests for mutual assistance to Germany, and one to France. Conversely, it responded to eight requests from abroad – six from Germany and one each from Hungary and Romania.

In autumn, media interest turned to a company that had signed contracts with parents of newborn children under which it stored umbilical cord blood and tissue for the purpose of subsequently extracting stem cells. The company moved the samples abroad without either notifying parents or obtaining their consent, causing them serious consternation. In addition, since the company was suspected of contravening therapeutic product regulations, penal measures were initiated.

House searches



Examination hearings



Unification with cantonal proceedings

2017 2018 2019

Decisions/verdicts by Swissmedic and the courts

Once cases have been investigated, a decision is made on a penalty. Alternatively, cases may be referred to the competent court or proceedings may be closed. Swissmedic represents the prosecution in cases that are brought to court.

Activities:
38 penalties were imposed during 2019, 34 of which were issued under an abridged procedure.

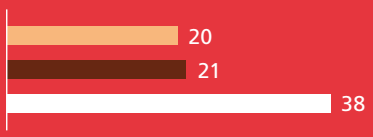
One case that had caught the public's attention during 2015 was concluded during 2019. A private clinic had removed adipose tissue from patients and used it to manufacture preparations to which it attributed a variety of health-promoting and even curative properties. However, the preparations should not have been placed on the market since the manufacturer did not possess the necessary licence. The company's managers were sentenced to fines and conditional financial penalties. Proceedings against the doctors who were involved at the clinic were dropped.

In one case involving Class II and III products with no EC certificates, Swissmedic issued a penalty for illegally placing non-compliant medical devices on the market for commercial gain, imposing a conditional financial penalty and six-digit damages for illegally obtained profits.

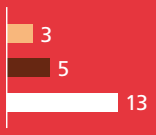
Administrative proceedings that lasted several years ended with a five-figure fine for violations of medicinal product advertising laws and for illegally offering pecuniary benefits. The company in question accepted the penalty ruling.

At the end of 2019, the Federal Supreme Court upheld Swissmedic's appeal against a verdict by the criminal chamber of a cantonal court quashing seven-digit damages previously imposed by Swissmedic for wholesale trading in medicinal products without the necessary licence over a period of many years. The case is now being referred back to the cantonal court for review.

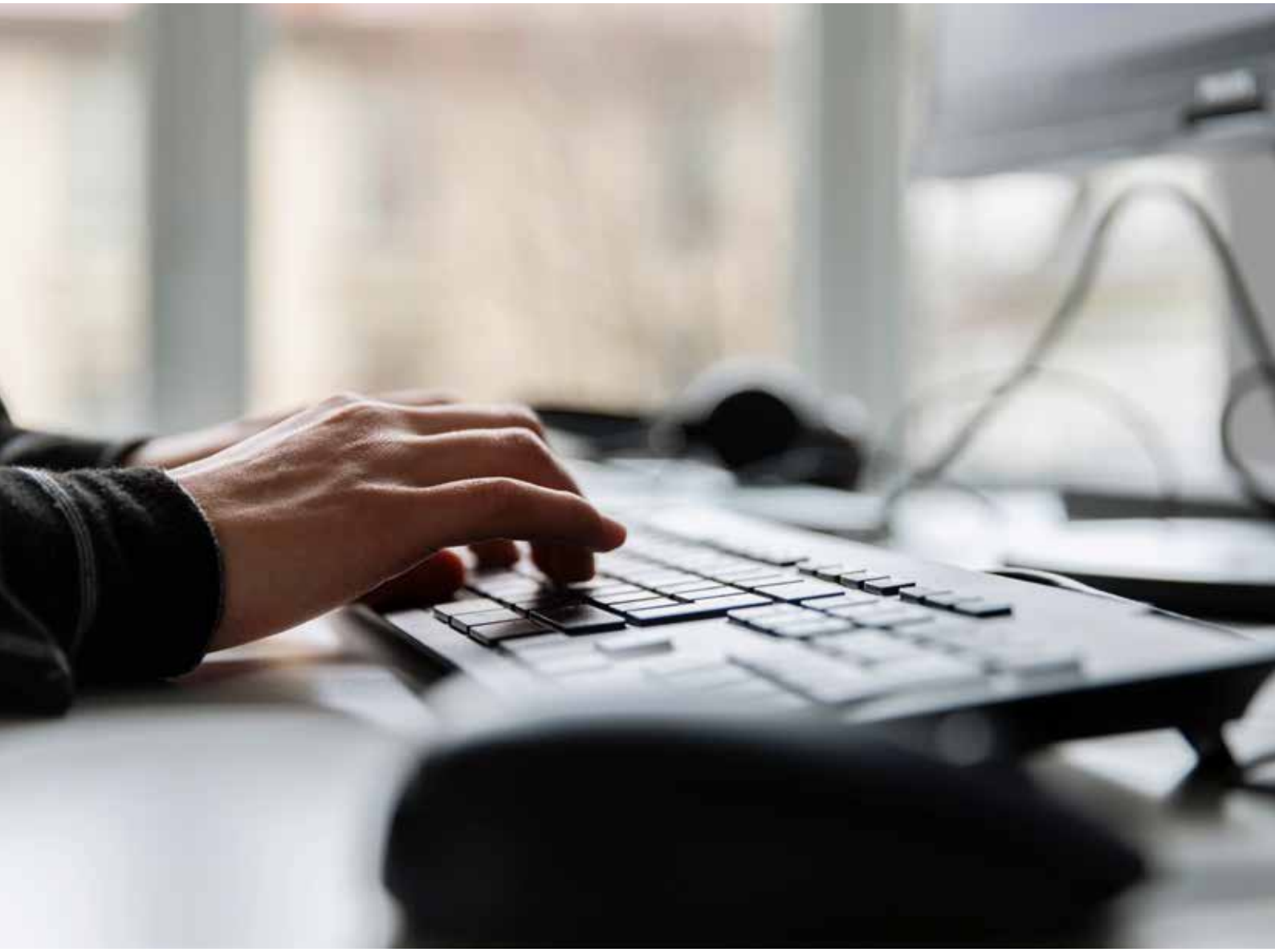
Penalties imposed



Cantonal judgements



Federal Supreme Court judgements



CORPORATE GOVERNANCE

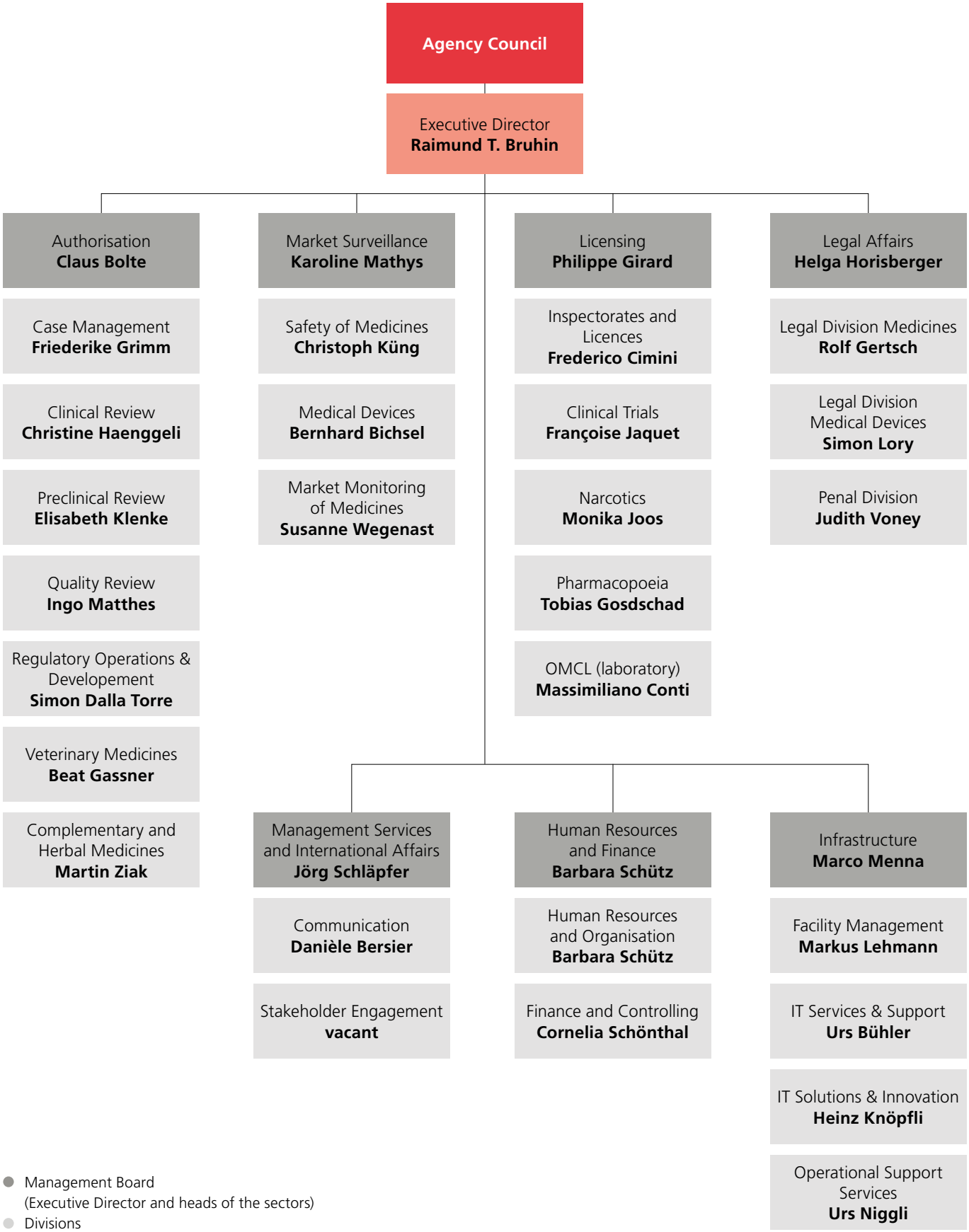
Organisation

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

The Federal Council designated the Swiss Federal Audit Office as the auditors for 2019.

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.

Organigram



- Management Board (Executive Director and heads of the sectors)
- Divisions

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 Chair. The Cantons have the right to propose three members for consideration. Members are elected for a four-year period of office, and may be reelected for two further periods of office.

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 and approves 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.

Stéphane Rossini stepped down from the Agency Council at the end of November 2019, since his new professional situation as of December 2019 would have been incompatible with Agency Council membership. Vincenza Trivigno is acting Chair until Lukas Bruhin, who was appointed by the Federal Council to succeed Stéphane Rossini, takes up his post. Reto Obrist stepped down from the Agency Council at the end of 2019 after many years as a member. The Federal Council appointed Prof. Daniel Betticher, Chief Physician at Fribourg Cantonal Hospital, to the Agency Council as his successor.

Remuneration for the Agency Council in 2019 totalled CHF 177,000 (including expenses), of which CHF 38,000 was paid to the Chair.

The CVs and current vested interests list for the individual members of the Agency Council are published on the Swissmedic website. Swissmedic's organisational rules and the Agency Council's business regulations can also be found on the website.

www.swissmedic.ch

Chair, Stéphane Rossini, Dr.
(until 30 November 2019)

Vice Chair, Vincenza Trivigno
(from 1 January 2016)

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

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

Reto Obrist, Prof. Dr. med.
(until 31 December 2019)

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 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 and the statement of estimates for submission to the Agency Council, represents the Agency externally and discharges the duties not assigned to a different body.

Petra Dörr, Deputy Executive Director and Head of Management Services and International Affairs, left Swissmedic at the end of June 2019. Jörg Schläpfer became Head of Management Services and International Affairs on 1 July 2019, while Philippe Girard became the new Deputy Executive Director.

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 1,855,300. The Executive Director received CHF 301,600.

The CVs of the Executive Director and members of the Management Board are published on Swissmedic's website.

www.swissmedic.ch

Raimund T. Bruhin, Dr. med.
Executive Director

Philippe Girard, Dr.
Deputy Executive Director,
Head of Licensing

Claus Bolte, Dr. med.
Head of Authorisation

Helga Horisberger
Head of Legal Affairs

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

Marco Menna, Dr.
Head of Infrastructure

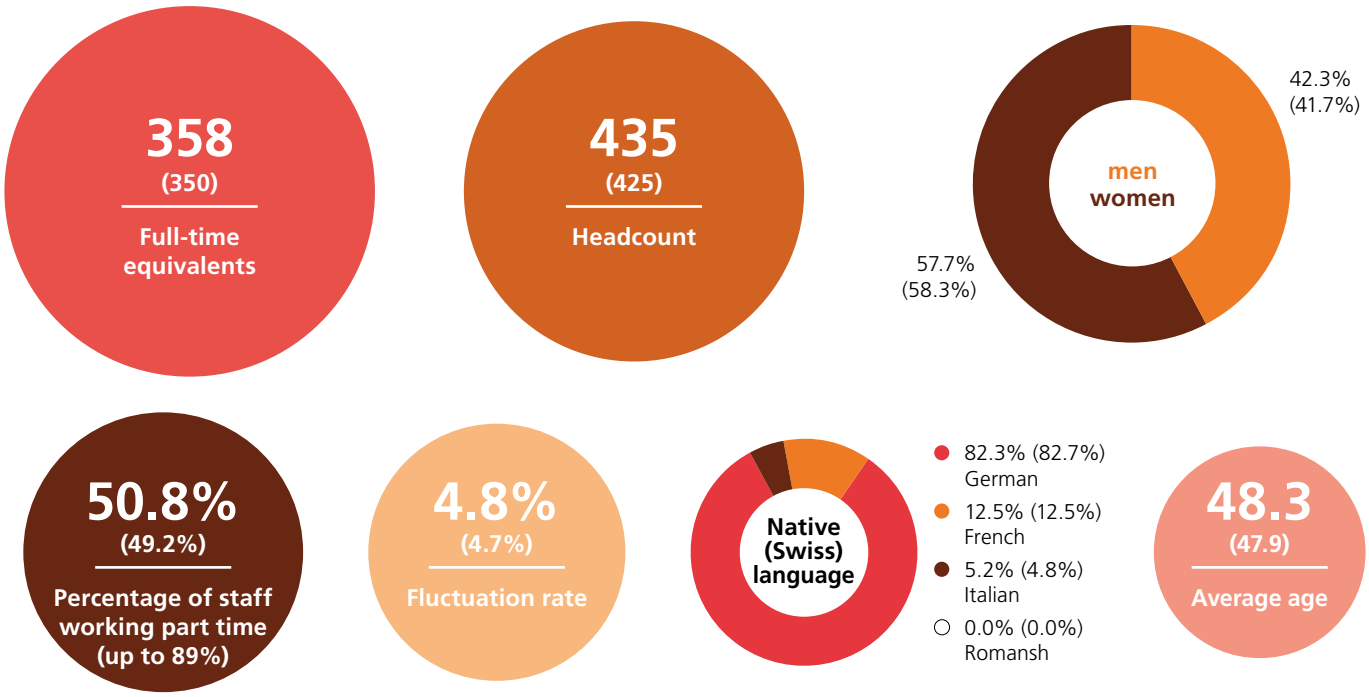
Jörg Schläpfer, Dr. med. vet., PhD
Head of Management Services
and International Affairs

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.

Key figures: human resources



At the end of 2019, 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, Althaus-Steiner Esther, Amstutz Yann, Andrejic Milan, Arnheiter Larissa, Bachmann Beat, Baeriswyl Gerda, Balli Sandra, Bapst Astrid, Bärtsch Martin, Baumann Yvonne, Beeler Patrick, Bellac Caroline, Bellwald Patricia, Berger Christoph, Bersier Danièle, Besinovic Zeljko, Bichsel Bernhard, Bigler Weber Cornelia, Bill Helena, Bitschnau Monika, Blanco Philippe, Blankenbach Kira, Blaser Beatrice, Blum Markus, Bögli Katja, Bögli-Schlüchter Franziska, Böhlen-Walther Caroline, Böhm Steffen, Bolli Richard, Bolte Claus, Borissov Petya, Borner Stefan, Boschung Andrea, Bruhin Raimund, Brunner Stefan, Büchi Jacqueline, Büchler Monika, Buchs Renato, Buchter Linda, Bühler Urs, Bulter René, Bur Kathrin, Bürge Michaela, Burgener Julia, Burgener Roger, Burkhalter Gabriele, Burri Michael, Camenisch Corina, Carrel Nadja, Carulli Amico Sabina, Cavaliero Tania Cecilia, Chatelain Barbara, Chodup Piotr, Christen Tobias, Cimini Federico, Cipolli Francesca, Cokoja Adisa, Colangelo Elena, Conti Massimiliano, Coso Marija, Crottet Pascal, Dalla Torre Simon, Damke Beat, De Matteis Isabella, Déverin Olivier, Dexheimer Petra, Diethelm Markus, Ditesheim Véronique, Djonova Julia, Dogan Nurhak, Drapela Aurélie, Drechsel-Weiss Bettina, Dunkel-de Raad Saskia, Dupasquier Thierry, Dürr-Kammer Eva, Eggenschwyler Doris, Egger Franziska, Ehmann Richard, Ehrensperger Edmund, Ehrensperger Murri Eva, Endress Eva-Maria, Endrich Michael, Engel Marie-Helene, Escandari Markus, Essen Renate, Eugster Urs, Eyal Eva, Eyquem Jeanne, Fahrni Ursula, Farré Viviane, Federer-Oetliker Martina, Feldkamp Astrid, Feldmann Danila, Feller Selina, Ferbitz-Scheurer Simone, Filgueira David, Fischer Bernt, Flechtner Olivier, Fotinos Nicolas, Frank Simone, Franscini Nicola, Fritzsche Constanze, Fuchs Sebastian, Fuhrer Therese, Fürer Andreas, Gafner Verena, Gamma-Lauber Madeleine, Gassner Beat, Gaudesius Giedrius, Gautschi Jonas, Gautschi Matthias, Geluk Charlotte, Gertsch Rolf, Gilgen Bernadette, Gilgen Michael, Giovannangelo Céline, Girard Philippe, Girčys

Arũnas, Glauser Daniel, Gloor Eveline, Gloor Nora, Gobet Magali, Gosdschan Tobias, Gottofrey James, Graber Angelika, Grimm Friederike, Grüter Eric, Grütter Daniela, Grützmacher Barbara, Guggisberg Stefan, Gugler Claudia, Gulkowska Anna, Gürtler Rolf, Gysin René, Häberli-Airoldi Isabelle, Haenggeli Christine, Hahn Spielmann Véronique, Haldemann Silvia, Hammel Mario, Häni Brigitte, Hatibovic Maja, 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, Hetzenecker Stefanie, Hildebrand Pius, Hofer Isabell, Hofmann Alexander, Hofmann Linda, Hofstetter Christiane, Horisberger Helga, Horn-Lohrens Ottmar, Hottiger Thomas, Hotz Rolf, Huber Cornelia, Huber Elisabeth, Huber Jasmina, Hug-Michel Christine, Hunkeler Thomas, Hürlimann Daniel, Iovino Mario, Jaggi Lukas, Jahn Katrin, Janitsary Anna, Jaquet Françoise, Järmann Stephan, Jentzsch Christoph, Jéquier Martine, Jermann Ronald, Johner Regula, Joos Monika, Joye Laetitia, Jungo Jacqueline, Junker Christian, Juritz Stephanie, Käser Michèle, Käser Sandra, Käsermann Donald, Keller Michael, Kempná Bukovac Petra, Keusen-Weyermann Katrin, Kindler Adrian, Kläy Barbara, Klenke Elisabeth, Kleppisch Thomas, Knöpfli Heinz, Kocher-Guggisberg Beatrice, Koeninger Franziska, Köhli Michael, Kolly Philippe, Krayenbühl Jean Christian, Krebs Franziska, Krebs Michael Oliver, Kühni Martin, Kummer Robert, Küng Christoph, Kunz-Greub Marianne, Kuster André, Langenkamp Anja, Langos-Mabboux Manuela, Lany Catharina, Lapke Conwitha, Lauer Gabriele, Lavanchy Vincent, Le Stanc Pascale, Lehmann Markus, Lehmann Thomas, Leidreiter Kirsten, Leimbacher Aurelia Caroline, Leist Roman, Lerch Sébastian, Lerch-Giunta Franca Lara, Leu Martin, Leuenberger Beat, Linder Ursula, Liniger-Thommen Andrea, Lippmann Hans-Georg, Lochmatter Cecchetto Priska, Löffel Werner Patrik, Löhr Kottmann Ingrid, Lory Simon, Lottaz Daniel, Lucas Christine, Ludwig Ljubica, Luginbühl-Weber Karin, Lüthi-Wyss Nicole, Lütolf Natalie, Maier Ralph, Manolio Silvana, Manzoni Isabella, Marazzi Céline, Marrer Edith, Marti Andreas, Mathys Badertscher Karoline, Matthes Ingo, Maurer Jessica Maria, Meincke Ricarda, Menna Carolin, Menna Marco, Meseguer Georges, Messerli Nicole, Messi Mara, Meusburger Madeleine, Meyer Rita, Meyer Simon, Meyer Ulrike, Meyer Urs, Mijatov Sacha, Miletzki Barbara, Mion Alexander, Mooser Guido, Morancy Meister Anne-Catherine, Morciano Julie, Moreno Rafael, Mosimann Lenzin Ruth, Müller-Mook Renate, Müntener Cedric, Mutti Sven, Nava Gabriela, Neeser Zaugg Rosmarie, Netsch Marco, Nick André, Niggli Urs, Nikolic Danijela, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Nyffeler Chiara, Op den Camp Roeland, Osswald Tschan Marco, Pagan Madrid Francisco, Paganini Lodovico, Paniga Nicoletta, Pavelic Ferretti Danijela, Pecaric Petkovic Tatjana, Pereira Claudia, Perez Eugenio, Pernusch Jenny, Petkovic Vibor, Pietropaolo Davide, Pinsard François, Plüss Ruth, Polatti Daniela, Poma Giorgio, Porporini Lucio, Prisching Andrea, Prost Francine, Puliafito Anita, Pürro Michel, Rached Eva, Ramelli Monica, Rätz Katerina, Remund Thomas, Renaudin Michael, Renftle Wolfgang, Reusser Daniel, Rickenbacher Nadja, Rieder Barbara, Riem Nicole, Riesen-Beer Sabine, Robbiani-Meier Corinne, Roduit Sandra, Rogl Schmid Jeannette, Rohr Ulrich-Peter, Roost Matthias, Roth Daniel, Roux Catherine, Ruch Claudia, Rudofsky Leonie, Rüfenacht Francine, Rumo Anton, Sandrowski-Ramseyer Alice, Sänger Michael, Santhirasegarar Luxshana, Satarasinghege Don Sandya, Schade Bettina, Schaffner Nils, Schärer Christian, Schäublin Martina, Scheidegger Michelle, Scheidegger René, Schläpfer Jörg, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Eggler Dorit, Schnyder Benno, Schochat Thomas, Schöni Damian, Schönthal Cornelia, Schorer Georg, Schütz Baumgartner Barbara, Schwab-Stampfli Rebekka, Schwartz Thomas, Schwyter Andrea, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Sen Jenifer, Senessie Charles, Sergejew Thomas, Sifrig Lia, Sommer Andrea, Sorg Regula, Spohn Margot, Spörri Bernhard, Spring Andrea, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stämpfli David, Stämpfli Ursula, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Storre Stephanie, Strack Guido, Straub Andrea Katharina, Sulser Mario, Tanner Soland Eveline, Tanner Yvonne, Terkovics Attila Leo, Teuscher Françoise, Thiess Maria, Thürig Soltermann Eva, Toma Valeriu, Tromp Jan, Tschalär Yolanda, Tschanz Lara Timea, Tschirren Markus, Tschopp Florence, Tschui Janie, Unger Matthias, Urwyler Stephan-André, Vihertola Mari, Vilei Edy, von Mühlenen Eva, Voney Judith, Vonlanthen Bianca, Wacker Christoph, Wagner Jan, Wälchli Sabine, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Walther Chantal, Wälti Markus, Wälti Rudolf, Waser Isabelle, Waser René, Weber Heidi, Wegenast Susanne, Wegmann Barbara, Weissmahr Richard, Weix Janine, Weller Katja, Werder Carine, Weyermann Andrea, Weyermann Philipp, Whitehead Frances, Whitehead Margaret, Wieland Christa, Wiget Jasmine, Wildner Oliver, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wittwer Regina, Wolfer Anita, Wullimann Esther, Wullschleger Stefan, Wüthrich Karin, Wyss Brigitte, Wyss Kaspar, Wyss Martin, Wyss-Romanello Sabine, Zaugg Kunz Sandra, Zbinden Raphael, Zelenko Ottilie, Zemp Markus, Zenhäusern Gabriela, Ziak Martin, Ziehli Salvisberg Mariette, Zurbuchen Andreas, Zurkinden Tanja

Consultant experts

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 organisational units' procedures; however, decisions are always made by Swissmedic.

The Agency Council elects the experts for a four-year period of office. The rules put in place to guarantee the experts' neutrality and govern vested interests are published on Swissmedic's website.

www.swissmedic.ch

The HMEC held 12 meetings and issued 61 recommendations on applications. The majority concerned new authorisations or additional indications for medicinal products. Furthermore, the Committee was informed of 44 authorisation decisions. In addition, HMEC experts carried out 14 assessments of parts of dossiers, and 23 individual expert opinions were obtained.

The VMEC assessed 11 applications for authorisation of variations at four meetings.

Members of the Human Medicines Expert Committee (HMEC)

Current as at December 2019

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

Ordinary members
Arand Michael, Prof. Dr. phil. nat.
Bauer Matthias, PD Dr. med.
Castiglione Monica, Prof. Dr. med.
Cerny Andreas, Prof. Dr. med.
Cerny Thomas, Prof. Dr. med.
Dayer Pierre, Prof. Dr. med.
Schild Laurent, Prof. Dr. med.
Vogt Markus, Prof. Dr. med.

Extraordinary members
Aicher Lothar, Dr. rer. nat.
Ballmer-Weber Barbara, Prof. Dr. med.
Beglinger Christoph, Prof. Dr. med.
Borner Markus, Prof. Dr. med.
Buser Katharina, Dr. med.
Caldelari Reto, Dr. phil. nat.
Cavin Frédy, phil. nat.
Cotting Jacques Ernest, PD Dr. med.
FitzGerald Reginald Edward, Dr. phil. nat.
Genton Blaise, Prof. Dr. med.
Giannopoulou-Politakis Catherine, PD Dr. med. dent.
Hullin Roger, Prof. Dr. med.
Hüsler Jürg, Prof. Dr. phil. nat.
John Hubert, Prof. Dr. med.
Klenke Frank, PD Dr. med. and Dr. phil. nat.
Meier Beat, Prof. Dr. sc. nat.
Meier Christoph Rudolf, Prof. Dr. pharm.
Messerli Jürg, Dr. med.
Möller Burkhard, Prof. Dr. med.
Munier Francis Louis Paul, Prof. Dr. med.
Nadal David, Prof. Dr. med.
Naegeli Hanspeter, Prof. Dr. med. vet.
Özsahin Hülya, Prof. Dr. med.
Pfeifer Dina, Dr. med.
Pittner Heribert, PD Dr. med.
Rabe Thomas, Prof. Dr. med.
Rodondi Pierre-Yves, Dr. med.
Sappino André-Pascal, Prof. Dr. med.
Schär Peyer Beatrice, Dr. sc. nat.
Seger Reinhard A., Prof Dr.med.

Sonderegger-Stalder Emanuel N., Dr. med.
Strik Werner, Prof. Dr. med.
Thomi Matthes Brigitte, Dipl. pharm.
Tramèr Martin, Prof. Dr. med.
von Ammon Klaus, Dr. med.
von Wolff Michael, Prof. Dr. med.
Wicki Andreas, PD Dr. med. and Dr. phil.
Wilks Martin F., Prof. Dr. med.
Wolf Ursula, Prof. Dr. med.
Yerly Daniel, Dr. phil. nat.
Zangemeister-Wittke Uwe, Prof. Dr. phil. nat.
Zimlich Klaus-Heinrich, Dr. rer. nat.

Advisory members
Angelillo Anne, Prof. Dr. med.
Farhad Hafezi, Prof. Dr. med.
Heinrich Michael, Prof. Dr. rer. nat.
Hofmann Heinrich, Prof. Dr. ing.
Hunger Robert Emil, Prof. Dr. med.
Lämmle Bernhard, Prof. Dr. med.
Saller Reinhard, Prof. Dr. med.
Streuli Isabelle, Dr. med.

Members of the Veterinary Medicines Expert Committee (VMEC)

Current as at December 2019

Chair
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.
Naegeli Hanspeter, Prof. Dr. med. vet.
Perreten Vincent, Prof. Dr. sc. tech.

Extraordinary members
Hoop Richard, Prof. Dr. med. vet.
Kümmerlen Dolf, Dr. med. vet.
Ruoff Kaspar, Ph.D.
Schmidt Andreas, Dr. med. vet.
Spadavecchia Claudia, Prof. Dr. med. vet.
Wahli Thomas, Prof. Dr. phil. nat.
Zinsstag Jakob, Prof. PhD DVM

Pharmacopoeia experts

Swissmedic's Pharmacopoeia division is the national authority responsible for the pharmacopoeia. It co-ordinates a network of around 120 Swiss specialists from industry, the universities, community and hospital pharmacies and other authorities, who contribute to the preparation of the Pharmacopoeia.

The Ph. Eur. is drawn up by the European Pharmacopoeia Commission, which is made up of delegations from contracting parties to the Ph. Eur. Tobias Gosdschan, head of the Pharmacopoeia division, is the first Swiss in the history of the Ph. Eur. to head the Commission.

In the triennial elections to appoint experts to the Ph. Eur.'s specialist committees, Swiss experts were elected to 89 of the approximately 850 mandates.

Operations

Energy consumption and energy label

Swissmedic buys in most of the energy that it consumes. Its energy sources are district heat and electricity. By continuously optimising building services installations and using energy-efficient technology, total energy consumption in the year under review fell by 5%.

Swissmedic is committed to using renewable energy and is expanding the sources it uses. 90% of its building heating and cooling is derived from groundwater. The commissioning of the first solar electricity installation at Swissmedic headquarters at Hallerstrasse 7 will further reduce the need to buy in electricity.

All Swissmedic properties have been certified to the Swiss MINERGIE standard since 2019. This standard reliably guarantees the energy efficiency of new and renovated buildings and thus contributes to climate protection. The renovation of the Hallerstrasse 7 and Erlachstrasse 8 properties shows that it is possible to reconcile the apparent conflict between preserving historical buildings and bringing them up to modern energy efficiency standards. High-quality renovation of protected buildings that equips them for contemporary use both guarantees their continued existence and maintains their value.

First step towards digital transformation

Digital transformation will bring about a lasting change in the way Swissmedic works in both the medium and long term. As it embarks on the transformation, Swissmedic intends to take a holistic view of its human, organisational and technological parameters.

During 2019 Swissmedic ran a pilot project to assess the potential of artificial intelligence as an aid to its daily work. The area chosen for the pilot was clinical trials monitoring. Publicly accessible documents were analysed automatically by machine and manually by Swissmedic specialists for relevant information on side effects. The resulting list of potential signals prepared by computer was of at least the same quality as that prepared by the humans, and the computer was substantially more efficient. Initial indicators as regards benefits and acceptance give cause for optimism.

Operating costs

Under Article 68 TPA, Swissmedic has its own budget and keeps its own accounts. In the year under review, over 85% of income was obtained from supervisory levies and fees, the rest from payments from the federal government. The federal contribution of CHF 14.2 million is intended to fund the public services that Swissmedic provides (Legal Framework and Penal Law products, and market monitoring and information activities relating to medical devices). As in previous years, this federal contribution was not sufficient to cover costs.

Operating costs remained largely stable in 2019. Personnel and IT costs account for around 70% and 12% of the total respectively.

ANNUAL ACCOUNTS

(in KCHF)	Annex	31.12.19	31.12.18
Cash and cash equivalents	1	19,384	2,081
Receivables from sales and services	2	32,274	19,256
Other receivables	3	5,605	4,886
Prepaid expenses	4	43	59
Current assets		**57,306**	**26,282**
Fixed assets	5	2,315	3,173
Real estate	6	68,301	70,009
Intangible assets	7	1,726	2,798
Right of use	8	3,076	0
Capital assets		**75,418**	**75,980**
Total assets		**132,724**	**102,262**
Commitments on sales and services	9	4,565	4,573
Other commitments	10	1,223	1,327
Short and long-term financial commitments	12	5,000	0
Deferred income and short-term provisions	11	3,499	3,780
Short-term commitments		**14,287**	**9,680**
Long-term fixed advances, long-term financial liabilities	12	5,000	10,000
Lease obligations	8	2,891	0
Provisions for loyalty bonuses	13	2,737	2,734
Provision for pension fund commitments (net)	13	68,840	58,509
Long-term commitments		**79,468**	**71,243**
Gain / loss		26,030	11,656
Reserves		24,542	12,886
Endowment capital		14,500	14,500
Accumulated actuarial losses		–26,103	–17,703
Own capital		**38,969**	**21,339**
Total liabilities		**132,724**	**102,262**

INCOME STATEMENT

(in KCHF)	Annex	2019	2018
Procedural fees and income pursuant to Art. 69 TPA	14	48,202	42,104
Supervisory levies	15	56,020	44,662
Other income	16	405	383
Federal contribution	17	14,212	14,056
Other operating income	18	28	56
Loss of revenues from procedural fees	19	–6,707	–8,920
Net income		**112,160**	**92,341**
Services for third parties	20	–1,023	–1,128
Personnel	21	–63,808	–57,006
Rental, maintenance, energy, transport and insurance	22	–2,373	–2,442
Administration	23	–3,690	–4,206
IT	24	–9,806	–9,940
Other expenses	25	–367	–269
Amortisation	5-8	–4,799	–5,555
Total operating expenditure		**–85,866**	**–80,546**
Operating income		**26,294**	**11,795**
Financial income	26	9	10
Financial expense	27	–273	–149
Financial result		**–264**	**–139**
Gain / loss		**26,030**	**11,656**

STATEMENT OF COMPREHENSIVE INCOME

(in KCHF)	Annex	2019	2018
Gain / loss		26,030	11,656
Other income			
Actuarial gains / losses	13	–8,400	–8,349
Total comprehensive income		**17,630**	**3,307**

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

CASH FLOW STATEMENT

(in KCHF)	Annex	2019	2018
Income/(expenditure) from business activities			
Total comprehensive income		17,630	3,307
Depreciation of tangible fixed assets	5	1,245	1,133
Writedowns on real estate	6	2,301	2,276
Depreciation of intangible assets	7	1,072	2,146
Writedowns on right of use	8	181	0
Reversal (–) / recognition (+) of provisions for loyalty bonuses	13	3	59
Reversal (–) / recognition (+) of pension fund commitments	13	10,331	2,375
Accrued interest on lease commitments	8	24	0
		32,787	**11,296**
Increase (–) / decrease (+) in receivables from sales and services	2	–13,018	1,632
Increase (–) / decrease (+) in other receivables	3	–719	619
Increase (+) / decrease (–) in prepaid expenses	4	16	–12
Increase (+) / decrease (–) in commitments from sales and services	9	–8	–515
Increase (+) / decrease (–) in other current, non-interest-bearing commitments	10	–299	–565
Increase (+) / decrease (–) in deferred income and short-term provisions	11	–281	–32
Net cash from (employed in) operating activities		**18,478**	**12,423**
Income/(expenditure) from investing activities			
Investments in tangible fixed assets	5	–387	–99
Disposals of tangible fixed assets	5	0	0
Investments in real estate	6	–593	–635
Disposals of real estate	6	0	0
Investments in intangible assets	7	0	–471
Disposals of intangible assets	7	0	0
Cash flow from investing activities		**–980**	**–1,205**
Income/(expenditure) from financing activities			
Change in current interest-bearing commitments	10	0	–10,000
Repayment of leasing obligations	8	–195	0
Change in long-term interest-bearing commitments	12	0	0
Cash flow from financing activities		**–195**	**–10,000**
Net increase / (decrease) in cash and cash equivalents		**17,303**	**1,218**
Cash and cash equivalents at start of year	1	2,081	863
Cash and cash equivalents at year end	1	19,384	2,081

STATEMENT OF CHANGES IN EQUITY

(in KCHF)	Gain/loss brought forward	Reserves	Endow-ment capital	Cum. vs. math. gains/losses	Total equity
Opening balance on 1 January 2018	**4,292**	**3,094**	**14,500**	**-9,354**	**12,532**
Adjustment for accounting method	0	5,500	0	0	5,500
Adjusted balance as at 1 January 2018	**4,292**	**8,594**	**14,500**	**-9,354**	**18,032**
Gain in 2018	11,656	0	0	0	11,656
Other income	0	0	0	–8,349	–8,349
Total result	**15,948**	**8,594**	**14,500**	**–17,703**	**21,339**
Reclassification of reserves	–4,292	4,292	0	0	0
Closing balance on 31 December 2018	**11,656**	**12,886**	**14,500**	**–17,703**	**21,339**
Opening balance on 1 January 2019	**11,656**	**12,886**	**14,500**	**–17,703**	**21,339**
Gain in 2019	26,030	0	0	0	26,030
Other income	0	0	0	–8,400	–8,400
Total result	**37,686**	**12,886**	**14,500**	**–26,103**	**38,969**
Reclassification of reserves	–11,656	11,656	0	0	0
Closing balance on 31 December 2019	**26,030**	**24,542**	**14,500**	**–26,103**	**38,969**

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, payments from the federal government and through services rendered to third parties. To ensure that its control activities are efficient, the Agency is managed according to the principles of good business practice.

Summary of the main accounting principles

Introduction

These annual accounts have been prepared in accordance with legal requirements and International Financial Reporting Standards (IFRS). The accounting principles have been applied consistently for 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 2019 to 31 December 2019. The balance sheet date is 31 December 2019. The 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 net realisable value – normally their nominal value – unless otherwise specified. Expenses and income are recognised in the period in which they were incurred or received.

These accounts were approved by the Agency Council on 8 May 2020.

Application of new and revised standards

The changes to accounting and valuation principles resulting from the first-time application of new or revised standards and interpretations have been retroactively applied unless prospective application is specifically prescribed.

Standards, interpretations and amendments to published standards applied for the first time in 2019.
Swissmedic applied the following amendments to existing standards with effect from 1 January 2019:
- IFRS 9 Financial Instruments (amendment, compensation in the event of early repayment)
- IFRS 16 Leases (issued in January 2016, supersedes IAS 17)
- IAS 19 Employee Benefits (amendment of assumptions for determining service cost in the event of a plan amendment, curtailment or settlement)
- IAS 28 Investments in Associates (amendment, long-term interests and loans – IAS 28 or IFRS 9)
- IFRIC 23 Uncertainty over Income Tax Treatments (issued in June 2017)
- Amendments stemming from annual improvements between 2015 and 2017 and affecting IFRS 3, IFRS 11, IAS 12 and IAS 23

The impact of the amended standards on Swissmedic's 2019 annual accounts will be explained below under the heading "Changes in accounting policies and impact on reporting".

Standards, interpretations and amendments to published standards that are not yet mandatory.
The following published standards, interpretations and amendments to existing standards that are mandatory for financial years starting on 1 January 2020 or later are not being adopted early at Swissmedic. It is anticipated that application of these standards (to the extent that they are relevant to Swissmedic) will be limited to additional disclosures in the annual accounts.
- IASB Conceptual Framework (revised framework), valid from 1 January 2020
- IFRS 3 Business combinations (definition of a business amended), valid from 1 January 2020
- IAS 1 Presentation of Financial Statements (amendment to materiality), valid from 1 January 2020
- IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors (amendment to materiality), valid from 1 January 2020
- IFRS 17 Insurance Contracts (issued in May 2017, supersedes IFRS 4), valid from 1 January 2020

Changes in accounting policies and impact on reporting

With the exception of the first-time application of IFRS 16 Leases, Swissmedic has consistently applied the accounting and valuation methods described in these financial statements.

Application of IFRS 16 Leases
The commitment from the rental agreement for the Swissmedic archive, which used to be posted under expenses for rented business premises. is now valued and recognised at the present value of the remaining lease instalments, applying the incremental borrowing rate at the time the standard was first applied. The archive is carried at the same amount as a right of use under assets and written down over the term of the agreement.

Apart from specific disclosure requirements, the primary effects of applying IFRS 16 at Swissmedic are an increase in both assets and liabilities. In the income statement, application has the effect of shifting redemption and interest expenses for the financing component from rental expenses to depreciation charges.

Swissmedic decided to adopt the modified retrospective approach for first-time application of IFRS 16. Under this approach, previous years' figures are not amended, but the cumulative effect of applying the standard for the first time is recorded as an adjustment of reserves at the time of first application, i.e. 1 January 2019. Swissmedic is applying an option under the standard and can therefore recognise right of use at the same value as the lease obligation. Accordingly, first-time application of the standard does not affect the equity shown in the opening balance sheet.

Cash and cash equivalents

Cash and cash equivalents comprise cash holdings in Swiss francs, free assets held with financial institutions (current accounts for payments) and short-term (max. 90 days) money market investments with financial institutions.

Cash in hand, sight deposits and short-term money market investments with banks (cash management) are stated at nominal value. Risk provisioning on receivables from financial institutions is carried out using the ECL (expected credit losses model) and is based on rating classifications issued by recognised ratings agencies. Key risk provisions are recognised as negative assets under cash and cash equivalents.

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 fall into the "hold" category and are stated at updated acquisition cost less risk provisioning. For this purpose, Swissmedic applies the simplified risk provisioning procedure, which includes a risk provision for the entire duration of the ECL on first recognition.

In addition to individual value adjustments – generally only for receivables obtained by legally enforced collection – Swissmedic makes a general allowance that is based on historic defaulting.

All receivables are in Swiss francs.

Other receivables

Other receivables are short-term receivables that are not recognised as receivables from services. They are stated at updated acquisition cost, less risk provisioning (where they qualify as financial instruments).

Swissmedic invoices the fee-based services it provides in accordance with the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products. Not all applications had been fully processed by 31 December. Services provided during the year under review but not yet invoiced are carried under other receivables. The cut-off point is determined and stated on the basis of costs incurred taking account of anticipated earnings.

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 amortised on a straight-line basis over their expected useful life or the agreed term of the contract, whichever is shorter, 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
16001	Assets under construction (properties)	–
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..

Financial assets

Swissmedic does not possess any financial assets.

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 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
17911	Assets under construction (intangible assets)	–

The residual value, useful life and depreciation 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. Right of use is amortised as a depreciation charge in the income statement.

Lease obligations

First-time valuation of lease obligations is based on the present value of the minimum lease payments over the expected term. Lease obligation 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 obligations.

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 obligation.

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.

Exchange rate differences for foreign-currency payments occur when the amount is debited at the bank. These differences are manually booked in the general ledger immediately after debiting.

Fixed advances

To bridge liquidity bottlenecks, Swissmedic has a CHF 10 million credit line, which it can draw in instalments of at least CHF 1 million for a maximum term of 10 years. Fixed advances are valued at updated acquisition cost.

Long-term financial commitments

Swissmedic finances its properties through a mortgage. Long-term financial commitments are valued at updated acquisition cost.

Provisions

Provisions are recognised in the balance sheet if they fulfil all of the following conditions:
– A current legal or de facto obligation is based on a past event.
– The event is likely to involve an outflow of resources with economic benefits.
– A reliable estimate can be made of the amount of the obligation.

The amount recognised as a provision represents the best estimate of the expenditure required to settle the present obligation at the balance sheet date.

Examples of short-term provisions at Swissmedic
– Provisions for holiday and flexitime
– Provisions for 13th monthly salary including social insurance contributions (always reversed during the current financial year)

Examples of long-term provisions at Swissmedic
– Provisions for future entitlement to loyalty bonuses
– Provisions for pension fund obligations

Provisions for pension fund 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 actuarial assumptions underlying the calculations 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 reported directly under equity as a component that does not impact the income statement.

The costs of the defined benefit plan are recognised 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, curtailments and settlements are immediately recognised in the income statement.

Provisions 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 TPA 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	31.12.19	31.12.18
Euro	1.1095	1.1510
US dollar	1.0015	1.0120
British pound	1.2900	1.3063
Swedish kronor	0.1039	0.1118

Income

Swissmedic's income mainly comprises earnings from fees, supervisory levies, payments from the federal government and various other small earnings items.

Procedural fees in accordance with Article 65 TPA and income in accordance with Article 69 TPA
In accordance with Article 65 paragraph 1 TPA, Swissmedic charges fees for authorising human and veterinary medicinal products, issuing establishment licences for the manufacture of and wholesale trading in medicines, approving clinical trials of therapeutic products and monitoring the medicinal products market. Swissmedic provides services in a sovereign capacity for a large number of customers. 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.

Billing is based on the Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO). The majority of fees are flat-rate fees.

On every balance sheet date, there are always applications that are still undergoing processing. The work in progress is apportioned between accounting periods as follows: At year end, the direct personnel expenses incurred in connection with all pending applications are evaluated from the system. If the direct personnel expenses on the cut-off date are greater than the flat-rate fees, only the total amount of all flat-rate fees on the balance sheet date is reported or capitalised. Income is recorded at the time the decision/official decision is issued.

Other income comprises speakers' fees for presentations given by Swissmedic staff, 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 TPA
In accordance with Article 65 paragraphs 2 and 3 TPA, 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. The levy is equivalent to 0.8% of the ex-factory price. The authorisation holder's self-declaration forms the basis for calculating the supervisory levy.

Authorisation holders, who paid at least CHF 15,000 in supervisory fees during the previous year, are required to make a payment on account. Income is recorded at the time of invoicing in accordance with the authorisation holder's self-declaration as at 31 December. The payments on account are not booked as income.

Other income
Other income comprises sales of small items, collection commission for withholding tax deductions, redistribution of CO2 taxes, Swiss National Accident Insurance Fund and loss of earnings compensation, the difference from VAT net tax rates and other minor sources of income. The income is recorded as soon as the service has been provided.

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. The income is recorded in monthly instalments.

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 obligations 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).

Financial risk management

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, i.e. they are 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 ICS is audited annually to review its fitness for purpose.

Risk assessment

Financial risks tend to be slight for the following reasons:
- Reserves are tied up in Swissmedic's fixed assets (property).
- Procedural fees and levies account for a large proportion of sales.
- Although procedural fees do not become due until the relevant service has been provided, the risk of default is marginal because customers are obliged to use Swissmedic's services.
- Supervisory levies are geared to the total sales of all medicinal and transplant products sold in Switzerland at ex-factory prices and the amount is based on authorisation holders' self-declaration. The risk of losses is slight since self-declarations are confirmed to be accurate either by the authorisation holder's auditors or by a management board member. Authorisation holders would not benefit from refusing to pay the levies because this could result in authorisation being suspended.
- Swissmedic does not hold any derivative financial instruments and does not undertake any hedging transactions.
- Swissmedic does not have holdings in other companies.

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, inventories or other assets that are exposed to market price fluctuations.

Credit risk

Fees and levies account for the majority of sales income. Although these do not become due until the relevant service has been provided, the risk of default and associated losses is marginal because customers are obliged to use Swissmedic's services by virtue of monopoly position. Accordingly, there is no material credit risk.

Liquidity risk

Swissmedic demands payments on account for supervisory levies. These are invoiced in such a way as to offset liquidity fluctuations.

Liquidity planning takes place on a monthly basis. To bridge liquidity bottlenecks for cash management purposes, and in addition to a current account credit facility, Swissmedic has a CHF 10 million credit line, which it can draw in instalments of at least CHF 1 million for a maximum term of 10 years. The option of being able to use fixed advances to bridge liquidity bottlenecks at any time ensures adequate risk coverage.

Cash flow and fair value interest rate risk

Since Swissmedic does not have any significant interest-earning assets, cash flow is essentially unaffected by fair value interest.

The effect of changes in market interest rates on Swissmedic's mortgages is not considered to be material.

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 significant risk of recognised assets and liabilities having to be adjusted within the next financial year. Material estimates are applied when determining the amount to be set aside in provisions, 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)	31.12.19	31.12.18
Cash	0	0
Current accounts at banks	19,384	2,081
Total cash and cash equivalents	**19,384**	**2,081**

As expected, cash and cash equivalents have increased. Many companies pay receivables to Swissmedic before they become due. Income rose compared with the previous year.

A risk provision of zero was determined on first-time application of IFRS 9 Financial Instruments. Risk provision changed only slightly during 2019. For reasons of materiality, no risk provision was stated.

2 Receivables from sales and services

Trade receivables from third parties

(in KCHF)	31.12.19	31.12.18
Not overdue	31,884	19,160
1–30 days overdue	72	52
More than 30 days overdue	347	93
Total receivables from sales and services (gross)	32,303	19,305
Individual value adjustments	–22	–47
Risk provision according to IFRS 9	–7	–2
Total receivables from sales and services (net)	**32,274**	**19,256**

Supervisory levies are recognised as at 31 December because they belong to the financial year just ended. However, they do not become due until the following year. Invoicing (less payments on account of around CHF 26 million already received) is based on the self-declarations that companies have to submit by late 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 (just under 99%), Confederation and Cantons (just under 0.6%) and private individuals (just under 0.5%). As at 17 March 2020, KCHF 6,625 in unpaid but not overdue supervisory levies was still pending.

Payment schedules

(in KCHF)	31.12.19	31.12.18
Non-overdue receivables for which the payment deadline was subsequently extended (payment schedules)	88	43
Total payment schedules	**88**	**43**

As at the end of 2019, there were 7 payment schedules (previous year: 5) for an unpaid amount of CHF 88,409. There are no foreign currency receivables.

Value adjustments on receivables

(in KCHF)	31.12.19	31.12.18
Total value adjustments on receivables 1 January	–49	–83
Recognition	0	0
Reversal	20	34
Use	0	0
Total value adjustments on receivables as at 31 December (Total of individual and flat-rate adjustments)	**–29**	**–49**

Since 2018, Swissmedic has been applying a flat-rate value adjustment in accordance with IFRS 9 in addition to individual adjustments. Value adjustments on receivables fell by KCHF 20 compared with the previous year.

3 Other receivables

(in KCHF)	31.12.19	31.12.18
Work in progress	5,605	4,876
Other	0	10
Total other receivables	**5,605**	**4,886**

The financial assets carried in other receivables are always valued using the three-stage risk provisioning model for financial instruments. There was no reportable risk provision for 2019. The likelihood of default on work in progress follows ECL for non-due receivables.

Since 1 January 2018, work in progress has been apportioned between accounting periods in accordance with IFRS 15. At year end, the direct personnel expenses incurred in connection with all pending applications are evaluated. If the direct personnel expenses on the cut-off date are greater than the flat-rate fees, only the total amount of all flat-rate fees on the balance sheet date is reported or capitalised. It is not possible to factor in the extent to which applications have been completed.

As at 31 December 2019, work in progress had increased as expected.

4 Prepaid expenses

(in KCHF)	31.12.19	31.12.18
Prepaid expenses	43	59
Total prepaid expenses	**43**	**59**

The following items are recorded as prepaid expenses:
- A small number of invoices for services due for delivery in 2020 but which had to be paid for in 2019.
- One outstanding service charge invoice for 2019
- One invoice for a contract dating from 2020

5 Fixed assets

Statement of changes (in KCHF)	Furnishings, office equipment	Archive facilities	Laboratory equipment	Computer systems	Total assets
Acquisition cost					
1 January 2018	**2,715**	**1,963**	**4,662**	**87**	**9,427**
Additions	0	0	99	0	99
Disposals	–7	0	–87	0	–94
31 December 2018	**2,708**	**1,963**	**4,674**	**87**	**9,432**
1 January 2019	**2,708**	**1,963**	**4,674**	**87**	**9,432**
Additions	15	0	372	0	387
Disposals	0	0	–23	0	–23
31 December 2019	**2,723**	**1,963**	**5,023**	**87**	**9,796**
Accumulated depreciation					
1 January 2018	**–665**	**–1,687**	**–2,781**	**–87**	**–5,220**
Additions	–511	–112	–510	0	–1,133
Disposals	7	0	87	0	94
31 December 2018	**–1,169**	**–1,799**	**–3,204**	**–87**	**–6,259**
Net carrying amounts as at 31 December 2018	**1,539**	**164**	**1,470**	**0**	**3,173**
1 January 2019	**–1,169**	**–1,799**	**–3,204**	**–87**	**–6,259**
Additions	–506	–95	–644	0	–1245
Disposals	0	0	23	0	23
31 December 2019	**–1,675**	**–1,894**	**–3,825**	**–87**	**–7,481**
Net carrying amounts as at 31 December 2019	**1,048**	**69**	**1,198**	**0**	**2,315**

During 2019, two dishwashers were replaced, a small amount of laboratory equipment was purchased, and a small amount of superannuated or faulty laboratory equipment was scrapped.

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

6 Real estate

Statement of changes (in KCHF)	Renovation account	Property	Land	Total real estate
Acquisition cost				
1 January 2018	**0**	**82,817**	**11,730**	**94,547**
Additions	567	68	0	635
Reclassifications	–199	199	0	0
Disposals	0	–366	0	–366
31 December 2018	**368**	**82,718**	**11,730**	**94,816**
1 January 2019	**368**	**82,718**	**11,730**	**94,816**
Additions	593	0	0	593
Reclassifications	–916	916	0	0
Disposals	0	0	0	**0**
31 December 2019	**45**	**83,634**	**11,730**	**95,409**
Accumulated depreciation				
1 January 2018	**0**	**–22,897**	**0**	**–22,897**
Additions	0	–2,276	0	–2,276
Disposals	0	366	0	366
31 December 2018	**0**	**–24,807**	**0**	**–24,807**
Net carrying amounts as at 31 December 2018	**368**	**57,911**	**11,730**	**70,009**
1 January 2019	**0**	**–24,807**	**0**	**–24,807**
Additions	0	–2,301	0	–2,301
Disposals	0	0	0	0
31 December 2019	**0**	**–27,108**	**0**	**–27,108**
Net carrying amounts as at 31 December 2019	**45**	**56,526**	**11,730**	**68,301**

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.

The following were capitalised in 2019: renovation of the southern pitched roof of the Hallerstrasse property and renovation/extension of the wastewater collection tank, laboratory ventilation system and emergency power supply of the Freiburgstrasse property.

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

7 Intangible assets

Statement of changes (in KCHF)	Software in development	Software developed by Swissmedic	Total intangible assets
Acquisition cost			
1 January 2018	**468**	**15,208**	**15,676**
Additions	471	0	471
Reclassifications	–939	939	0
Disposals	0	0	0
31 December 2018	**0**	**16,147**	**16,147**
1 January 2019	**0**	**16,147**	**16,147**
Additions	0	0	0
Reclassifications	0	0	0
Disposals	0	0	0
31 December 2019	**0**	**16,147**	**16,147**
Accumulated depreciation			
1 January 2018	**0**	**–11,203**	**–11,203**
Additions	0	–2,146	–2,146
Disposals	0	0	0
31 December 2018	**0**	**–13,349**	**–13,349**
Net carrying amounts as at 31 December 2018	**0**	**2,798**	**2,798**
1 January 2019	**0**	**–13,349**	**–13,349**
Additions	0	–1,072	–1,072
Disposals	0	0	0
31 December 2019	**0**	**–14,421**	**–14,421**
Net carrying amounts as at 31 December 2019	**0**	**1,726**	**1,726**

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.

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 2019	**0**	**0**
Adjusted owing to first-time application of IRFS 16	3,257	3,257
Adjusted balance as at 1 January 2019	3,257	3,257
Additions	0	0
31 December 2019	**3,257**	**3,257**
Accumulated depreciation		
1 January 2019	**0**	**0**
Adjusted owing to first-time application of IRFS 16	0	0
Adjusted balance as at 1 January 2019	0	0
Additions	–181	–181
31 December 2019	**–181**	**–181**
Net carrying amounts as at 31 December 2019	**3,076**	**3,076**

Owing to the first-time application of IFRS 16 Leases, disclosure is only for the reporting year.
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 obligations. The rental agreement runs until the end of 2036.
As at the balance sheet date, there were no indications of any unanticipated impairments.

Lease obligations

(in KCHF)	
1 January 2019	0
Adjusted owing to first-time application of IRFS 16	3,257
Adjusted balance as at 1 January 2019	**3,257**
Redemption	–195
Accrued interest	24
Additions	0
31 December 2019	**3,086**

Owing to the first-time application of IFRS 16 Leases, Swissmedic recorded lease obligations of KCHF 3,257 in its opening balance sheet.
The weighted average incremental borrowing rate for the lease obligations reported at the time of first-time application was 0.85 per cent.

9 Commitments on sales and services towards third parties

(in KCHF)	31.12.19	31.12.18
In CHF	4,563	4,547
In EUR	2	25
In USD	0	1
Total commitments on sales and services towards third parties	**4,565**	**4,573**

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

10 Other commitments

(in KCHF)	31.12.19	31.12.18
Short-term leasing commitments	195	0
Other current commitments towards third parties	1,028	1,327
Total other commitments	**1,223**	**1,327**

As at the balance sheet date, Swissmedic did not have any current fixed advances. Assets confiscated by Swissmedic are recorded under other current commitments towards third parties.

11 Deferred income and short-term provisions

(in KCHF)	31.12.19	31.12.18
Deferred income	141	474
Provision for holiday and flexitime	3,233	3,193
Other short-term provisions	125	113
Deferred income and short-term provisions	**3,499**	**3,780**

Deferred income includes:
- 3 outstanding invoices from 2019 (approx. KCHF 107)
- Outstanding experts' invoices and employees' expenses from 2019 (approx. KCHF 35)

Details of the provision for holiday and flexitime

(in KCHF)	31.12.19	31.12.18
Starting balance as at 1 January	3,193	3,437
Effective recognition	40	0
Effective reversal	0	–244
Final balance as at December 31	**3,233**	**3,193**

12 Short and long-term financial commitments

(in KCHF)	31.12.19	31.12.18
Short-term commitments	5,000	0
Long-term commitments	5,000	10,000
Total short- and long-term financial commitments	**10,000**	**10,000**

The properties owned by Swissmedic are financed by fixed-rate mortgages. Swissmedic has two CHF 5 million mortgages that are subject to the following terms:
– 0.7%, matures 24 November 2020
– 0.9%, matures 24 November 2022

The long-term fixed-rate mortgages are valued at updated acquisition cost. Their fair value is detailed below:

(in KCHF)	31.12.19	31.12.18
Valuation date		
Fair value (CF discounted) 5 mn 2020	101.14%	102.50%
Fair value (CF discounted) 5 mn 2022	104.35%	105.09%
(Excluding accrued interest)	10,274	10,379

13 Pension provision

Disclosure note loyalty bonuses (in KCHF)	31.12.19	31.12.18
Balance sheet		
Liability for loyalty bonuses at start of year	2,734	2,675
Length-of-service expenditure	289	305
Interest expense	26	21
Actuarial loss	292	301
Loyalty bonuses paid out	–604	–568
Liability for loyalty bonuses at year-end	**2,737**	**2,734**

Description of pension plans and pension institution

All Swissmedic employees and pension recipients are insured by the Swissmedic pension fund, which operates a defined contribution scheme. This pension fund is attached to the PUBLICA collective pension fund. PUBLICA is an autonomous public institution of the Swiss Confederation.

The pension plan provides disability, death, old-age and departure benefits that exceed the minimum required by law. The risk benefits are determined on the basis of the projected interest-bearing savings capital and a conversion rate and are limited to a fixed percentage of insured income (to 60% in the case of disability). Insured members can choose from different savings contribution plans. Their choice of plan does not affect the amount of the employer contribution.

Responsibilities of the joint committee and fund commission

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 from Swissmedic.

The fund commission is PUBLICA's supreme governing body. It provides leadership, supervision and control for PUBLICA's management board. The commission has 16 members – 8 member representatives and 8 employer representatives from affiliated pension funds.

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 attains equilibrium once more.

Financing agreements on future contributions

Occupational pension regulations (Federal Act on Occupational Old Age, Survivors' and Invalidity Pension Provision) provide for minimum benefits on retirement. Legislation prescribes minimum annual contributions. However, employers can also pay higher contributions than those prescribed by law. The contributions 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. Such contributions cannot be repaid to employers. However, employers can draw on them to pay future employer contributions (employer contribution reserve).

By law, minimum annual contributions still have to be paid even if a surplus exists. Both employer and employee contributions have to be paid for active members. The employer contribution must be at least equal to the employee contribution.

Pension fund status is calculated as follows:

(in KCHF)	2019	2018
Change in obligations and assets		
Dynamic present value of benefit obligations at start of year	**–316,424**	**–318,128**
Actuarial pension benefit expenses	–8,270	–8,375
Employee contributions	–3,632	–3,576
Past benefit expenses	0	–13,315
Interest expense	–2,706	–2,242
Curtailment, settlement	0	20,494
Benefits paid	3,819	6,635
Actuarial gain (+) / loss (–) on obligations	–30,237	2,083
Dynamic present value of benefit obligations at year-end	**–357,450**	**–316,424**
Plan assets at market value at start of year	257,914	261,993
Anticipated investment income	2,209	1,849
Employer contributions	6,651	7,605
Employee contributions	3,632	3,576
Benefits paid	–3,819	–6,635
Administrative expenses	–107	–43
Actuarial gain (+) / loss (–) on investments	22,129	–10,431
Plan assets at market value at year-end	**288,609**	**257,914**
Balance sheet	**31.12.19**	**31.12.18**
Plan assets at market value	288,610	257,914
Dynamic present value of benefit obligations (DBO)	–357,450	–316,424
Surplus (+) / deficit (–) / provision on balance sheet	**–68,840**	**–58,510**
Duration	18.5	17.8

Income statement (in KCHF)	2019	2018
Actuarial pension benefit expenses	–8,270	–8,375
Interest expense	–2,706	–2,242
Plan amendment (retirement credit rates)	2,209	1,849
Past benefit expenses	0	–13,315
Gain (loss) from curtailment, settlement	0	20,494
Administration costs	–107	–43
Actuarial net cost of benefits to employer	**–8,874**	**–1,632**
Change in the balance sheet	**31.12.19**	**31.12.18**
Provision on the balance sheet at start of year	**–58,510**	**–56,135**
Net benefit expenses (employer)	–8,874	–1,632
Employer contributions	6,651	7,605
Prepaid (underpaid) benefit costs	**–2,223**	**5,973**
Total amount recognised in equity (gains / losses)	–8,108	–8,348
Provision on the balance at year-end	**–68,840**	**–58,510**
Anticipated employer contribution payment in following year	6,820	6,636
Effective return on plan assets	24,338	–8,582
Key actuarial assumptions as at balance sheet date	**31.12.19**	**31.12.18**
Discount rate (technical interest rate)	0.25%	0.85%
Future payroll increases	1.25%	1.25%
Future pension increases	0.00%	0.00%
Actuarial bases	OPA 2015 GT	OPA 2015 GT
Probable rate of turnover	High	High
Retirement age	63.5	63.5
Life expectancy at retirement age	24.14/26.25	24.03/26.14
Asset allocation	**31.12.19**	**31.12.18**
Cash and cash equivalents	3.10%	3.00%
Bonds	57.90%	59.90%
Equities	27.70%	27.40%
Real estate	9.20%	7.50%
Other	2.10%	2.20%
Total	**100.00%**	**100.00%**
Of which stock exchange-traded	88.60%	90.00%

Defined benefit pension plans	31.12.19	31.12.18
Revaluation of actuarial gain/loss from obligations	**–30,237**	**2,083**
owing to changes in holdings	–756	–3,664
owing to financial assumptions	–29,481	5,747
Revaluation of actuarial gain/loss from investments	**22,129**	**–10,431**
Total amount recognised in equity	**–8,108**	**–8,348**

Sensitivities – impact on DBO (in KCHF)	2019	2018
Discount rate + 0.25%	–12,788	–10,735
Discount rate - 0.25%	13,569	11,370
Payroll increase + 0.25%	1,144	978
Payroll increase - 0.25%	–1,118	–956
Pension increase + 0.25%	12,018	10,112
Pension increase – 0.25% (not lower than 0%)	0	0
1-year increase in life expectancy	14,663	12,794

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 earnings

(in KCHF)	2019	2018
Authorisation (with no fee rebates)	29,794	27,983
Licensing	14,463	10,425
Therapeutic products information	50	9
Information for the general public	2	0
Market supervision	2,428	1,255
Penal law	263	1,018
Fee surcharges	645	776
Earnings from conferences (Art. 69 TPA)	205	488
Earnings from publications (Art. 69 TPA)	11	0
Earnings from services for third parties (Art. 69 TPA)	341	150
Total procedural fees	**48,202**	**42,104**

The increase in procedural fees compared with the previous year is essentially due to the increase in fees for licences (plus CHF 4 million). Since 1 January 2019, Swissmedic has been charging flat-rate fees that reflect the workload involved. Furthermore, requests for changes to GMP/GDP licences issued under the old legislation automatically result in a one-time renewal, for which a fee is charged. Income will fall again in the future as GMP/GDP renewals will become obsolete under the new legislation.

15 Supervisory levies

(in KCHF)	2019	2018
Supervisory levies	56,020	44,662
Total supervisory levies	**56,020**	**44,662**

In accordance with the new legislation, levies have been charged at a uniform rate of 0.8% since 1 January 2019. Assessment is based on total turnover from medicinal and transplant products sold at ex-factory prices. During budgeting, it was assumed that the standard levy rate would result in an increase in income.

16 Other income

(in KCHF)	2019	2018
Miscellaneous sales and income	405	383
Total other income	**405**	**383**

17 Federal contribution

(in KCHF)	2019	2018
Federal contribution	14,212	14,056
Total federal contribution	**14,212**	**14,056**

The strategic goals for the 2019–2022 period approved by the Federal Council define the activities and products that can be financed using the federal contribution. 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.

18 Other operating income

(in KCHF)	2019	2018
Income from properties (rental of parking spaces to employees)	28	56
Total other operating income	**28**	**56**

19 Revenue losses

(in KCHF)	2019	2018
Fee reductions	–6,707	–8,920
Total loss of revenues from procedural fees	**–6,707**	**–8,920**

20 Third-party services

(in KCHF)	2019	2018
Medical and pharmaceutical services	–765	–767
Laboratory services	–29	–32
Other third-party services	–229	–329
Total expenditure on services for third parties	**–1,023**	**–1,128**

All expenditure for medical and pharmaceutical services derives from contracts with the vigilance centres and Tox Info Suisse.

21 Personnel

(in KCHF)	2019	2018
Wages and salaries	–49,159	–49,744
Net benefits expenses as per IAS 19	–8,874	–1,631
Social security	–4,349	–4,243
Other personnel expenses	–1,420	–1,376
Work by third parties	–6	–12
Total personnel expenses	**–63,808**	**–57,006**

22 Rental, maintenance, energy, transport and insurance

(in KCHF)	2019	2018
Rent and service costs, cleaning and maintenance of business premises	–432	–697
Own business premises	–608	–535
Maintenance of office equipment, furnishings and fixtures and laboratory equipment	–653	–503
Fixed asset leasing	–21	–55
Repairs, service vehicles, vehicle insurance and taxes	–2	–1
Couriers and transport	–213	–199
Property and liability insurance	–100	–109
Electricity, water, district heating and waste disposal	–344	–343
Total rental, maintenance, energy, transport and insurance	**–2,373**	**–2,442**

23 Administration

(in KCHF)	2019	2018
Office and laboratory materials, other consumables	–780	–716
Professional literature, subscriptions and membership contributions	–456	–477
Telecommunications	–19	–23
Publications	–64	–67
Travel and entertainment	–703	–872
Administrative services (translations, auditing, services not associated with added value process, accreditation/certification fees)	–1,668	–2,051
Total administration	**–3,690**	**–4,206**

24 IT

(in KCHF)	2019	2018
Operating and support services	–5,714	–5,428
Hardware	–114	–60
Software licences	–344	–284
Development services	–3,249	–2,558
Maintenance services	–385	–1,610
Total IT	**–9,806**	**–9,940**

The way in which development and maintenance services are reported was modified during the year under review. The cost of minor change requests is now also recorded under development services. Overall expenditure on both items declined compared with the previous year since it was not possible to implement all projects as planned.

25 Other expenses

(in KCHF)	2019	2018
Catering	–156	–172
Other expenses	–102	–22
Security	–76	–72
Losses on accounts receivable	–32	–1
Rebates (accounts payable)	1	1
Bank charges	–2	–3
Total other expenses	**–367**	**–269**

26 Financial income

(in KCHF)	2019	2018
Interest income from receivables	3	6
Exchange rate gains	6	4
Total financial income	**9**	**10**

27 Financial expense

(in KCHF)	2019	2018
Interest expense, banks	–241	–142
Interest expense, leases	–25	0
Exchange rate losses	–7	–7
Total financial expense	**–273**	**–149**

Other notes

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	0	5,000	5,000	0	10,000
Commitments on sales and services towards third parties	2,340	0	0	0	2,340
Commitments on sales and services towards related parties	2,199	0	0	0	2,199
Lease obligations toward third parties	0	195	780	2,111	3,086
Total financial liabilities	**4,539**	**5,195**	**5,780**	**2,111**	**17,625**

Contingent liabilities and contingent assets

Pending proceedings

Pending administrative appeals procedures: 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 maximum average is unlikely to exceed CHF 50,000 per year.

Business 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 (FDHA)
- 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)	2019	2018
GS FDHA, federal contribution	14,212	14,056
Total net sales involving related parties	**14,212**	**14,056**
PUBLICA, SOCIAL INSURANCE CONTRIBUTIONS	10,288	11,190
FOITT, IT expenses	5,386	4,846
CFC, social insurance contributions	6,169	5,976
Total operating expenses involving related parties	**21,843**	**22,012**

Remuneration to management

The following fees and salaries were paid:

(in KCHF)	2019	2018
Chairman of the Agency Council (incl. expenses)	38	41
Total Agency Council excl. Chairman (incl. expenses)	139	148
Executive Director of Swissmedic	302	296
Total management excl. Executive Director	1,553	1,580
Chairman of the Agency Council (incl. expenses)	**2,032**	**2,065**

The Agency Council consists of a maximum of seven members. In the reporting year there were seven members, including the Chairman (previous year: 7).

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

The salaries of all staff were increased by an average of 1.2% as of 1 January 2019. The Executive Director's salary increased by 1.6%, while the total remuneration paid to the other members of the Management Board has fallen slightly (change in personnel).

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

EIDGENÖSSISCHE FINANZKONTROLLE
CONTRÔLE FÉDÉRAL DES FINANCES
CONTROLLO FEDERALE DELLE FINANZE
SWISS FEDERAL AUDIT OFFICE

Reg. Nr. 1.20006.995.00343.002 (transl.)

Report of the statutory auditor

to the Agency Council of the Swiss Agency for Therapeutic Products, Berne

Report on the audit of the financial statements

Opinion

According to article 74 of the Therapeutic Products Act (SR 812.21) we have audited the financial statements of the Swiss Agency for Therapeutic Products (Swissmedic), which comprise the statement of financial performance 2019, the balance sheet as of 31 December 2019, the statement of changes in equity and the cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion the accompanying financial statements (pages 70 to 104) present fairly, in all material respects, the financial position of Swissmedic as of 31 December 2019, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS) and the Therapeutic Products Act.

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 standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent based on the Federal Audit Office Act (SR 614.0) and the requirements of the audit profession 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 and our auditor's report 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.

Responsibilities of 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 legal requirements, 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 Swissmedic's ability to continue as a going concern, disclosing, as applicable, matters related to going concern.

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, Swiss Auditing Standards and ISAs 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.

As part of an audit in accordance with Swiss law, Swiss Auditing Standards and ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Swissmedic's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Agency Council's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on Swissmedic's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the notes to the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Swissmedic to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Management Board, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Report on other legal and regulatory requirements

In accordance with the Federal Audit Office Act and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of the financial statements according to the instructions of the Agency Council.

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

Berne, 16. April 2020

SWISS FEDERAL AUDIT OFFICE

Andreas Baumann
Auditor in Charge
Licensed audit expert

Christine Neuhaus
Licensed audit expert

swissmedic

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