swissmedic

Annual Report 2017

Mission:
Our competence –
for therapeutic products you can trust.

Guiding principles of Swissmedic

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Christine Beerli

Foreword by Christine Beerli and Jürg H. Schnetzer

Competent, credible and respected

The year 2017 marked the transition to a new line-up at the top of the Agency. Over the last ten years many issues have been addressed, much has changed or progressed, targeted investments have been made and the pace has accelerated in all areas. Our stakeholders also confirm that this is the case. In an international comparison, Swissmedic is now viewed as a modern, efficient authority. This makes it the ideal time to entrust the roles of Executive Director and Chair of the Agency Council to fresh hands.

Today Swissmedic is an efficient and consistent safety authority that is clearly positioned, nationally and internationally networked and politically autonomous, as the reports, figures and commentaries in this Annual Report demonstrate. The Agency fulfils its mandate reliably and professionally in its day-to-day business, in optimising its processes and in its legislative projects.

2017 was dominated by work on the implementation of the revised Therapeutic Products Act. Revising the implementing legislation (Therapeutic Products Ordinance Package TPO IV) and adapting processes, requirements and IT systems are complex tasks.

The primary goal of the new legislation is to simplify market access to medicinal products, improve drug safety and increase transparency.

By 1 January 2019, Swissmedic intends to be operationally and functionally ready to conduct its business activities in compliance with the new legal requirements. In the short time available, we want to continue our constructive dialogue with pharmaceutical industry associations to ensure that the industry's legitimate concerns are addressed, yet without compromising our role as the oversight authority.

Medical devices legislation is being revised and closely approximated to the new EU provisions. Over the past year, the EU has tightened its requirements in this area with the aim of increasing medical device safety and quality. Two new Regulations that have to be implemented within transitional periods of up to five years will raise safety standards.

Jürg H. Schnetzer

Transposing these requirements into Swiss law is a matter of urgency in enabling our country to continue to participate in the European internal market for medical devices and to avoid technical trade barriers. Credibly implementing the new rules in the public interest will mean that capacities have to be specifically expanded. The new rules are scheduled to enter into force in 2020.

The revision of the Medicinal Products Licensing Ordinance (MPLO) should help improve supply chain monitoring and so provide protection against counterfeit or illegal therapeutic products. A coordinated international approach is essential to efforts to combat trade in counterfeit medicines, and such is the intention of the Medicrime Convention. Switzerland largely satisfies the requirements of the Convention, although the Therapeutic Products Act and Criminal Procedure Code will have to be modified to enable Swissmedic to order covert monitoring measures by the prosecuting authorities.

The Agency Council is currently working on the development of the strategic thrusts for 2019–2022. For example, the sector analysis that preceded the work identified the following strategically important developments.

- The rapid pace of transformation in science and technology is a challenge to authorities when it comes to speed and the prompt provision of specialist expertise. How does the Agency safeguard its monitoring and response capabilities?
- The development of innovative technologies goes hand in hand with the rapid advances in digital technology. How does an agency progress from Big Data to Smart Data so that it can remain operationally effective?
- It is becoming increasingly difficult for legislation to keep pace with technological progress. How can this situation be reconciled?
- The general public is swamped with health-related information and demands transparency and access, but also expects objective validation by competent authorities. The use of social networks is growing, and it is becoming increasingly difficult to distinguish between "real" and "fake" news.
  How far does Swissmedic's mandate extend?
- etc.

The strategy process is clearly managed, and the dialogue between the Agency Council and the Management Board is well established.

Christine Beerli and Jürg Schnetzer are stepping down and would like to thank all staff members, and particularly Swissmedic's management, for their commitment, loyalty and integrity over the past few years, and wish the new decision-makers and the Agency continued success in the future.

Into the future together

Stéphane Rossini and Raimund Bruhin

Stéphane Rossini

Mr Rossini, you have been Chairman of Swissmedic's Agency Council since January 2018. What are your impressions after your first few months?

I've met people who are both professional and motivated, and who are aware of Swissmedic's role and the responsibilities it bears towards the population, authorities and stakeholders. I've discovered an organisation with a transparent and ambitious management. I can rely on a dynamic Council with members who have complementary experience and are anxious to uphold the Agency's credibility. My impressions are very positive.

What are the major challenges that need to be addressed to maintain the current high level of therapeutic products regulation?

For the Agency Council, it's the challenge of presenting the 2019–2022 strategy and its implementation to the Federal Department of Home Affairs and Federal Council. This is a fundamental step. The resources this should yield will be key in ensuring we have a highly skilled workforce, modern working conditions and tightly knit, effective international networks.

How do you intend to guarantee that the Agency will be able to prepare itself quickly for change in the scientific, social or political environment in which it operates?

By putting the professional quality of our workforce and a stimulating working environment first; by encouraging continuous development; by having cutting-edge technological resources; and by working with international regulatory bodies. We will achieve this by maintaining good relations with the political authorities and our partners on the ground. A collective approach and shared culture are the only way to success.

Swissmedic is investing a lot in national and international collaboration. What is the significance of this involvement?

A globalised economy and consumption of therapeutic products entails synergies and collaboration. This is just as essential to Swissmedic as to other countries' regulatory authorities. Since there are no longer any borders as far as substances and medical devices are concerned, authorities are obliged to work together if they want to retain their credibility and legitimacy.

What will Swissmedic's role and mission be in the healthcare system in ten years' time?

To guarantee the safety of patients and ordinary people as they become ever more anxious about their health and their bodies, especially as the health business will involve increased risks of loss of control and abuse. Protecting the public interest will remain the essence of our mission.

Raimund Bruhin

Mr Bruhin, you took up the post of Executive Director of the Swiss Agency for Therapeutic Products in April 2018. What do you plan to do?

Swissmedic ought to be in a position to continue to fulfil its mandate as an independent authority with supervisory powers in areas affecting safety and the economy effectively and efficiently at national and international level, on an equal footing with partner institutions in other countries and with its stakeholders. A learning organisational culture must be established at all levels with the aim of enabling Swissmedic to respond flexibly to the challenges presented by our operating environment and to make the necessary adaptations in good time.

Swissmedic's 2017 Annual Report gives a positive assessment of its 16th year of operation. What does the future hold?

The Agency faces several challenges: 1. Replacing its service mandate and service level agreement with strategic goals. 2. Extensive, time-critical legislative work to bring Swiss medical products regulations into line with the legal environment in the EU; 3. Adapting ordinances following the revision of the Therapeutic Products Act; 4. Parallel implementation of operational measures (IT systems, processes); 5. Timely adaptation to new developments in research, technology and science; 6. Optimising and broadening international cooperation.

What do you feel is important for cooperation between the Management Board and Agency Council?

I'd like cooperation to be well coordinated, uncomplicated, transparent, objective and solution-driven. I'd like to be able to rely at all times on the loyalty and lasting support of the Council in our dialogue with politicians and stakeholders with regard to the Swissmedic cause.

The revised Therapeutic Products Act is due to enter into force at the beginning of 2019. What are the major changes?

Key aspects are simplifying market access, making self-medication easier, increasing transparency and integrity by clarifying legal requirements and strengthening enforcement, introducing a requirement to pass on discounts in accordance with the Health Insurance Act, strengthening market surveillance and increasing the safety of medicinal product use in paediatrics.

Is there anything that is personally important to you in your new role?

In general, Swissmedic must be able to keep pace with the requirements in its operating environment in a service-centred way, and, where necessary, push up the pace of change – all while retaining its focus on its core task of guaranteeing the quality, safety and efficacy of therapeutic products for the Swiss population.

We perform our mandate reliably and professionally. We observe deadlines set and make consistent decisions. As far as legally admissible, we ensure that our work is transparent. We define the quality of our work and document the results reproducibly.

Guiding principles of Swissmedic

Improved public access to medicines

Adding headache tablets and nasal sprays to the shopping basket next to the bread, butter and eggs in future?

Patients in Switzerland currently obtain their non-prescription ointments or headache tablets mainly from pharmacies and druggists. The sale of these products is subject to the provision of expert advice. But from 2019, certain non-prescription medicines will also be available in ordinary retail outlets. It should not be assumed that the situation in Switzerland will be the same as that in the USA or Germany, even though certain retailers might wish this to be the case.

Drug dispensing is heavily liberalised in the USA, where stores even stock bulk packs of painkillers that would either be available on prescription only in Switzerland or dispensed exclusively in pharmacies or druggists with appropriate expert advice. There is strong opposition to the excessively free sale of non-prescription medicines in Switzerland. Consumer safety remains the top priority.

Self-medication to be made easier

As part of the revision of therapeutic products legislation, the Swiss parliament has decided to simplify public access to medicines. It will be easier to self-medicate, and better use will be made of the expertise of pharmacies and druggists. In future, druggists will be able to dispense all non-prescription medicines, while pharmacists will even be able to dispense certain prescription-only medicines for specific indications without the need for a doctor's prescription. Dispensing category C, which covers pharmacy-only dispensing, will cease to exist. But the legislator has also decided against the introduction of "American circumstances", and to limit unrestricted sales outside of pharmacies and druggists to medicines that do not require expert advice.

Since consumer safety is the top priority, patients must continue to receive adequate advice in future when purchasing medicines. They need to know how to use a particular medicine correctly, how it works and what side effects might occur.

Review of dispensing categories

Accordingly, all existing medicines in dispensing category C will be reviewed as part of a project. They will be evaluated according to defined scientific criteria with input from external specialists who will, at the same time, also represent the professional associations of the dispensing outlets. Most medicines in dispensing category C will be reclassified in category D. The aim is to fulfil the political mandate to simplify access and make more effective use of expertise while simultaneously guaranteeing patient safety. Certain medicines will be placed in higher categories, particularly with a view to reducing the misuse of medicines and possible serious interactions with prescription-only medicines.

The project will also review medicines that are currently in dispensing category D to determine whether they can be dispensed without expert advice in the future. Suitable medicines will be reclassified in dispensing category E, enabling them to be sold in any shop and implementing the policy of improved access to medicines for self-medication.

The review will be completed by the end of 2018. This means that the reclassification of medicines will be able to start when the revised legislation comes into force. A new provision added to the Therapeutic Products Act will also give Swissmedic the authority to specify which medicines Swiss-qualified therapists will be able to dispense as part of their professional activities.

The discussions surrounding the documented dispensing of prescription-only medicines by pharmacists without the need for a doctor's prescription are proceeding separately in an expert group under the lead of the Federal Office for Public Health (FOPH).

So from 2019, consumers should be able to put medicinal teas, herb lozenges and certain liniments in their shopping basket alongside the milk and sugar.

Horizon scanning – identifying opportunities and risks in good time

CRISPR-Cas, Continuous Manufacturing, Real World Evidence. What's it all about and what might these terms have to do with Swissmedic and its mandate?

As a therapeutic products authority, Swissmedic operates in a field that is subject to rapid scientific and technical change. To be able to fulfil its statutory mandate, Swissmedic must at all times possess the powers that it needs to carry out its remit. To be equipped to face future challenges, the authority must be able to identify emerging developments in good time, assess the impact these will have on its work and take the necessary measures.

What can an authority like Swissmedic do to identify current and relevant developments? Introduced in 2016, "horizon scanning" is a systematic and continuous process for identifying at an early stage the opportunities, risks and future developments that are relevant or specific to Swissmedic and then proactively addressing them. Horizon scanning does not just deal with longer-term, clearly emerging developments, it also tracks short- to medium-term developments whose impact is not yet fully apparent. The results of horizon scanning are used mainly as a basis for decisions, but also for disseminating information.

Relevant developments and trends are recorded by constantly monitoring internal and external sources, including for example media reports, scientific literature, or information from events, working groups or existing databases. The relevant developments that are identified are prioritised by classifying them according to their urgency and importance.

Horizon scanning has proved to be an effective and established tool for the early identification of new trends, as the fact that the European Medicines Agency (EMA) also identifies relevant developments, checks their relevance and evaluates their impact demonstrates. The process is similar to horizon scanning at Swissmedic, but the Agency has adopted a more comprehensive approach, i.e. one that not only reviews scientific, technological, and regulatory developments, but also monitors economic and social trends.

One development covered by horizon scanning is CRISPR/Cas. The CRISPR method (Clustered Regularly Interspaced Short Palindromic Repeats) is a biochemical technique for cutting and modifying DNA in a targeted manner (genome editing). The CRISPR/Cas system can be used to insert, remove or switch off genes. Nucleotides in a gene can also be modified. CRISPRs are gene sequences that were first discovered in the genomes of bacteria in 1987.

But when CRISPR is mentioned nowadays, it is usually in connection with the genome editing method CRISPR-Cas, which was developed around five years ago. The method is accurate, versatile, easy to use and cost-effective. The CRISPR-Cas technology is used as part of gene therapies. Major pharmaceutical companies have recognised the potential of this technology.

Swissmedic therefore had to assess how, given the existing structures and legal bases, to process authorisation applications for clinical trials connected with treatments developed with the use of the CRISPR-Cas method. An internal review has revealed that the legal bases in Switzerland are adequate, and that Swissmedic possesses the required specialist know-how. Within the Agency, the Transplant Unit is responsible for the corresponding authorisation applications.

Another relevant trend covered by horizon scanning is continuous manufacturing. Continuous manufacturing is a production method for manufacturing or processing materials without interruption. In other words, raw materials are fed into the production process continuously, while processed products are constantly removed at the same time. Although the proportion of processed material is fairly small at any given time, continuous manufacturing still achieves the desired quantity of completed products of the requisite quality.

This is an attractive process for the pharmaceutical industry. The advantages of the technology for medicinal products include improved verifiability and quality and the fast market availability of the product. Other benefits include greater flexibility in production, a minimal percentage of waste products, low energy consumption and reduced raw material requirements. However, continuous manufacturing also involves technical, commercial, operational, staffing and regulatory challenges.

It should therefore be assumed that ever more companies will be investing in these technologies. Continuous manufacturing enables manufacturers to respond more quickly to periods of fluctuating demand and thus avoid bottlenecks in the supply of medicines. Swissmedic is constantly confronted with such bottlenecks. Regulatory authorities such as the US Food and Drug Administration (FDA) are encouraging the pharmaceutical industry to switch to continuous manufacturing, even though this is a complex change. Swissmedic also positively welcomes the submission of applications involving continuous manufacturing.

An initial authorisation application for a product manufactured in Switzerland by the continuous manufacturing process was approved by Swissmedic in 2017. The Agency has therefore already had to deal with this issue. The EMA and the FDA are working on a pilot project designed to harmonise industry requirements for continuous manufacturing. Swissmedic will take the results of this project into account when it draws up a regulatory strategy for dealing with continuous manufacturing.

CRISPR-Cas and continuous manufacturing are just two examples of numerous innovations or developments that have, or could have, specific implications for the way Swissmedic fulfils its mandate. The list could go on and on.

Furthermore, and as mentioned above, the horizon scanning process also takes account of regulatory developments. As a result, European therapeutic products legislation is subject to systematic observation. Swissmedic intends to use the instrument to create an overview of regulatory developments within the EU so that the Agency's management is able to identify the need for regulatory action and the options for action at an early stage. This is important given Switzerland's extremely high level of networking in the therapeutic products sector.

The research and development activities of the pharmaceutical industry are a key contributor to making Switzerland one of the most innovative countries in the world. Ensuring that this trend continues and new successes are achieved requires innovative research and a strong, independent, competent and efficient regulatory agency.

Swissmedic promotes young talent

As an expert organisation, Swissmedic is not just an attractive employer for experienced specialists, it also invests in the development and training of young talent or career entrants in the various task areas covered by the Agency. Thus, for example, several laboratory technicians are trained each year in Swissmedic's laboratory (OMCL). The Agency also offers internships for university graduates. As representatives of all the young people who took their first steps in professional life at Swissmedic, two lawyers and university interns in the Legal Service report below on the experiences and benefits that they have acquired for their future career.

A university internship in the Legal Service – Two interns report

For most students, working life starts after they have obtained their degree. Professional life often starts with an internship. This is the case for most lawyers who, after studying for around five years, often look for a job in their chosen profession for the first time.

Swissmedic offers graduates from a law faculty the opportunity to complete an internship in the Penal Division. During the 6-12-month internship, they worked hand in hand with the eight investigators-in-charge. They gained an insight into the various tasks of an investigator-in-charge and assisted them with various cases.

Every case starts with studying the files and various searches, including internet research, obtaining information from other authorities or sharing information with internal specialist departments. An intern generally has access to the same information as the investigators-in-charge, and they also take part in all meetings. Working with the relevant investigator-in-charge, the interns acquire an initial overview of the case and initiate the next steps. These often involve house searches and hearings, in which the graduates also take an active part. The working days, which can sometimes last as long as 15 hours, are full of exciting, unpredictable events and offer the interns a chance to put theory into practice. Working with the cantonal police authorities invariably leaves a lasting impression and is highly instructive. These are experiences and exploits that will remain in the memory of the young lawyers long after they have completed their internship.

The advantages of an internship at Swissmedic stem from the subject matter and the structure of the organisation. The subject matter of the internship is a combination of criminal law, administrative law, therapeutic products legislation and science. This interdisciplinarity makes an internship extremely challenging, but also interesting. The cases and the individuals concerned are all different, and when embarking on an investigation, it is often not possible to predict how it will end. The ability to work independently and good communication skills are essential. Interns can also benefit from the multilingualism within Swissmedic.

The training interns receive in the Penal Division is a good grounding for a subsequent legal internship, and a move to a law office is often the next step. In certain cantons, the internship at Swissmedic is also credited. Thus, for example, lawyers who now work in a wide variety of jobs, including prosecutors, investigators-in-charge, employees at Swissmedic and other federal agencies, completed a university internship at Swissmedic. An internship in the Penal Division of Swissmedic opens many doors and prospects for a future professional career.

Key issues in 2017

Increased safety of therapeutic products thanks to vigilance of veterinary medicines

At the end of 2016, increasing numbers of adverse reactions were observed in horses following the administration of an antibiotic. Several horses suffered episodes of sweating, rapid heartbeat and increased respiration rate during and immediately after intravenous administration of gentamicin. Intensive investigations during 2017 showed that these cases could be explained by a quality defect in the active substance used. Imported from China, the gentamicin is manufactured by a fermentation process in which fish peptone serves as a source of protein. Microbial processes during the incorrect storage of the processed fish led to the formation of histamine and to histamine contamination of the fermentation medium. However, contamination with the biogenic amine also manifested itself as a histamine contamination of the active substance batches obtained in the fermentation process. The side effects that ultimately appeared during the treatment of horses in Switzerland and various European countries correlate very closely with the biogenic activity of histamine. Reactions to histamine are unpleasant, or even dangerous, not just for animals but also for humans. In the light of the histamine problem, the investigation of these side effect reports subsequently led to regulatory activities that focused on a general improvement in the safety of the manufacture of pharmaceutical substances by fermentation.

Cannabidiol (CBD)

As of August 2016, when it was notified by the FOPH, the first tobacco substitute containing CBD cannabis has been legally on sale in Switzerland. This resulted in numerous media reports on the one hand, and in the opening of new hemp shops and new products containing CBD on the other. The authorities subsequently had to deal with numerous queries about the legality and marketability of corresponding products.
In order to clarify the classification of and legal situation for CBD products, simplify the process for answering the numerous queries and harmonise cantonal enforcement, in February 2017 the "technical platform" managed by FOPH-FSVO-Swissmedic published the Information Sheet "Products containing cannabidiol (CBD) – Overview and implementation guide".

Since it does not have comparable psychoactive effects, CBD, unlike THC (tetrahydrocannabinol), is not subject to the Narcotics Act. However, this does not mean that CBD can simply be added to random preparations at will or advertised arbitrarily. Products can be marketed legally only if they comply with the legislation of the country where they are placed on the market. This varies depending on their classification. The subject of CBD featured in the media throughout the year, and occupied authorities and experts in equal measure.

Vaccine supply bottlenecks

Like the entire EU, Switzerland was repeatedly affected by vaccine supply bottlenecks during 2017. One reason for this is the growing worldwide demand for vaccines and the lack of competition in this area. The number of companies that produce vaccines is dwindling. The products approved in Switzerland come from two suppliers. Vaccine production is a complex process that can frequently take several months. Furthermore, production capacity is limited, and production cannot simply be increased at short notice if bottlenecks occur. In addition, the Swiss market is small and not economically appealing for individual manufacturers. To ensure that demand for vaccines – particularly basic vaccines for infants and children – can be covered, Swissmedic issues time-limited licences to distribute foreign versions of preparations in response to such applications. This measure has had the effect of limiting supply shortfalls. Many European countries have introduced a state-operated, centralised ordering system for vaccines. Establishing a system of this kind in Switzerland would first require the appropriate legal framework. At present hospitals and doctors' practices are responsible for purchasing vaccines themselves.

Outlook

Innovations in cancer medicines

As progress is made in personalised healthcare, targeted treatments are becoming possible for a growing number of small genetically defined patient populations. Since clinically relevant efficacy can often be demonstrated even in the early development phases, applications are submitted for approval after a relatively short period of development. Due to the small numbers of patients involved, the medicinal products are eligible for orphan drug status, for which review is free of charge. Furthermore, if they display a substantial therapeutic benefit, they are also eligible for the fast-track procedure. At the same time, immuno-oncology agents, particularly checkpoint inhibitors, are being successfully tested in many different cancers, either as an addition to a multimodal treatment programme (standard chemotherapy before or after a surgical procedure, in some cases combined with radiotherapy), or even as monotherapy and are increasingly being reviewed in the fast-track procedure. The resulting abundance of oncology medicines now means that a substantial number of combination options can be tailored precisely to the stage, spread, degree of differentiation and, in particular, the genetic features of the cancer in affected patients, hence the talk of "precision medicine" in oncology.

Paperless official batch release

Materials of human or animal origin, including blood components, cell cultures and micro-organisms, are used in the manufacture of vaccines, blood products and animal sera. This is one reason why these preparations are more risky in terms of pathogen transmission than pharmaceuticals manufactured by standardised processes. To take these risks into account, blood products, vaccines and animal sera in Switzerland are subject to what is known as Official Batch Inspection. Every batch of the preparations in question may only be placed on the market after it has been thoroughly inspected by the Official Medicines Control Laboratory (OMCL) at Swissmedic. Batch inspection forms part of the Bilateral Agreements with the EU/EEA. Therefore, the batch release certificates issued by the OMCL of each member state are mutually recognised. Documents are still exchanged with the companies by post. However, as of the second half of 2018, it will be possible to submit applications – and Swissmedic will issue documents such as certificates – electronically.

Entry into force of the revised Therapeutic Products Act

On 18 March 2016, the Swiss parliament adopted the revised Therapeutic Products Act. The new legislation is designed in particular to facilitate market access for medicinal products, improve drug safety and increase transparency. It also decided to ratify the Council of Europe's Medicrime Convention on 29 September 2017.

Swissmedic aims to be ready to carry out its business activities in accordance with the new legal requirements by the time the revised Therapeutic Products Act and associated enforcement legislation enter into force, which is likely to be on 1 January 2019. To this end, numerous refinements will be made in 2018, including the updating of internal processes and systems and a comprehensive revision of the regulatory requirements for Swissmedic's stakeholders. During 2018, these will be systematically adapted to the revised legal requirements and, at the same time, streamlined and simplified.

Swissmedic's stakeholders can find the latest progress updates on the Swissmedic website. By the end of September 2018, all the relevant information on the regulatory and operational changes will be published on the Swissmedic website.

In addition, Swissmedic will be holding a full-day information event in the 4th quarter of 2018, during which the regulatory and operational changes will be presented, focusing on the authorisation of human and veterinary medicines, as well as complementary and herbal medicinal products. Changes in areas related to market surveillance and licensing will also be addressed in detail.

Modifications to Corporate Governance

In accordance with Art. 70 of the Therapeutic Products Act of 15 December 2000 (TPA; SR 812.21), Swissmedic has until now been managed via a service mandate issued by the Federal Council. In the revised TPA, it will in future be managed by way of strategic goals in keeping with the federal government's Corporate Governance principles. According to Corporate Governance guiding principle no. 17, the strategic goals of units that perform economic or safety-related supervisory tasks will be defined by the Board of Directors or Agency Council. As Swissmedic is a unit that performs safety-related supervisory tasks, its Agency Council will draft the strategic goals and submit them to the Federal Council for approval (as per Art. 72a and Art. 70 of the revised TPO).

Improved safety and quality of medical devices

In the next few years, the requirements governing the safety and quality of medical devices will be increased significantly to give patients better protection. Not only clinical trials, but also the manufacture, use and monitoring of medical devices will be subject to much stricter requirements in the future.

Around 500,000 different medical devices are currently on the market in Switzerland (e.g. implants, technical equipment such as CT scanners and software, diagnostic devices such as pregnancy tests or blood pressure monitors). Unlike medicinal products, medical devices are not officially authorised, but undergo a conformity assessment procedure instead. If the outcome is positive, the products are given CE marking and can be marketed throughout Europe.

Switzerland falls within the European internal market by virtue of a bilateral agreement. In line with developments in the EU, Switzerland is also modifying its legal provisions in order to increase product quality and improve patient safety. These amendments are also designed to ensure that Swiss manufacturers continue to enjoy equal access to the EU market.

As a first step, the Federal Council approved the first amendments to Swiss legislation on 25 October 2017, thereby ensuring that medical devices certified in Europe under the new law can also be marketed and made available to patients in Switzerland. The next steps, will involve amending the Therapeutic Products Act (TPA), the Human Research Act (HRA) and the Federal Act on Technical Barriers to Trade (TBA) to take account of the new EU Regulation on Medical Devices. The Medical Devices Ordinance (MedDO) will then be completely revised, and a new ordinance for in vitro diagnostic medical devices introduced. These amendments to the laws and ordinances are due to enter into force in 2020.

Facts and figures

Business statistics as at end 2017

Firms with a Swissmedic licence
The licences below were attributed to a total of 1,093 firms (medicinal products, excluding blood).

Manufacturing of medicinal products	305
Manufacturing of medicinal products (with a licence for wholesale distribution)	215
Manufacturing of medicinal products (without a licence for wholesale distribution)	90

Wholesale distribution of medicinal products	
Import of medicinal products	554
Wholesale trade of medicinal products	831
Export of medicinal products	449
Foreign trade with medicinal products	387
Laboratories with a Swissmedic licence to carry out microbiological or serological tests on blood, blood products or transplants for the identification of transmissible diseases, with a view to transfusion, transplant or processing	119
Blood transfusion services or hospitals with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	26

Controlled substances	
Establishment licences for handling controlled substances	361

Laboratories with FOPH recognition	
Microbiological and serological laboratories inspected by Swissmedic	35

Number of authorisations by product type as at end 2017

Therapeutic products code	Number of authorised medicinal products
Synthetics human	4,938
Biotechnologicals	338
Vaccines	60
Blood products	114
Radiopharmaceuticals	52
Generators	4
Bacterial and yeast products	23
Allergens	345
Transplant/tissue products	3
Phytopharmaceuticals	621
Homeopathics	653
Ayurvedic medicinal products	1
Anthroposophics	418
Tibetan medicinal products	6
Veterinary medicines	720
Total	**8,296**

Number of authorisations by dispensing category as at end 2017

Dispensing category/ Authorised medicinal products		Number of authorised medicinal products
A	Dispensed once only on medical or veterinary prescription	1,769
B	Dispensed on medical or veterinary prescription	3,783
B/C	Dispensed on medical or veterinary prescription/ after expert advice from medical personnel	34
B/D	Dispensed on medical or veterinary prescription/ after expert advice	47
C	Dispensed after expert advice from medical personnel	577
C/D	Dispensed after expert advice from medical personnel/ Dispensed after expert advice	24
D	Dispensed after expert advice	1,898
E	Dispensed without expert advice	164
Total		**8,296**

Homeopathic and anthroposophic medicinal products without indication authorised by the notification procedure as at end 2017

Single products	11,047
Combined products	1078

Swissmedic as an agency

Staff headcount at year end	424
Full-time positions at year end	349
Total women	56.8 %
Total men	43.2 %
Staff working part time (part time is defined as working up to 89 % of a full-time post)	49.1 %
Average age of staff	48.7
Women	47.1
Men	50.8
Fluctuation rate	3.8 %

Language distribution	
German	84.1 %
French	12.1 %
Italian	3.8 %
Rhaeto-Romanic	0 %

Market access
Marketing authorisation

Authorisation overview

The Marketing Authorisation sector is involved in all phases of a medicinal product's life cycle. As early as during the development phase of a medicinal product, firms can obtain scientific advice with regard to the various aspects of a development programme. The main task of the Marketing Authorisation sector consists in examining and approving authorisation applications for all medicinal products to be placed on the domestic market. By doing so, the sector ensures that all medicinal products available to the Swiss population are of high quality, safe and effective. This also includes constantly evaluating new information on the characteristics of a product throughout its entire life cycle.

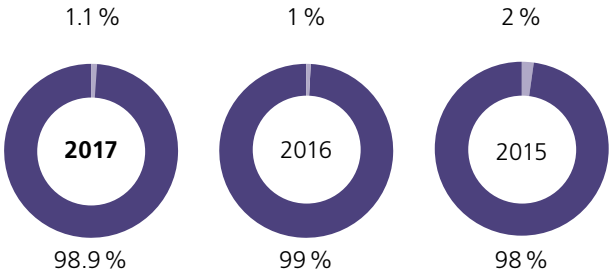
Activities

- A total of 12,903 applications were submitted in 2017, while 13,435 applications were finalised. The results for the last 12 months show that 99 % of all applications were finalised on schedule.
- Of the 23 scientific advice meetings, 15 pre-submission meetings and 16 clarification meetings requested in 2017, 33 were answered in writing, while face-to-face meetings took place in 21 cases.
- In 2017, the Clinical Trials department sent a total of 19 and 45 queries to the Preclinical Review (PCR) and Quality Review (QR) departments respectively. In this context, 17 initial preclinical reviews were undertaken for the notification of clinical trials, while QR issued 37 reports with licences.
- Authorisation holders were entitled to receive an open evaluation report for 286 applications resulting in an official decision of approval or rejection. An open evaluation report was sent for 112 of these applications (39 %).

Time limits

In 2017, around 99 % of all applications were completed within the prescribed time limits. For innovative medicinal products, the time limits were respected in 100 % of cases, and for non-innovative medicinal products the figure reached 89 %. Excluding delayed CHM applications – ZL1B – submitted prior to 2015, the figure for this category was also 100 %. The percentage for variation applications was 99 %.

Time limits respected (A) for all completed applications for human and veterinary medicines



Authorisation of human medicinal products

First authorisations

A first marketing authorisation of a medicinal product is granted after comprehensive checking 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 pharmaceutical ingredients or major variations thereto) and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients and co-marketing medicinal products). Major variations, such as a new indication, paediatric use or a new pharmaceutical form of a medicinal product, require a new authorisation procedure.

Activities

- In 2017, Swissmedic received 287 applications for first authorisations of innovative medicinal products and major variations thereto, and 290 applications were completed.
- Of the 32 medicinal products with new active pharmaceutical ingredients that were authorised for the first time, seven were completed by means of the fast-track procedure.
- Of the 210 applications completed for non-innovative first authorisations, 32 concerned co-marketing products.
- Two requests for the parallel importation of a medicinal product were completed in 2017.

Human medicinal products with a new active pharmaceutical ingredient authorised in 2017

Therapeutic area (ATC)	Active pharmaceutical ingredients	Product name	Application
Alimentary tract and metabolism	Lixisenatidum	Lyxumia, solution for injection	Second-line treatment of type 2 diabetes mellitus, in combination with oral antidiabetic agents and or basal insulin
Anti-infectives for systemic use	Neisseria meningitidis B: Outer membrane vesicles, NadA protein, NHBA fusion protein, fHbp fusion protein	exsero, suspension for injection	Active immunisation against Neisseria meningitidis, serotype B, in patients aged 11-24 in epidemic situations
	Isavuconazonium	Cresemba, hard capsules	Invasive aspergillosis; mucormycosis, second-line after amphotericin B (fungal infections)
	Glecaprevirum, Pibrentasvirum	Maviret, film-coated tablets	Chronic hepatitis C of genotypes 1 to 6 in adults
	Sofosbuvirum, Velpatasvirum, Voxilaprevirum	Vosevi, film-coated tablets	Chronic hepatitis C
	Bezlotoxumabum	Zinplava, concentrate for solution for infusion	Prevention of recurrence of Clostridium difficile infection in patients with a high risk for recurrence

Therapeutic area (ATC)	Active pharmaceutical ingredients	Product name	Application
Antineoplastic and immunomodulating agents	Daclizumabum beta	Zinbryta, solution for injection in pre-filled syringe	Relapsing forms of multiple sclerosis (MS) in adults
	Ixazomibum	Ninlaro, hard capsules	Multiple myeloma, second-line in patients with a high risk or third-line
	Alectinibum	Alecensa, hard capsules	Advanced non-small cell lung cancer (NSCLC), second-line after crizotinib
	Palbociclibum	Ibrance, capsules	Advanced breast cancer, only in combination with other medicinal products
	Pegaspargasum	Oncaspar, solution for injection	Acute lymphoblastic leukaemia, only in combination with other medicinal products
	Atezolizumabum	Tecentriq, concentrate for solution for infusion	Advanced non-small cell lung cancer (NSCLC), second-line
	Baricitinibum	Olumiant, film-coated tablets	Moderate to severe rheumatoid arthritis, second-line
	Ocrelizumabum	Ocrevus, concentrate for solution for infusion	Primary progressive and relapsing forms of multiple sclerosis (MS) in adults
	Tipiracilum, Trifluridinum	Lonsurf, film-coated tablets	Metastatic colorectal cancer, second-line
	Inotuzumabum ozogamicinum	Besponsa, powder for concentrate for solution for infusion	Relapsed or refractory acute lymphoblastic leukaemia
	Midostaurinum	Rydapt, soft capsules	Acute myeloid leukaemia; advanced systemic mastocytosis
	Olaratumabum	Lartruvo, concentrate for solution for infusion	Advanced soft tissue sarcoma in combination with doxorubicin
	Ribociclibum	Kisqali, film-coated tablets	Advanced breast cancer, in combination with an aromatase inhibitor
	Cabozantinibum	Cabometyx, film-coated tablets	Advanced renal cell carcinoma, second-line
	Avelumabum	Bavencio, concentrate for solution for infusion	Metastatic Merkel cell carcinoma, second-line

Therapeutic area (ATC)	Active pharmaceutical ingredients	Product name	Application
Blood and blood-forming organs	Lonoctocogum alfa	Afstyla, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in previously treated patients with haemophilia A
	Nonacogum beta pegolum	Refixia, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in previously treated patients with haemophilia B
Hormones, systemic (excluding sex hormones)	Etelcalcetidum	Parsabiv, solution for injection	Secondary hyperparathyroidism in patients on haemodialysis
Cardiovascular system	Regadenosonum	Rapiscan, solution for injection	Supplementary diagnostic agent for myocardial perfusion imaging
Musculoskeletal system	Lesinuradum	Zurampic, film-coated tablets	Hyperuricaemia with gout, second-line
	Nusinersenum	Spinraza, solution for injection	5q-associated spinal muscular atrophy (genetic disease)
Respiratory tract	Reslizumabum	Cinqaero, concentrate for solution for infusion	Add-on therapy for severe eosinophilic asthma in adults
Genitourinary system and sex hormones	Follitropinum delta	Rekovelle, solution for injection	Follicular stimulation during in vitro fertilisation
Miscellaneous	Flutemetamolum (18-F)	Vizamyl, solution for injection	Radiodiagnostic agent for positron emission tomography (PET) of the brain
	Florbetabenum (18-F)	Neuraceq, solution for injection	Radiodiagnostic agent for positron emission tomography (PET) of the brain
	Patiromerum	Veltassa, powder for oral suspension	Hyperkalaemia

Human Medicines Expert Committee (HMEC)

The HMEC is a panel of experts providing support and advice to Swissmedic when authorisation documents relating to human medicinal products require scientific assessment.

Activities

- The HMEC advisory panel met 12 times during 2017 and issued 73 recommendations regarding marketing authorisation applications. The majority of them concerned new authorisations or additional indications for medicinal products.
- Furthermore, 14 expert reports for the purpose of full assessments and 24 reports on individual aspects were provided by the HMEC experts.

A Number of HMEC recommendations relating to marketing authorisation applications

2017	2016	2015
73	83	75

Extensions and discontinuations

The marketing authorisation for a human medicinal product is always issued for a five-year period. The authorisation holder must apply for an extension of the authorisation: if the conditions continue to be fulfilled, the authorisation is extended for a five-year period at a time. If the marketing of a medicinal product is discontinued, it is mandatory for Swissmedic to be notified accordingly. The notification must be provided at least two months prior to the discontinuation. The discontinuation of a dosage strength requires approval since the product information must be adjusted.

Activities

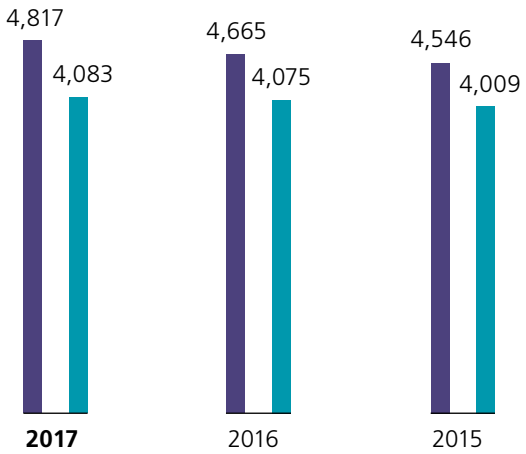
- A total of 1,276 applications to extend the marketing authorisation were submitted, and 1,371 of these applications were completed.
- 260 applications for the discontinuation of a product and 14 applications for the discontinuation of a dosage strength of a product were submitted.
- 250 applications for the discontinuation of a product and 18 applications for the discontinuation of a dosage strength of a product were completed. At the same time, authorisation was not extended for 106 products.

Variations requiring approval and variations requiring notification

An application must be made for any variation to a medicinal product authorised by Swissmedic. A finalised list that groups together minor changes may be submitted as a variation requiring notification. All other variations to a medicinal product require approval. These applications are examined with or without scientific assessment.

Activities

- 4,824 variations requiring notification were submitted, of which 4,817 were completed.
- As regards variations requiring approval with scientific assessment, 3,683 applications were submitted and 4,083 were completed.
- Collective applications and multiple applications are counted here as one application.



- Completed applications for variations requiring notification
- Completed applications for variations requiring approval with scientific assessment

The fast-track authorisation procedure

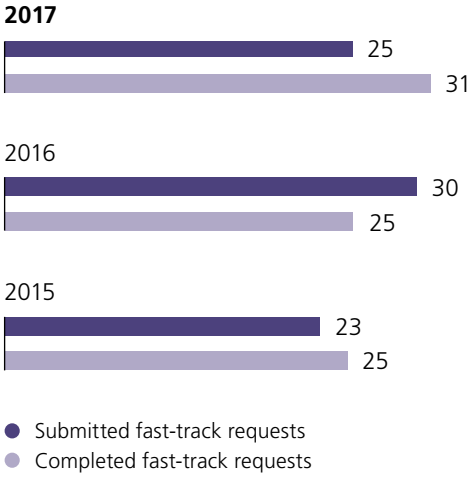
Applicants may ask for the fast-track procedure to be applied to human medicinal products or major variations to these, as long as three conditions are all fulfilled:
– expected successful treatment in the case of a serious illness,
– lack of other treatment possibilities with medicinal products or unsatisfactory treatment option,
– the use of the medicinal product indicates a significant therapeutic benefit.

After a positive assessment of these conditions on the part of Swissmedic, the request for the fast-track procedure is approved and a corresponding application may subsequently be submitted. Swissmedic then reduces the time limit for processing the authorisation application from 330 to 140 days.

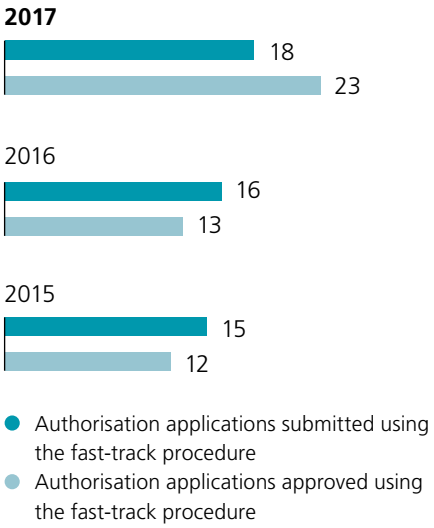
Activities

- In 2017, 25 requests for the fast-track procedure to be applied were submitted, and 31 fast-track requests were approved.
- 18 authorisation applications using the fast-track procedure were submitted, and 23 were completed.
- All of the applications submitted using the fast-track procedure were completed on time.

Fast-track requests



Fast-track authorisation applications



The Procedure with Prior Notification (PPN)

Since 1 January 2013, Swissmedic has offered applicants the option of having the assessment carried out 20 % more rapidly, provided that they give early notification of the submission date of their application (3 – 6 months beforehand). For this to be accepted by Swissmedic, the following conditions must all be fulfilled:

– The authorisation application must concern the first authorisation of a human medicinal product with a new active substance (NAS) or an additional indication.
– The clinical and preclinical studies should have been fully completed by the time the application is submitted. Intermediate analysis must be submitted together with the planned, complete and final study report in accordance with the study protocol, reflecting the status once the primary end point of the study is reached. Full documentation must also be submitted.
– Swissmedic must have the necessary human resources available in order to complete the assessment of the application within the required time and by the date foreseen.

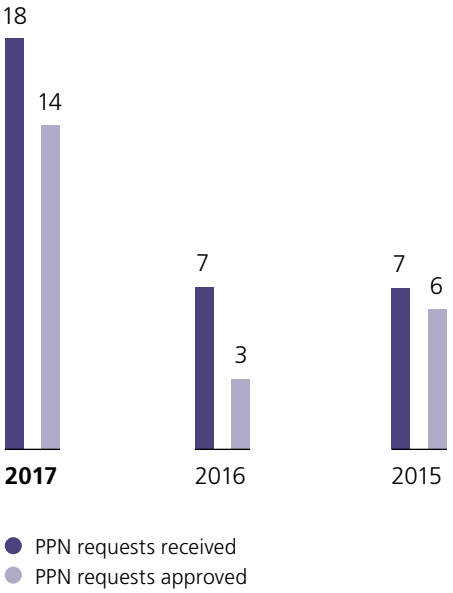
If these conditions are fulfilled, the PPN request is approved and the application can then be submitted using the procedure with prior notification. For Swissmedic, the time limit for processing the authorisation application is reduced from 330 to 264 days.

The prior notification period for a request for a PPN was shortened in 2016 from between 8 and 5 months before planned submission to between 6 and 3 months beforehand. Since then, companies have been able to request a PPN directly when applying for a fast-track procedure. If the application for a fast-track procedure is rejected, a PPN can be started for the application at the agreed time. This new option has had a positive impact on the number of submissions in 2017.

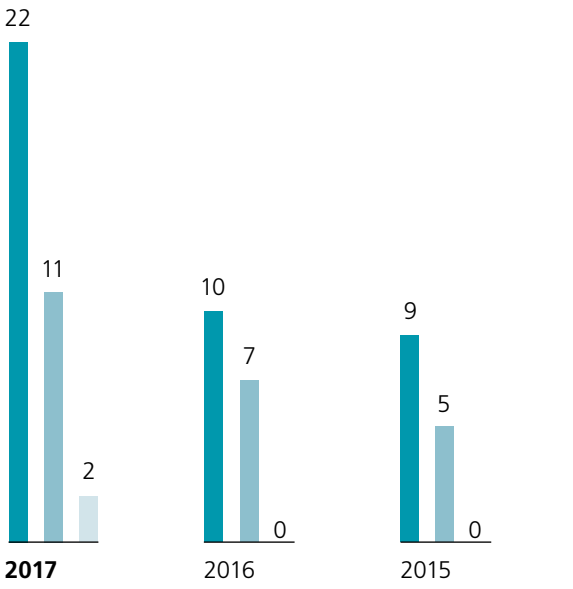
Activities

- Of the 18 PPN requests submitted in 2017, 14 were approved. Four requests are currently still being processed.
- In 2017, 22 authorisation applications using PPN were submitted and 13 were completed; two further submissions are already planned.

Requests for PPN



Applications using PPN



Applications under Article 13 TPA

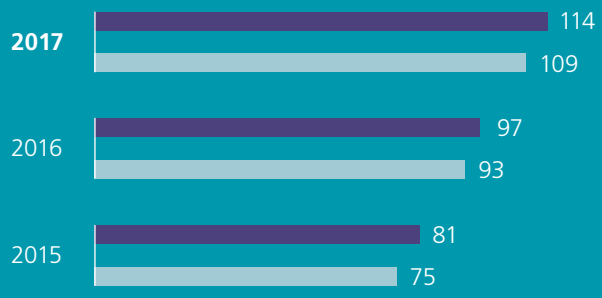
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose if the following requirements are satisfied:

– The submitted documents from the foreign procedure, including all variations, are no older than five years and correspond to the authorisation status in the other country.
– All assessment decisions, including the associated trial results submitted in connection with foreign authorisation procedures, are available.
– The documents contain all the information required for Switzerland, particularly the medicinal product information and labelling texts.
– The documents are available in an official language, in English or in a translation into one of these languages. If a translation is submitted, the applicant must confirm that it is correct.

Further details on the application of Article 13 TPA can be found in the Administrative ordinance "Instructions on the authorisation of human medicinal products already authorised in foreign countries (Art. 13 TPA)" published on the Swissmedic website.

Activities

- Of the 114 authorisation applications completed in 2017 and fulfilments of authorisation conditions under Art. 13 TPA, 109 were approved (96 %), three were withdrawn, one was rejected and one was not admitted.
- These involved two new notifications of a new active substance, 12 known active pharmaceutical ingredients with innovation, 39 known active pharmaceutical ingredients without innovation, five major variations including three additional indications, 49 variations requiring approval and 7 fulfilments of authorisation applications.
- These results indicate a growing trend in the application of Art. 13 TPA.



● Completed applications / fulfilled authorisation conditions under Art. 13 TPA
● Approved applications / fulfilled authorisation conditions under Art. 13 TPA

Human medicinal products	2015		2016		**2017**	
	Appr.	Rej.	Appr.	Rej.	Appr.	Rej.
New notification of a new active substance	0	0	4	0	0	2
Known active pharmaceutical ingredients with innovation	7	2	12	2	10	2
Known active pharmaceutical ingredients without innovation	24	3	26	1	38	1
Known active pharmaceutical ingredients of complementary and herbal medicines	6	0	8	0	0	0
Variations requiring approval	34	0	27	0	49	0
Additional indications	1	0	4	1	3	0
Other major variations	3	1	3	0	2	0
Other applications / conditions	0	0	9	0	7	0
Total	**75**	**6**	**93**	**4**	**109**	**5**

● Approval ● Rejection/withdrawal of the application

Special categories of human medicinal products

Orphan drugs

Swissmedic recognises the status as a medicinal product for a rare disease (orphan drug) on application. The applicant must prove that the medicinal product is used for the diagnosis, prevention or treatment of a rare, life-threatening or chronically debilitating disease that affects at most 5 out of 10,000 people in Switzerland. Most applications are based on the recognition of the 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). A medicinal product can be authorised as an orphan drug either in parallel with, or as the result of, recognition of the orphan drug status. The authorisation procedure for orphan drugs is exempt from processing fees.

Activities

- In 2017, 37 applications for recognition of orphan drug status were submitted.
- Orphan drug status was granted in 36 cases involving 27 products.
- 20 products were newly authorised as orphan drugs. Further orphan indications were approved for 13 previously authorised orphan drugs.
- The status was discontinued for one product.

Paediatric medicinal products

Since the entry into force of EU Regulation EC 1902/2006 and the Food and Drug Administration Amendment Act (FDAAA), it has been mandatory for pharmaceutical firms to submit their paediatric investigation plans (PIPs) to the authorities and to develop their medicinal products for use by children in accordance with these plans. The Swissmedic Paediatrics Working Group is responsible for the consistent handling of this specific group of medicinal products. The Ordinance on Fees foresees a reduction of 90 % in fees for the authorisation of medicinal products with exclusively paediatric indications and for corresponding major variations. This measure is intended to encourage developments in the area of paediatric medicines. Inspections relating to paediatric clinical trials are considered important:
Annual planning will continue to take account of inspections to assess compliance with GCP.

Activities

- In 2017, the submission of PIPs once again proved helpful with regard to the notification of paediatric clinical trials. A total of 16 paediatric trials were authorised.

New processes

Swissmedic also grants authorisations for 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.

Activities

- No new applications for the authorisation of inactivation processes for blood products or procedures with transplant products were submitted during 2017.
- The authorisation for one procedure was renewed, while amendments to the quality documents for another procedure were reviewed.

Transplant products

Products from somatic cell therapy, tissue cultures and ex vivo gene therapy are, in accordance with the Transplantation Act, equivalent to medicinal products and thus also subject to the Therapeutic Products Act. Investigations are carried out relating to compliance with the legal provisions. These products are also assessed for safety and efficacy using a risk-based approach.

Activities

- In 2017, two marketing authorisation applications were submitted for transplant products, and these are currently under review. Accordingly, no cell- or tissue-based products or gene therapy products were authorised. On the other hand, a "conventional" product, albeit one that is similar in principle to gene therapy, was reviewed and authorised in a fast-track procedure.
- Three applications for review in a fast-track procedure were submitted, one of which was rejected.
- The conditions for five products were approved. The extension of the authorisation for a procedure was also approved.
- Four PSUR were assessed
- Six variations requiring approval were assessed, four of which were completed. Two variations requiring notification were also completed. A trend towards increasing product complexity was observed among submissions, as was a predominance of oncological indications.

Complementary and herbal medicines

Complementary and herbal medicines are widely used in Switzerland and enjoy a high level of acceptance by the population. For these product groups, Swissmedic ensures that the main authorisation requirements are respected. Basically, a simplified authorisation procedure is possible for all complementary and herbal medicines, in accordance with the general provisions of the Complementary and Phytotherapeutic Products Ordinance (CPTPO). Quality, safety and tolerability must be guaranteed in each case.

Activities

- All of the delayed complementary and herbal medicine applications (first authorisations and variation requests) submitted between 2014 and 2015 were processed.
- Compliance with the processing time limits was 96 % for applications completed in 2017.
- Swissmedic employees spoke on the subject of complementary and herbal medicinal products at several international congresses.
- Swissmedic attended the 10th meeting of the IRCH (International Regulatory Cooperation for Herbal Medicines) in Bonn as an observer.

Complementary medicinal products

Complementary medicinal products encompass homeopathic, anthroposophic and Asian medicinal products. With regard to marketing authorisation, Swissmedic takes into account the fact that the considerable value placed on complementary medicine is anchored within the Swiss Constitution. For this product group, and in addition to medicinal products stating an area of use (indication), a wide range of medicinal products without an indication are authorised.

When authorising medicinal products without an indication, a simplified authorisation procedure is applied. In addition to quality and safety, the focus is above all on tolerability.

Activities

- In the notification procedure, assessment times were shortened from 330 days to 150 days and processes were optimized.
- Applications for the notification procedure can be submitted via the Swissmedic Portal.
- In 2017, Swissmedic completed 15 applications for the first authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication.
- One product without an indication was also authorised in the simplified procedure according to Art. 17 para. 2 CPTPO.
- Official decisions were issued for 159 products without an indication in the notification procedure. 126 of these were single products, 33 were combined products.
- 17 applications for simplified authorisation with a reduced dossier were completed in 2017. 11 of these products were authorised and 6 applications were rejected or withdrawn.

Herbal medicinal products

Herbal medicinal products or preparations contain only herbal substances or preparations. Within the framework of the simplified authorisation procedure it is possible to prove efficacy and safety by citing bibliographic evidence. No simplification is possible for the quality documentation. For herbal medicinal products that have been used for medicinal purposes for at least 30 years, including at least 15 years in Western European cultures, traditional authorisation can be requested.

Activities

- 12 applications for non-innovative first authorisation of herbal medicinal products were completed. Four of these concerned co-marketing products.

Asian medicinal products

Most of the medicinal products concerned are from traditional Chinese medicine (TCM), applied by persons with specific training. The notification procedure is intended for the authorisation without an indication of single medicinal products and classical formulations without components of animal origin.

Activities

- The TAS list (list of documented traditional Asian substances) has been revised with input from an HMEC expert.

Veterinary medicinal products

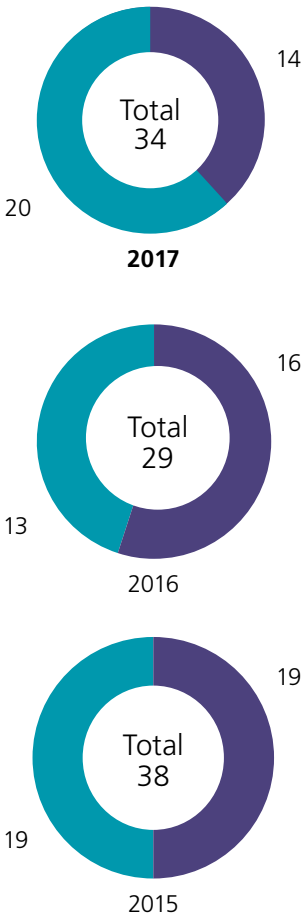
Authorisation of veterinary medicinal products

The first marketing authorisation of a veterinary medicinal product is granted following the examination 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 pharmaceutical ingredients or major variations thereto) and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients and co-marketing medicinal products). Major variations to a medicinal product require a new authorisation procedure. An important aspect of the safety assessment of products that are used on livestock concerns their effect on the safety of foodstuffs. Within the authorisation procedure, the currently valid standards specified in legislation on foodstuffs are used to specify the level of possible residues from a veterinary medicinal product that are tolerated in foodstuffs such as meat, milk, eggs or honey when a product has been administered to cattle, poultry or bees.

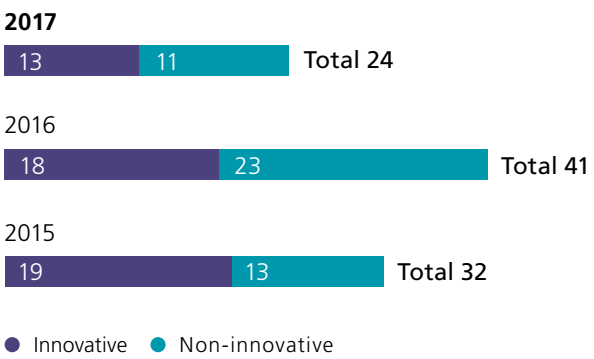
Activities

- 14 applications for innovative first authorisation and major variations were submitted, and 12 applications were completed.
- 11 applications for non-innovative first authorisation were completed:
- All of these applications were processed within the prescribed time limits.

Number of applications for first authorisation submitted:



Number of applications for first authorisation completed:



Veterinary medicinal products with a new active pharmaceutical ingredient authorised in 2017

Therapeutic area	Active pharmaceutical ingredients	Product name	Application
Interferons	Pegbovigrastimum	Imrestor ad us. vet., solution for injection	Pegylated bovine Granulocyte Colony Stimulating Factor for use in cattle
Proton pump inhibitors	Omeprazolum	GastroGard ad us. vet., oral paste	Prevention and treatment of gastric ulcers in horses
ACE inhibitors	Spironolactonum	Cardalis ad us. vet., chewable tablet	Treatment of chronic degenerative mitral valve disease with congestive heart failure in dogs
Systemic ectoparasiticides	Sarolanerum	Simparica ad us. vet., chewable tablet	Ectoparasiticide against fleas, ticks and mites for systemic use in dogs

Veterinary Medicines Expert Committee (VMEC)

The VMEC is a panel of experts providing support and advice to Swissmedic when authorisation documents relating to veterinary medicinal products require scientific assessment.

Activities

- At its four meetings in 2017, the VMEC assessed nine applications for authorisation or a variation of the authorisation.

Extensions and discontinuations

Authorisations for a veterinary medicinal product are issued for five years. The authorisation holder must apply for an extension of the authorisation: If the conditions continue to be met, the authorisation is extended for five years at a time. Discontinuing the marketing of a medicinal product or a dosage strength of the product is also subject to mandatory notification at least two months before marketing is ceased.

Activities

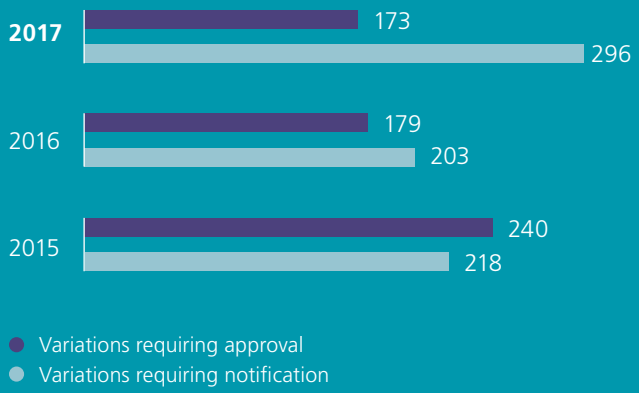
- In 2017, the authorisation was extended for 134 products.
- At the same time, the authorisation holders discontinued the marketing of 27 products.
- Applications to discontinue 12 products were completed, and the authorisations of 15 products were not extended.

Variations requiring approval and variations requiring notification

A request must be submitted to Swissmedic for any change to a veterinary medicinal product that has already been authorised. Minor variations can take the form of a notification, whereas variations requiring approval take the form of an application. The variations are examined with or without scientific assessment.

Activities

- In 2017, 173 variations requiring approval with scientific assessment and 296 variations requiring notification were completed.
- The increase in the number of variations requiring notification compared to the previous year reflects the growing trend in the veterinary medicines business: These variation applications primarily concern the quality of authorised veterinary medicinal products, for example changes in the manufacturers of the active substances or the deposition of new Certificates of Suitability (CEP) issued by the European Directorate for the Quality of Medicines (EDQM).



Minor Use – Minor Species (MUMS)

The authorisation of veterinary medicinal products used only for minor animal species or for rare indications is not lucrative for the veterinary medicinal products industry because of the low sales volumes involved. Various therapeutic agencies therefore adopt supportive measures to enable the supply of these so-called MUMS products. In Switzerland veterinary medicinal products can be granted MUMS status if they are essential for defined minor animal species such as bees or fish. Once the Agency has granted MUMS status, the fees for processing the authorisation and variation applications are waived.

Activities

- No new MUMS status was granted during 2017.
- One application for the authorisation of a product with a known active ingredient was approved.

Applications under Article 13 TPA for veterinary medicinal products

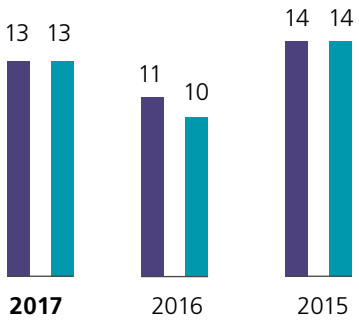
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose if the following requirements are satisfied:

– The submitted documents from the foreign procedure, including all variations, are no older than five years and correspond to the authorisation status in the other country.
– All assessment decisions, including the associated trial results submitted in connection with foreign authorisation procedures, are available.
– The documents contain all the information required for Switzerland, particularly the medicinal product information and labelling texts.
– The documents are available in an official language, in English or in a translation into one of these languages. If a translation is submitted, the applicant must confirm that it is correct.

Further details on the application of Article 13 TPA can be found in the information sheet on the "Authorisation of veterinary medicinal products already authorised in foreign countries (Art. 13 TPA)" published on the Swissmedic website.

Activities

- All 13 authorisation applications for veterinary medicinal products under Art. 13 TPA that were completed in 2017 were approved.
- Of the 13 completed applications, two involved "known active pharmaceutical ingredients with innovation", five "known active pharmaceutical ingredients without innovation", two "major variations" and four "variations requiring approval".



● Completed applications under Art. 13 TPA
● Approved applications under Art. 13 TPA

Veterinary medicines	2015		2016		**2017**	
	Appr.	Rej.	Appr.	Rej.	Appr.	Rej.
Known active pharmaceutical ingredients with innovation	3	0	1	1	2	0
Known active pharmaceutical ingredients without innovation	3	0	5	0	5	0
Variations requiring approval	4	0	2	0	4	0
Additional indications	2	0	1	0	0	0
Other major variations	2	0	2	**0**	2	0
Total	**14**	**0**	**11**	**1**	**13**	**0**

● Approval ● Rejection/withdrawal of the application

Appeals procedure regarding the authorisation of human and veterinary medicinal products

Appeals against official decisions issued with regard to the authorisation procedure may be lodged with the Federal Administrative Court within 30 days. A judgement by the latter court may in turn be contested before the Federal Supreme Court.

Activities

- In 2017, one appeal was lodged with the Federal Administrative Court against an official decision taken by the Agency in connection with product authorisations. This case is still pending. One decision by the Federal Administrative Court was contested before the Federal Supreme Court. This case is also still pending.
- Of the appeals already pending before the Federal Administrative Court, two were rejected. One appeal was dismissed. One appeal was approved.

Table of performance indicators for human and veterinary medicinal products

The key figures for respecting time limits encompass all medicinal products, whether human or veterinary.

Performance indicator	Target	Result
Application category	**2017**	**Total 2017**
Authorisation procedures (all application categories), proportion of procedures completed within the prescribed time limits	95 %	99 %
First marketing authorisations of innovative medicinal products (ZL1A); proportion of procedures completed within the prescribed time limits	95 %	100 %
First marketing authorisations of non-innovative medicinal products (ZL1B); proportion of procedures completed within the prescribed time limits	95 %	89 %
Extensions / discontinuations of marketing authorisations (ZL2); proportion of procedures completed within the prescribed time limits	95 %	99 %
Scientific variations (ZL3A); proportion of procedures completed within the prescribed time limits	95 %	99 %
Administrative variations (ZL3B); proportion of procedures completed within the prescribed time limits	95 %	99 %

Special activities and events: Authorisation of human and veterinary medicinal products

Pipeline meetings

Since mid-2017, companies have been able to request a voluntary "pipeline review" in connection with a request for a Pre-Submission or Scientific Advice Meeting. This review focuses on medicinal products that are still in development and for which an application for authorisation could be submitted to the Agency in the near future. This applies particularly to companies with several new medicinal products (a "full pipeline") nearing the end of development and eligible for first authorisation or additional indications. The focus is on applications that have a time horizon of one year and are therefore potential candidates for the fast-track authorisation procedure. The aim is to improve planning and optimise resource use for companies and the Agency alike.

Continuous manufacturing

Swissmedic was one of the first authorities to approve continuous manufacturing for a product, specifically for Prezista® (darunavir) manufactured by the company Janssen on 28 May 2017. Further details on continuous manufacturing can be found in the article on horizon scanning.

Licensing

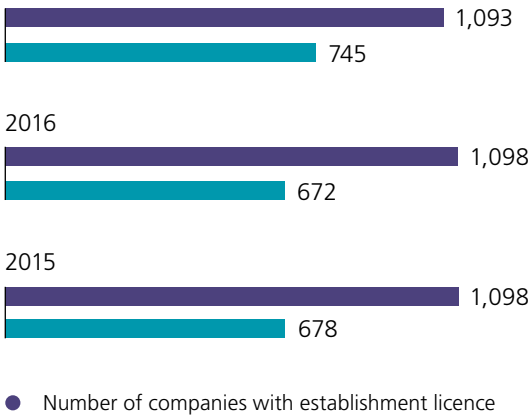
Licensing of medicinal and transplant products

Establishment licences for medicinal and transplant products

Companies that manufacture or distribute medicinal or transplant products in Switzerland (manufacturing, wholesale, import, export and trade in foreign countries) require an establishment licence. Swissmedic issues this licence on the basis of a successful inspection or other evaluation.

Activities

- At the end of 2017, 1093 companies held an establishment licence for the manufacture, wholesale, import, export and trade in foreign countries of medicinal and transplant products. Some of these companies carry out several of the activities mentioned. This figure has remained stable in recent years.
- In 2017, the number of licences issued for the first time, extended or amended was 745, which represents an increase compared to 2016.



- Number of companies with establishment licence
- Number of establishment licences issued for the first time, extended or amended

Performance indicator

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

● Target ● Result

Special licences for medicinal and transplant products

On application and within two working days, Swissmedic issues medical professionals with a special licence to import small quantities of medicinal and transplant products that are not authorised in Switzerland but are essential for the treatment of specific patients. The import, use or dispensing of these products is the sole responsibility of the medical professional in question.

Activities

- In 2017, as in the previous year, the number of special licences granted fell. A marked reduction in special licences was particularly apparent for specific allergens. Furthermore, special licences for radiopharmaceuticals also fell by half once more thanks to the use of fixed-term establishment licences.

Total special licences issued

Performance indicator

Special licences; proportion of procedures that were completed within 24 hours

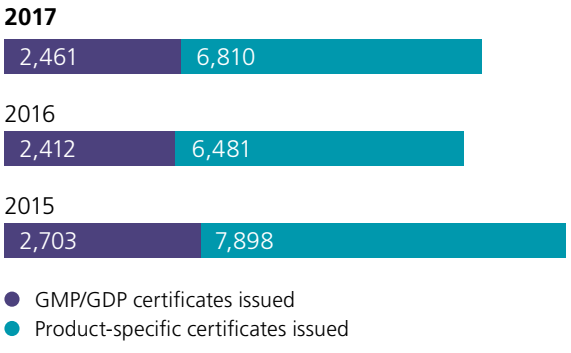
● Target ● Result

Certificates for medicinal and transplant products

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

Activities

- Since December 2017, it has been possible to upload product certificates via the online portal. This new ordering option provides secure electronic communication between the ordering party and Swissmedic.
- The number of product-specific certificates increased slightly in 2017.
- The number of GMP/GDP certificates remained stable.



Performance indicator

GMP/GDP certificates; proportion of procedures completed within 14 days

Target Result

Control of the flow of narcotics

Swissmedic issues establishment licences to companies 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 from Lists A, B and D. Accounts must be kept by the licence holder of all transactions involving controlled substances. Corresponding annual accounts should be prepared and submitted to Swissmedic. Swissmedic examines these annual accounts and forwards a consolidated report to the "International Narcotics Control Board" (INCB, UNO, Vienna) in accordance with international agreements.

Activities

- In 2017, 361 companies held an establishment licence for handling controlled substances. The number of processed applications for modifications, renewals or the start of operations remained stable, at 194.
- Swissmedic examined the annual accounts submitted by 460 company sites for the purpose of reporting to the International Narcotics Control Board (INCB).
- The Agency analysed 19 new psychoactive substances, 16 precursors and 23 narcotic or psychotropic substances, and made a request to the Federal Office of Home Affairs to have them included in the relevant Ordinance (BetmVV-EDI) or reclassified in the BetmVV-EDI.
- As part of an official mission of the INCB in Switzerland, Swissmedic received a delegation from the Board.
- Swissmedic hosted an international user group meeting on the National Drug Control System (NDS).

Import and export permits granted for controlled substances:

2017	2016	2015
7,314	7,380	7,747

Performance indicator

Import and export permits for controlled substances; proportion of procedures completed within 10 working days

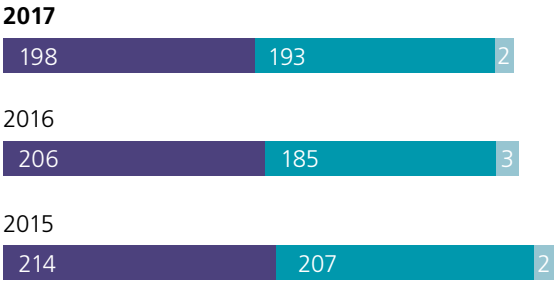
● Target ● Result

Clinical trials with medicinal products

Clinical trials are used to systematically gather information on medicinal products when used in humans. Swissmedic verifies whether the quality and safety of the test product is guaranteed. Clinical trials may only be carried out in Switzerland if they have been approved by an Ethics Committee and by Swissmedic.

Activities

- Swissmedic received 198 applications for clinical trials with medicinal products in 2017. It was possible to process 187 of these applications as the rest were either incomplete or fell outside Swissmedic's remit. In total, 193 clinical trials were approved, including 47 in category B and 146 in category C. Three of the applications in the latter category concerned first-in-human trials. Two clinical trials were rejected and two were withdrawn by the sponsor during evaluation. The other applications are currently being processed. The trend observed in 2016 towards more complex products and, as a result, more complex dossiers, was confirmed in 2017.
- On the other hand, 2,874 other requests or notifications relating to clinical trials of medicinal products were processed (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, End-of-trial Reports, as well as 100 reports of suspected unexpected serious adverse reactions (SUSAR).
- Swissmedic continued to work with the FOPH and swissethics, the Association of Swiss Ethics Committees, on research involving humans, with the aim of coordinating and harmonising the three bodies' interpretation of certain provisions of the law. In connection with these efforts, Swissmedic took part in four meetings organised by the FOPH agency responsible for coordinating research involving humans. A round table was also held with the SCTO (Swiss clinical trial organisation).
- A new strategy for disseminating information was successfully tested in the form of a symposium designed to train 1-2 individuals in each organisation (e.g. clinical trial units), so that these individuals can then train others at the local level. This symposium is intended to replace the numerous presentations that used to be given to these organisations and will be repeated in 2018.



● Clinical trials: (processable) new submissions
● Approved clinical trials
● Submitted trials, rejected

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

Activities

- In 2017, Swissmedic received 12 applications for clinical trials with transplant products, including four with gene therapy products. These were all category C trials involving products tested in humans for the first time. In total, nine clinical trials were authorised, while an end-of-trial notification was received for two others. Although the quality of the submitted dossiers has improved substantially, in most cases further checks and/or additional documents had to be requested. Moreover, the established method of benefit-risk assessment made it possible to authorise six clinical trials subject to the fulfilment of certain conditions.
- 73 amendments during the course of clinical trials were notified and 66 were authorised during 2017.
- Special mention should be made of the biovigilance system, which received over 700 reports of suspected unexpected serious adverse reactions (SUSAR). This system has grown substantially following an awareness-raising campaign and the receipt of feedback from the stakeholders concerned. As a result, safety signals were identified and appropriate measures taken to improve safety. Eight DSUR were also reviewed and three end-of-trial notifications were received.
- It should be noted that the products under investigation are becoming increasingly complex and indicated for "serious" conditions, such as the treatment of cancers with "tumour vaccines", multiple sclerosis, etc.

Performance indicator

First submissions of clinical trials; proportion of notifications assessed within 30 days

● Target ● Result

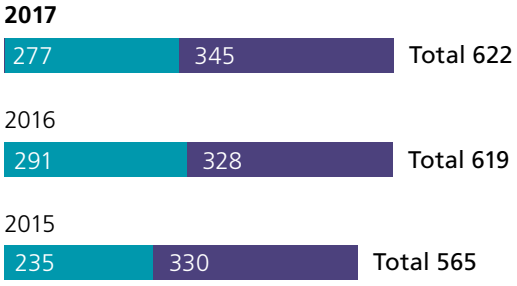
Inspections

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

- In 2017, the Swissmedic inspectorate carried out 60, the regional inspectorates 562 GMP/GDP inspections of manufacturers and wholesale companies, giving a total of 622 inspections.
- The inspections carried out by the Swissmedic inspectorate concerned the following areas: transplant products 21 %, blood transfusion services 26 %, pre-approval inspections 10 %, "for cause" inspections 9 %, pharmaceutical sector inspections 34 %.
- Both the Swissmedic inspectorate and a number of regional inspectorates passed the monitoring audits carried out as part of accreditation to ISO/IEC 17020:2012.
- In 2017, Swissmedic extended its involvement in international inspection programmes organised by partner authorities outside Switzerland. Six active pharmaceutical ingredient manufacturers – four in India and two in China – were inspected in collaboration with the European Directorate for the Quality of Medicines & Healthcare (EDQM), while one manufacturer in Kenya was inspected with the WHO. Swissmedic also took part in ongoing assessments of partner authorities within the framework of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).
- A national focus during inspections was reviewing the compliance of manufacturers' information in the authorisation dossier and the underlying monitoring and qualification of suppliers in other countries by Swiss manufacturers. Authorisation holders were checked at random as part of routine inspections.
- A common SharePoint platform for the electronic exchange of documents between Swissmedic and the regional inspectorates was set up during 2017.
- Reports of major changes to installations (in accordance with Art. 30 para. 2 MPLO) increased sharply.



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

● Manufacturers ● Wholesale companies

Performance indicator

Licensing inspections; degree to which the annual plan was achieved

● Target ● Result

GCP and GVP inspections

Swissmedic inspects clinical trials of medicinal products conducted in Switzerland by sponsors, contract research organisations, trial centres, facilities and laboratories on a random basis according to defined risk criteria to assess compliance with the relevant Swiss legislation, the rules of Good Clinical Practice (GCP) and other international guidelines on the implementation of clinical trials. The inspections focus on whether the safety and personal rights of trial participants are guaranteed. They also verify whether the trials are being conducted in accordance with the scientific criteria for quality and integrity.

Pharmacovigilance inspections (Good Vigilance Practice, GVP) are above all designed to examine compliance with the legally prescribed mandatory reporting of adverse drug reactions in clinical trials as well as spontaneous reports.

Activities

- During 2017, Swissmedic conducted 30 GCP inspections in connection with clinical trials of medicinal products in Switzerland.
- Swissmedic also carried out 11 GVP inspections in Switzerland.
- Within the framework of the Geneva-based PIC/S (Pharmaceutical Inspections Cooperation Scheme) convention, Swissmedic participated in one programme of GCP inspections and one programme of GVP inspections. In this context, Swissmedic accompanied one GVP inspection carried out by foreign authorities in Lithuania. One of the 30 GCP inspections conducted in Switzerland was also part of the PIC/S programme.
- On the other hand, Swissmedic provided specialist support during GCP inspections conducted in Switzerland by the EMA, FDA and BfArM.
- In 2017, Swissmedic's GCP/GVP inspectors again participated in the EMA's Inspectors Working Groups.
- One inspection relating to a clinical trial with a transplant product was conducted in 2017.

Performance indicator

GCP/GVP inspections; degree to which the annual plan was fulfilled

Target Result

GLP inspections

With the exception of pharmacodynamics for notification or authorisation procedures, non-clinical assessments for authorisation in Switzerland are to be carried out in accordance with Good Laboratory Practice (GLP). Swissmedic's GLP unit carries out monitoring activities (inspections or study audits) with the relevant divisions of 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 US or European authorities, such as the FDA's requirements for medical devices, are also taken into account.

Activities

- The number of test facilities continued to decline in 2017. A further three test facilities withdrew from the GLP monitoring programme at their own request, necessitating a reorganisation within Swissmedic's GLP unit. In future, monitoring activities will be in the hands of four, instead of the current eight, individuals. This will ensure that the quality of GLP inspections remains high with an adequate number of routine inspections. As a further measure, cooperation with the other GLP units at the FOPH and FOEN is being stepped up.
- A total of six inspections was carried out.
- Internationally, the Swiss monitoring programme was represented in the GLP Working Groups of the EU Commission and the OECD.

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, for which a fee is applied. For the Federal Office of Public Health (FOPH), Swissmedic carries out inspections and other implementation tasks in the fields of transplants and genetic tests on humans. Swissmedic also carries out some of the inspection activities in the therapeutic products sector for the Principality of Liechtenstein.

Activities

- In 2017, Swissmedic carried out 15 inspection procedures for the FOPH and two for the Principality of Liechtenstein.
- Following the revision of the Transplantation Ordinance, the legislator has now assigned the extended oversight of activities involving tissues and cells for autologous transplantation to Swissmedic. Until the revised Ordinance came into force in November 2017, Swissmedic carried out inspections relating to autologous transplants on behalf of the FOPH.

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. In so doing, the Swiss inspectors assume the role of representatives of the Swiss inspections system.

Activities

- In 2017, foreign authorities carried out 90 GMP inspections at pharmaceutical companies in Switzerland. The inspecting authorities were the USA with 35 inspections, Brazil with 13, Russia with 10, Belarus with nine, Turkey with six, Mexico and China with four each, Korea and Kazakhstan with three each, and Jordan, Libya and Iran with one inspection each.
- Swissmedic also accompanied two GCP inspections carried out in Switzerland by the EMA, one by the FDA and one by BfArM.
- The new Art. 64a of the revised Therapeutic Products Act, which regulates cross-border controls was enacted by the Federal Council earlier than planned on 1 January 2018. This will result in a change for the inspections carried out in Switzerland by foreign authorities. Authorisation by SECO is now no longer required.
  Every foreign authority intending to carry out a control in Switzerland must notify Swissmedic in advance. After each inspection, an inspection report must be sent to the Agency.

A Inspections by foreign authorities in Switzerland

2017	2016	2015
94	82	60

Monitoring of the blood transfusion service

Swissmedic monitors Swiss blood transfusion activities by means of inspections, licences, market surveillance of devices and standardisation. The blood obtained from donors and the labile blood products manufactured from it are considered to be medicinal products in accordance with the Therapeutic Products Act. It is mandatory to have a Swissmedic licence for the collection of blood, the manufacturing of labile blood products and the distribution of labile blood products.

Activities

- Swissmedic has approved the application of Swiss Transfusion SRC to relax the unlimited ban on men who have sex with men (MSM). The new ruling came into force in July and envisages a 12-month deferral period after the last MSM contact. In a second phase, Swiss Transfusion SRC intends to draft an application calling for the donation criteria to take greater account of the various risk behaviours.
- At the same time, Swissmedic has revised its guidance document on test methods and thereby tightened the requirements pertaining to the testing of donated blood. This should ensure that the safety of the products continues to be guaranteed by even more sensitive test methods despite the relaxation of the criteria.
- An increase in the number of hepatitis B virus-positive donations observed following the introduction of the more sensitive test methods prompted various further investigations to ascertain whether blood previously donated by donors who have now tested positive has led to cases of hepatitis B transmission. However, according to the findings obtained to date, no case of hepatitis B transmission from the relevant donors has been detected.
- As in other countries, a sharp rise in cases of hepatitis A has been observed in Switzerland since mid-2017, particularly among MSM.
- Since higher rates of hepatitis E virus transmission from blood transfusions have occurred in other countries, a working group of Swiss Transfusion SRC, with input from Swissmedic, has drawn up appropriate recommendations and test scenarios.
- Other risks (dengue fever or Chagas disease, West-Nile Virus (WNV) and cases of Chikungunya disease in nearby countries) have been addressed by regularly adapting donor suitability criteria to the epidemiological situation.

Licensing of microbiological laboratories

Establishment licences for microbiological laboratories

Following the introduction of the revised Federal Act on Combating Communicable Human Diseases (Epidemics Act, EpidA; SR 818.101), laboratories that conduct, or want to start conducting, microbiological tests for the identification of communicable diseases now require an establishment licence from Swissmedic and are subject to monitoring by Swissmedic. This includes 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 2017, 75 microbiological laboratories held a microbiological laboratory licence issued by Swissmedic under the new legislation. Around two-thirds of the approved activities involved patient diagnostics, whereas only a fairly small proportion of laboratories has also applied for a licence for screening and, in particular, for environmental analytics.
- This leaves 44 laboratories which, as a result of the transitional provisions, still possess a valid FOPH certificate of recognition or Swissmedic licence as a microbiological laboratory issued under the old legislation.
- Swissmedic published information about the current status of the new rulings, and particularly the applicability of the ordinance to hospital laboratories and decentralised near-patient diagnosis in hospitals (point-of-care testing), in professional journals, the Swissmedic Journal and on its specific website.

Inspections of microbiological laboratories

Microbiological laboratories must satisfy the requirements defined in the Ordinance on Microbiological Laboratories (SR 818.123.1) and comply with Good Laboratory Practice guidelines. Swissmedic monitors compliance with the statutory provisions and periodically carries out inspections.

Activities

- Swissmedic drew up an inspection plan in 2017, under which approved laboratories will be inspected every three years. These inspections will take account of whether or not a laboratory possesses an accreditation issued by the Swiss Accreditation Service (SAS). Swissmedic checks the information available on the accreditation and does not carry out an inspection if the licence conditions are satisfied. Accordingly, Swissmedic carried out 26 inspections in 2017.
- Discussions with the SAS made it clear that the SAS will not be able to take on any additional monitoring tasks on behalf of Swissmedic until further notice. Nevertheless, further discussions will be take place on harmonising requirements and avoiding duplication of activities.
- In response to a complaint, a "for cause" inspection was carried out in a microbiological laboratory for the first time in order to ascertain the exact circumstances.

A Inspections of microbiological laboratories (since 2016)

2017	2016
26	41

Official Medicines Control Laboratory (OMCL)

The accredited Swissmedic laboratory is responsible for the official batch release of stable blood products and vaccines, and supports the various sectors of Swissmedic by means of laboratory analysis and method developments and assessments.

Activities

- After almost 10 years, the structure of the OMCL was analysed and redefined. Official batch release is now concentrated in one laboratory unit. The remaining activities have been transferred to two additional laboratory units. The purpose of this restructuring is to enhance flexibility and to separate OCABR (Official Control Authority Batch Release) from laboratory tasks. The new structure has been operative since 1 May 2017.
- The OMCL is very well networked both nationally and throughout Europe and plays an active role in developing and optimising European pharmacopoeial monographs within various expert groups maintained by the European Directorate for the Quality of Medicines (EDQM) and in Swiss expert committees.
- The OMCL collaborates with the EDQM in close consultation with the Pharmacopoeia Division, its activities encompassing practical tasks in the laboratory, the production of draft monographs and their experimental testing. One focus of this work is the improvement of chromatographic detection methods for impurities in pharmaceutically active substances.
- Last year 30 pharmacopoeial requests involving a total of 280 samples were processed.
- In the year under review, medicines that did not have an authorisation were analysed for the Penal Division, Antidoping Switzerland and Market Surveillance. Most of the work done for Market Surveillance involved neuro-enhancers, anabolic substances and erectile stimulants.
- The five-yearly re-accreditation of the OMCL by the Swiss Accreditation Service in accordance with ISO/IEC standard 17025:2005 was performed during a three-day audit in August 2017. The audit confirmed the staff's high level of technical skills and identified potential for optimisation. This external evaluation enables the OMCL to demonstrate its expertise as a testing centre in the national and international arena, while at the same time improving its laboratory work and quality management.
- Batches of plasmatic coagulation factors for the treatment of haemophilia A and haemophilia B patients were analysed as part of a market surveillance activity. All the batches tested complied with the specifications in the authorisation.

Analysis conclusions for new marketing authorisations and market monitoring

	2015	2016	2017
Authorisation procedure: number of medicinal products examined	37	39	16
Market monitoring: number of medicinal products examined	1,333	1,187	686
Other (pharmacopoeia, round robin tests)	526	479	522
Total	**1,896**	**1,705**	**1,224**

Batch assessments and plasma pool analysis

	2015		2016		2017	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU and WHO)	748	65	712	64	703	40
Notifications	321	135	357	157	406	172
Plasma pool analyses	2,375	–	2,467	–	2,680	–
Product analyses as WHO reference laboratory	–	13	–	9	–	0

Performance indicator

Batch releases; proportion of assessments completed within the prescribed time limit

● Target ● Result

Appeals procedures regarding licences

Appeals against decisions in connection with the licensing procedure may be lodged with the Federal Administrative Court within 30 days. A judgement by the latter court may in turn be contested before the Federal Supreme Court.

Activities

- No appeals were lodged before the Federal Administrative Court against official decisions by the Agency in connection with licences in 2017.
- Of the appeals already pending before the Federal Administrative Court, three were dismissed. Appeals against two decisions were made to the Federal Supreme Court. One appeal was not admitted by the Federal Administrative Court.

Special activities and events: Licensing

Swissmedic now oversees autologous transplant products

New tasks have been assigned to the Agency following the revision of the Transplantation Ordinance. Regulatory oversight of activities involving tissues and cells for autologous transplantation was expanded and at the same time transferred to Swissmedic. Responsibility was thus transferred from the FOPH to Swissmedic when the Ordinance came into effect on 15 November 2017. Institutions that perform activities involving tissues and cells for autologous transplantation must notify Swissmedic of their activities, and Swissmedic reviews compliance with the legal requirements for assuring quality in the handling of cells and tissues on a random basis.

Expansion of the MRA with the EU

The bilateral agreement between Switzerland and the EU was expanded and now also includes inspections performed by one of the two parties outside Switzerland or the EU respectively.

Market surveillance

The quality, safety and efficacy of medicinal products and medical devices continue to be monitored by Swissmedic once they have obtained a marketing authorisation. This comprises evaluation of reports from Switzerland, international safety signals and reports of quality problems. The Agency also intervenes in conjunction with other authorities if illegal therapeutic products are marketed in Switzerland.

Medicinal products

Medicinal product vigilance

Swissmedic records safety signals associated with medicinal products, vaccines, labile blood products and veterinary medicines based on reports of adverse drug reactions (ADR) from within Switzerland. If investigation confirms a new risk, Swissmedic initiates the necessary actions following international consultation.

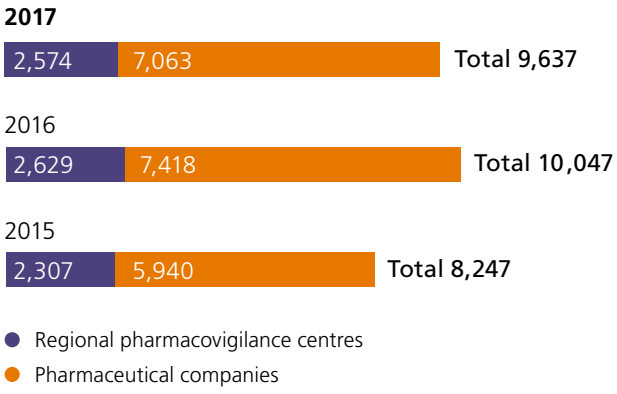
Pharmacovigilance

Within the framework of the pharmacovigilance network, the direct reports from professionals and patients on adverse drug reactions are assessed in six regional pharmacovigilance centres (RPVC) on behalf of Swissmedic and recorded in the national database. The professionals who submit the reports receive appropriate feedback. Reports on adverse reactions from within Switzerland are also sent to Swissmedic by the pharmaceutical firms.

Activities

- In the year under review, Swissmedic received 9,637 initial reports of suspected adverse drug reactions (ADR) associated with medicinal products, evaluated them and recorded them in the national VigiFlow database. The regional pharmacovigilance centres (RPVC) sent 2,574 reports, the pharmaceutical industry 7,063. In addition, 4,207 follow-up reports were processed and evaluated.
- The proportion of reports from the pharmaceutical industry that were submitted electronically increased to nearly 100 %. 90 % of these reports reached Swissmedic via the Pharmacovigilance Gateway (25 firms), the remainder via the online reporting portal ElViS (electronic vigilance system).
- The preparations for the introduction of a new, modern pharmacovigilance database in 2018, which took place in parallel to day-to-day business, represented a particular challenge and dominated the working day in the year under review.

Adverse drug reactions, human medicinal products: Number of initial reports from



Performance indicator

Serious adverse reactions: proportion of assessments carried out and transmitted to the companies within 15 calendar days

Target Result

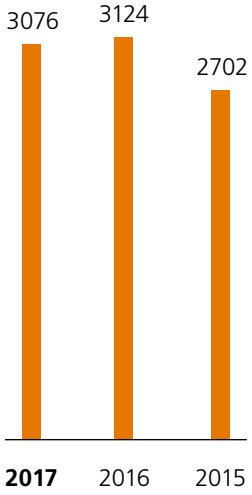
Haemovigilance

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

Activities

- Organisation of a half-day scientific and regulatory programme at the Swisstransfusion annual conference in Biel.
- Two training sessions for haemovigilance officers were held, one in German, the other in French.
- Two working visits were made to hospitals with the aim of improving quality assurance processes.
- Based on the results of the Haemovigilance Annual Report 2016, findings and preventive actions relating to the following focus areas were published:
  - Transfusion reactions in children
  - Transfusion errors and quality assurance in hospitals
  - Infectious diseases and protective measures

Adverse events involving blood products: number of reports



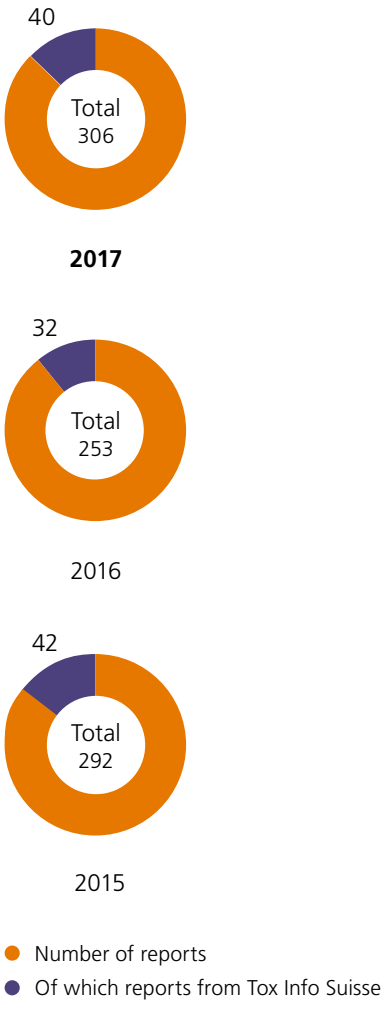
Vigilance for veterinary medicinal products

Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich for the collection and assessment of 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 has no evaluations of these reports.

Activities

- A report on the evaluation of adverse drug reaction (ADR) reports relating to veterinary medicinal products was published in the journal Swiss Archive of Veterinary Medicine (Müntener et al., Schweiz. Arch. Tierheilk., 159: 581-585, 2017).
  For the first time, more than 300 reports on adverse drug reactions relating to veterinary medicinal products were received. This represents an increase of 4.8 % compared with the previous peak year in 2015 and as much as 21 % compared with the previous year. Forty reports were passed on to Swissmedic by Tox Info Suisse.
- Once again, the ADR reports primarily involved dogs (180) and cats (59), followed by cattle (38) and horses (14). The medicinal product categories most frequently involved were antiparasitic drugs (158 reports) or products containing hormonally active substances (26). In third place in 2017 were anti-inflammatory products (25). The distribution is largely comparable to that in previous years.
- Nine signals were generated from the 306 reports and from the analysis of the periodic safety update reports (PSUR). Three of them involved products for use in farm animals. One activity that deserves special mention is the investigation with international partners of allergic reactions in horses. Contamination during manufacture of the active pharmaceutical ingredient was identified as the source of the reactions. This investigation led to the quality requirements (pharmacopoeial monograph) being modified. The new monograph will be implemented in early 2018 (cf. Activities relating to veterinary medicinal products in 2017).

Adverse drug reactions, veterinary medicinal products



Risk management

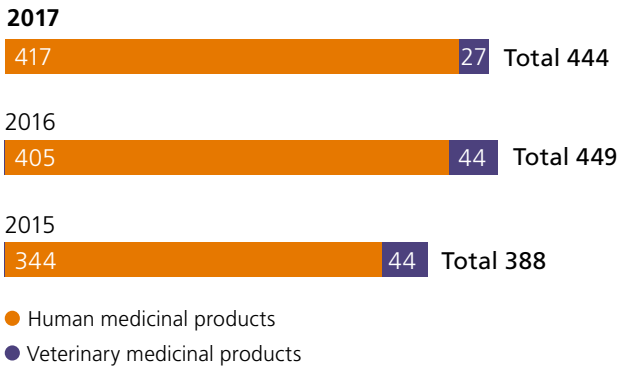
As part of the procedure for authorisation of new medicinal products, firms must provide, for assessment, a pharmacovigilance plan (PVP) in accordance with the guidelines of the International Conference on Harmonisation (ICH). This plan must be kept up to date by the firms and submitted, for example, as an update within the framework of regular post-authorisation reporting. In the plan, the authorisation holder must take a stance regarding both the known and the potential risks associated with the new medicinal product and demonstrate how they will be prevented, followed up, and what measures will be taken to address any missing findings. Swissmedic also assesses the regular reports that must be submitted by the firms – Periodic Safety Update Reports (PSUR) and Periodic Benefit Risk Evaluation Reports (PBRER). Swissmedic's tasks also include the assessment of international data on the safety of medicines. A central element is the identification, assessment and follow-up of safety signals from national and international sources.

Activities

- 2017 saw a further increase in the number of PVP assessed.
- Such plans were evaluated as part of 150 applications for first authorisation and substantial variations. A brief summary of the planned measures to monitor post-authorisation safety is published on the Swissmedic website. The purpose of this publication is to provide healthcare professionals with more information about product risks and their specific post-authorisation monitoring.
- The criteria for submitting PVP and PVP updates and the requirements that PVP must meet were updated and published in an information sheet.
- Swissmedic processed 158 signals in 2017, 56 originating from ADR reports from Switzerland and 102 from international observations.

A Pharmacovigilance plans: Number of assessments

PSUR/PBRER: Number of assessments



Performance indicator

Number of signals identified from national reports or international sources

Target Result

Risk mitigation measures

It is mandatory, even after a medicinal product is authorised, for firms to apply for a change to the product information in the case of any new findings and particularly those related to the safety of medicines. If Swissmedic becomes aware of new risks and the firm responsible has not spontaneously applied for risk mitigation measures, Swissmedic takes the corrective measures ex officio. The texts of the circulars to experts (Direct Healthcare Professional Communications, DHPC) and the intended recipients thereof are examined and approved by Swissmedic. These DHPC and information from Swissmedic on risks associated with medicinal products are also published on the Swissmedic website, in the Swiss medical journal Schweizerische Ärztezeitung and in the pharmaJournal.

Activities

- Administrative proceedings relating to medicinal products containing codeine or dihydrocodeine were concluded in 2017. These products may no longer be administered to children and adolescents under 12 years of age. Information was added to the texts of the package leaflets and packaging supplied with the products and the texts were published.
- Swissmedic again drew attention to the risk of multiple vertebral fractures (MVF) following discontinuation of Prolia® (containing the active substance denosumab) and provided information on the modification of the information for healthcare professionals.
- Swissmedic also drew attention to the risk of fulminant liver failure associated with Zinbryta® (containing the active substance daclizumab beta) and published a DHPC restricting the indication.

Performance indicator

Number of completed procedures (including reviews)

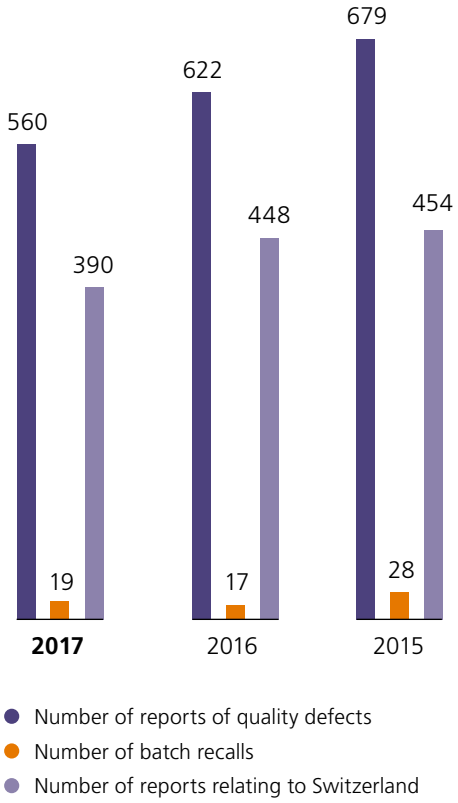
● Target ● Result

Quality defects and batch recalls

Swissmedic records reports on quality defects in medicinal products and takes the necessary actions. The reports are assessed, prioritised and, where a potentially high health risk is identified, a batch recall is initiated and/or information is sent to professionals/the public. Swissmedic also reviews foreign reports of quality defects specifically to ascertain whether Swiss products are affected. It is involved in a lively international exchange of information for this purpose. On request, Swissmedic authorises the distribution of medicinal products produced for other countries in order to avoid supply shortages.

Activities

- In 2017, a total of 560 reports on quality defects were received. Switzerland was affected by 390 of them.
- There has been an increase in the number of cases of package leaflets or packaging containing incorrect text. This often leads to a batch recall, for example if the texts contain translation errors that could result in incorrect use.
- Twenty-three Class I quality defects (potentially life-threatening health risk) were reported in Switzerland and neighbouring countries. The deficiencies reported include the following: A cough syrup contained splinters of glass; an infusion solution was labelled with the wrong dosage; injection solutions contained particles. Batch recalls were initiated in these cases.
- A total of 19 batch recalls were carried out and published.
- Thirty-nine applications to temporarily distribute a medicinal product manufactured for other countries ("out-of-stock applications") were processed. Swissmedic approved 32 applications so that deliveries of medically important products would not suffer delays. In 28 cases, the authorisation holder was able to make the foreign stock available and Swissmedic informed healthcare professionals accordingly through the publication of a notice on its website.



Measures against illegal medicinal products

Swissmedic increases public awareness of the dangers associated with 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, reviews them and initiates corrective action as necessary or passes them on to the competent office. The Agency works closely with the customs authorities to monitor imports of medicinal products and orders the return or destruction of illegal shipments.

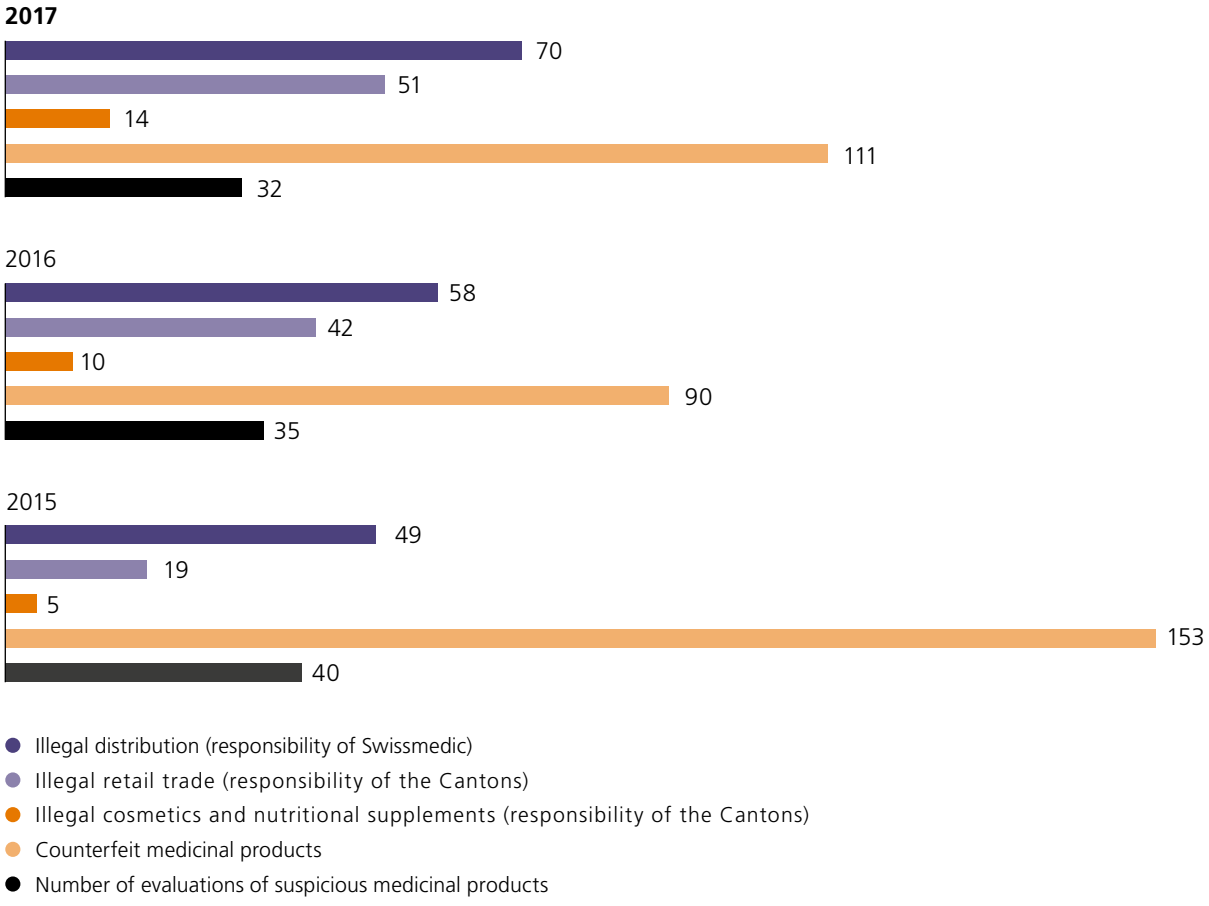
Activities

- Activities to combat online infringements of the Therapeutic Products Act were intensified. Closer cooperation between the Penal, Authorisations, IT and Market Monitoring Divisions reflects the significance attached to this important aspect of market surveillance.
- Stakeholder meetings: Swissmedic again held a number of meetings with national authorities. The aim in each case was to exchange information on current trends and the challenges of following up illegal activities relating to the Therapeutic Products Act.
- The Swiss customs authority reported 1,060 illegal imports of medicinal products to Swissmedic. These resulted in the initiation of 1,006 administrative proceedings and the destruction of the goods in 93 % of the cases.

Confiscated shipments by type of product

	2017	2016	2015
Erectile stimulants	59 %	55 %	51 %
Sleeping tablets and tranquillisers	12 %	13,5 %	15 %
Medically important, prescription-only medicines	16 %	13 %	9 %
Slimming preparations	2,5 %	5 %	13 %
Hair growth preparations	1,5 %	2,5 %	1 %
Other	9 %	11 %	12 %

(All figures rounded)



Control of advertising

Swissmedic controls and monitors the advertising of medicinal products. A risk-based approach to prior control was implemented at the start of 2017. Irrespective of the advertising medium (television, newspaper advertisement, Internet etc.), prior control of advertising is now limited to advertising for medicinal products considered to be sensitive (such as laxatives or sleeping aids) and for which the potential for dependence or abuse is mentioned in the product information.
Swissmedic also follows up information regarding infringements of advertising legislation and decides whether administrative proceedings need to be initiated, or in which cases legal compliance can be re-established 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

- Prior control of advertising for medicinal products declined to two applications as a result of the new approach to the requirement for prior submission.
- At the same time, Swissmedic increased its post-publication monitoring activities in order to check whether firms are fulfilling their responsibilities in this regard.
- Swissmedic examines advertising for medicinal products on television and in the print media. The majority of this advertising was considered to be in conformity with the Therapeutic Products Advertising Ordinance. Objections were raised, for example, to the mandatory warning about the need to consult a professional and read the information leaflet if this did not correspond to the legally required phrasing and, in isolated cases, to advertising in which indications were mentioned that did not correspond to the patient information leaflet supplied with the product. Swissmedic will continue to make random checks on advertising in the future.

The following performance indicators concern all activities related to the market monitoring of medicinal products (quality defects, advertising control, illegal activities).

Performance indicator

First actions taken within 10 days for priority 1 reports

● Target ● Result

First actions taken within 30 days for priority 2 reports and within 90 days for priority 3 reports

● Target ● Result

Number of presentations, publications and circulars organised to raise stakeholder awareness

● Target ● Result

Appeals procedures regarding the market monitoring of medicinal products

Appeals against decisions in connection with the licensing procedure may be lodged with the Federal Administrative Court within 30 days. That Court's judgement may in turn be contested before the Federal Supreme Court.

Activities

- In 2017, appeals were lodged with the Federal Administrative Court against four official decisions by the Agency in connection with the market surveillance of medicinal products. Three appeals were not admitted. One appeal is pending. One decision by the Federal Administrative Court was contested before the Federal Supreme Court. This appeal was dismissed.
- Of the appeals already pending before the Federal Administrative Court, three were dismissed.

Special activities and events: Market surveillance of medicinal products

Swissmedic raises professionals' awareness of counterfeit medicines

Since counterfeit medicinal products have increasingly been found in the European Union, even in the legal distribution chain, Swissmedic raised hospital pharmacists' awareness of this issue at their annual meeting, providing specific examples. One of the reasons behind this move was the fact that hospitals are increasingly importing foreign medicinal products directly in response to growing supply shortages.

Guidelines for quality assurance in transfusion practice

Quality assurance is an essential component of blood transfusions in providing patients with the best possible treatment, avoiding transfusion errors and preventing harm to patients. Feedback from the real-life setting showed that the lack of guidelines and recommendations for transfusion-related quality assurance (QA) leads to uncertainty or to hospitals resorting to the time-consuming practice of producing guidance specific to their own organisation. Against this background, Swissmedic coordinated a working group comprising cantonal medical officers, cantonal pharmacists, haemovigilance officers and experts from Swissmedic, who together produced joint guidelines for quality assurance in transfusion practice. These guidelines were approved in 2017 by all the bodies responsible for oversight of transfusion activities: the Association of Cantonal Pharmacists, the Association of Cantonal Medical Officers and the Swiss Transfusion Medicine Association. They are making a major contribution to improving the safety of transfusions.

Meeting of the Working Group of Enforcement Officers (WGEO) in Montreux

In September, Swissmedic organised the 22nd Heads of Medicines Agencies (HMA) WGEO Meeting in Montreux. For three days, over 80 experts from authorities in 26 countries met to share their knowledge and experience. The effective collaboration between the various country-specific agencies plays an important role in market surveillance and measures to counter illegal medicines. Another issue addressed at the meeting was the trade in illegal medicines on the internet and the question of what means and instruments the authorities can use to combat illegal websites and sales channels. The discussions focused on the worrying trend towards counterfeiting in the legal markets of various EU countries. For the first time, a speaker from the world of social media (Facebook) took part in the meeting. She reported on the measures introduced by Facebook to prevent the appearance of non-legal-compliant articles (incl. product advertising) on the platform.
Together with her, the attendees discussed and highlighted ways in which illegal trading through social platforms could be combated in future. Further information was provided by a representative of the WHO, who reported on the efforts being initiated and coordinated worldwide to stem trading in illegal pharmaceuticals.

Medical devices

Market monitoring of medical devices

Medical devices encompass a very large range of products, including implants such as hip prostheses and heart pacemakers, in vitro diagnostics such as HIV or pregnancy tests, or products for the general public such as contact lenses. Before these products can be placed on the market, the manufacturer has to carry out its own conformity assessment procedure, under its own responsibility. In the case of higher-risk products, an officially designated "notified body" – a conformity assessment bureau (CAB) – in Europe must also examine the product. The assessment procedure, carried out in compliance with the requirements, leads to the CE marking of products. Swissmedic is responsible for the surveillance of medical devices that are already available on the market and of the notified bodies in Switzerland. Swissmedic also monitors and approves clinical trials of medical devices that are not yet authorised for the market.

Integration within the European system

With regard to medical devices, Swissmedic is integrated within the European system. 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) as an information system for market monitoring. CE-marked medical devices are considered as being compliant and may be distributed in all contracting states.

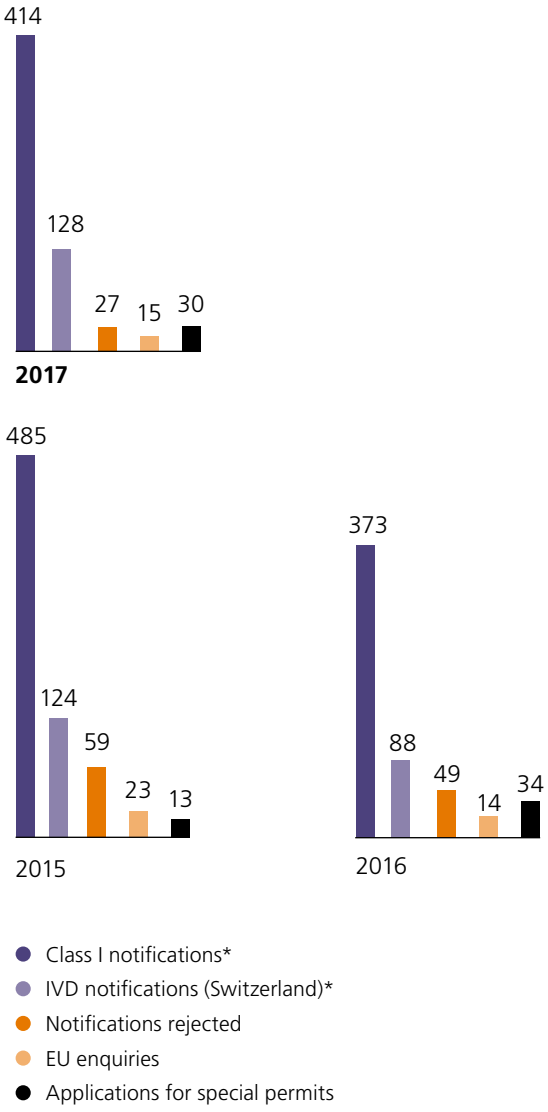
Swissmedic took part in meetings of the higher-level body of the Member States, i.e. meetings of the Competent Authorities Medical Devices (CAMD) and its working groups. Swissmedic additionally sits on its steering committee, the Executive Group (CEG). Swissmedic is also an observer within the Medical Device Coordination Group (MDCG) of the European Commission and its working groups.

Placing on the market

Manufacturers of medical devices associated with greater risks must bring in officially recognised notified bodies for the conformity assessment. Notification is mandatory for certain medical devices, and for these Swissmedic receives the notifications, carries out random checks on their classification, issues instructions regarding any necessary corrections, and records the notification in EUDAMED, the European database.

Activities

- In 2017, 414 notifications in accordance with Art. 6 para.1 MedDO were received. They involved classic Class 1 medical devices, custom-made classic or active implantable medical devices, systems and treatment units. These may be products such as reusable surgical instruments, adhesive plasters and rolling walkers.
- A total of 128 notifications in accordance with Art. 6 para. 2 and para. 2a MedDO were submitted for in vitro diagnostic (IVD) devices.
- Nine notifications in accordance with Art. 6 para. 3 MedDO were received for classic and active implantable medical devices which are made using or which contain devitalised human tissue. In addition, 34 change notifications concerning devitalised human tissue were processed.
- In 27 cases, Swissmedic rejected notifications of medical products from firms because of incorrect categorisation or classification, or because the product did not fall within its area of responsibility.
- In 2017, Swissmedic took part in 15 EU enquiries on delimitation questions regarding the classification of devices.
- Swissmedic may issue special permits for the import of non-compliant medical devices if these devices are able to resolve a life-threatening situation for a patient. The number of applications for special permits that were reviewed and approved decreased from 34 to 30.



* In each case applications received plus changes received

European market monitoring activities

Since Switzerland is integrated into the European system for medical devices, market monitoring activities in consultation with partner authorities from contracting states are also carried out in addition to the national market control activities.

Activities

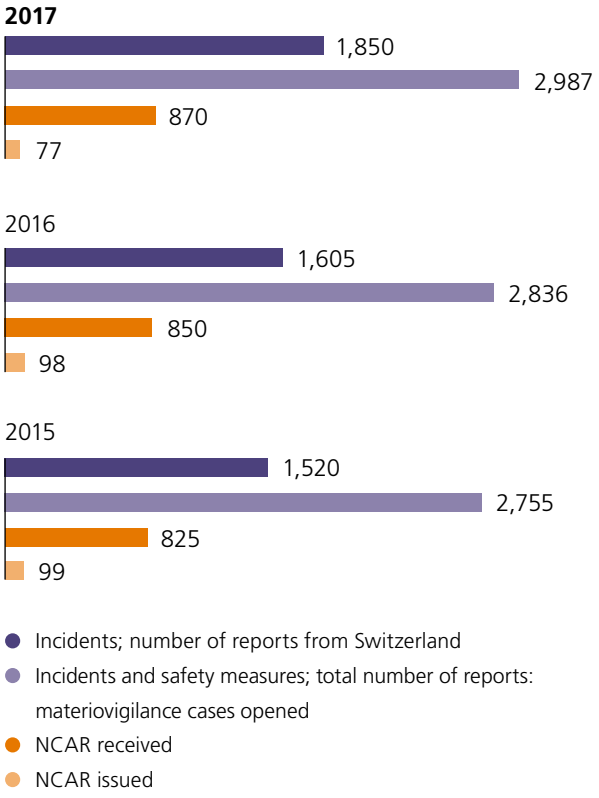
- The number of requests for mutual assistance from European partner authorities remained stable compared to 2016 at 144.
- In 2017 Swissmedic made 31 requests for mutual assistance from European partner authorities, substantially more than in the previous year (2016: 18).
- Intensified monitoring of the CAB led Swissmedic to take part in internationally accompanied audits of these CAB again in 2017, an activity that included the review of product documentation.

Materiovigilance

It is mandatory for manufacturers and users to inform Swissmedic of adverse events that take place in Switzerland. The firms also inform Swissmedic of measures taken, such as product recalls, which are then monitored. Swissmedic is integrated within the European reporting system and also informs contracting states that are affected about incidents and measures that are taken in Switzerland.

Activities

- A total of 1,850 incidents were reported in Switzerland. This represents a further increase compared with the previous year.
- The implementation of corrective safety measures in Switzerland was monitored in 682 cases. A total of 77 reports on defective medical devices (National Competent Authority Reports, NCAR) were drawn up for the attention of foreign authorities, and Swissmedic received 870 NCAR from the European partner authorities.
- In 620 cases, a public safety report was published on the Swissmedic website for the information of users.
- In 2017, new cases of suspected incidents or concrete actions to be taken on pending cases were again discussed during monthly telephone conferences with the other European surveillance authorities.

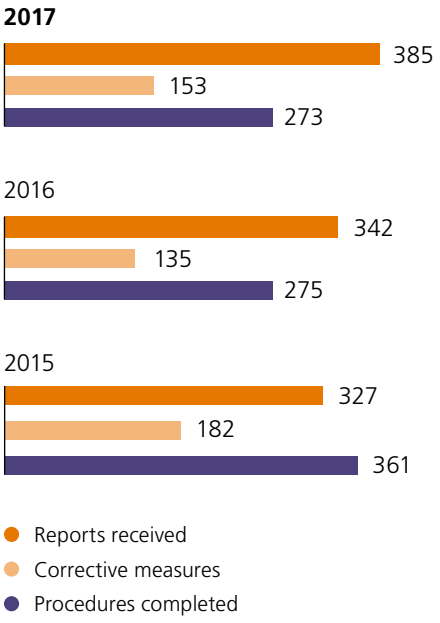


Market monitoring

Efficient state-organised controls are of decisive importance in guaranteeing a high level of safety for patients. Distributors of medical devices in Switzerland must guarantee the conformity of the products. Swissmedic receives suspicion reports, initiates the necessary corrective measures and monitors their implementation. Swissmedic works closely with the Cantonal authorities in this area.

Activities

- In November 2017, all processes, including data from the market monitoring of medical devices, were migrated to the central SAP system. These cases are now recorded and managed in a single system, which will also have repercussions on data evaluation.
- The number of reports remains high, as a result of which they were processed stringently according to the risk involved.
- Swissmedic intensified on-site inspections in order to clarify the background to reports (see CAB and inspections).



Clinical investigations

Swissmedic approves and monitors clinical investigations of medical devices for human use if the products or the intended uses are not yet CE certified. Planned investigations of this type have required mandatory approval since 1 January 2014. During the investigations, Swissmedic monitors incidents for which reporting is mandatory, such as serious events and reports on the safety of the participants. Swissmedic may inspect investigators, sponsors and research institutions throughout Switzerland, and records notifications and measures from Switzerland in EUDAMED. Swissmedic moreover takes part in the drafting of international guidelines and training events with a view to enhancing their implementation.

Activities

- The number of applications for new investigations with medical devices that are not yet CE marked rose by some 32 % to 45 in 2017.
- Two ongoing clinical investigations were inspected.

Monitoring of conformity assessment bodies (CAB) and inspections

Swissmedic monitors the Swiss CAB in collaboration with the Swiss Accreditation Services (SAS), designates them as notified bodies and inspects them, collects their reports on certificates issued, and records these in EUDAMED. Swissmedic takes part in quality assurance measures carried out by the authorities in Europe that designate notified bodies, and carries out other inspections in connection with medical devices.

Activities

- As part of market monitoring activities, on-site inspections of 14 Swiss firms were performed.
- In 2017, Swissmedic carried out a total of 26 inspections in hospitals in the areas of reprocessing, maintenance and reporting systems.
- Swissmedic co-ordinates inspections carried out in Switzerland by foreign authorities with the State Secretariat for Economic Affairs (SECO) and, if needed, accompanies the inspectors on site.

	2015	2016	**2017**
CAB inspections (including ISO 13485 and ISO 17021)	6	3	6
Joint assessments	2	2	2
On-site inspections of clinical investigations	3	6	2
Hospital inspections (reprocessing, maintenance and reporting system)	4	12	26
Inspections by foreign authorities*	40	74	50
Inspections of market controls	8	10	14

* (Co-ordination with SECO, including accompanying inspectors on site if needed)

Export certificates

Swissmedic issues export and manufacturing certificates for medical devices for Swiss companies. In doing so, Swissmedic confirms that the product concerned is lawfully on the Swiss market. These export certificates are needed, depending on the requirements of the various foreign authorities, for import into the country in question.

Activities

- In the year under review, 3,039 export certificates were issued.
- In 99 % of cases this service was provided within 30 days, despite the above-average increase in the number of requests received.

3,039	2,677	2,575
2017	2016	2015

Appeals procedure concerning the market monitoring of medical devices

Appeals against decisions in connection with the licensing procedure may be lodged with the Federal Administrative Court within 30 days. A judgement by the latter court may in turn be contested before the Federal Supreme Court.

Activities

- Appeals were lodged with the Federal Administrative Court against three official decisions by the Agency in connection with the market surveillance of medical devices. One appeal was dismissed. One appeal was not admitted, and one is pending. One decision by the Federal Administrative Court was contested before the Federal Supreme Court. The appeal was rejected.
- Of the appeals already pending before the Federal Administrative Court, one was rejected.

Special activities and events: Market monitoring of medical devices

Revision of the medical devices regulations

The Federal Office of Public Health (FOPH) is working on the new Swiss legislative framework for medical devices. This is being done in close cooperation with Swissmedic, the State Secretariat for Economic Affairs (SECO) and the Directorate for European Affairs (DEA). The project plan foresees a procedure comprising several stages. The first revision of the Medical Devices Ordinance (MedDO) entered into force at the end of 2017, with the full revision of the Swiss medical devices legislation scheduled for completion by 2020. Swissmedic's technical input into this project is particularly substantial (for the revision of the legal foundations for medical devices see the section on standards and legislation).

Higher number of inspections

In 2017 Swissmedic intensified monitoring of the maintenance and reprocessing of medical devices in Swiss hospitals, leading to an increase in the number of related inspections for the second year in succession. Furthermore, in the context of the newly issued guidelines on the operation and monitoring of heater-cooler devices (HCD) in operating theatres, additional random inspections of compliance with these guidelines were performed in some hospitals.

Standards

Legal foundations

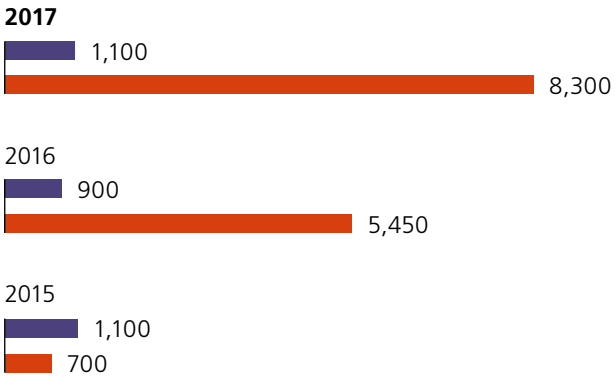
Legislation

Swissmedic's legal mandate, its areas of competence and its enforcement role in the therapeutic products sector are laid down in binding laws and ordinances. In a rapidly developing environment, the area of legislation – meaning work in connection with enacting and maintaining the legal basis – is one of Swissmedic's key tasks. On the administrative level, the lead entity for enacting and revising the Therapeutic Products Act (TPA) and the implementing ordinances (both issued by the Federal Council) is the Federal Office of Public Health (FOPH). Swissmedic is integrated within this legislative work as the competent enforcement authority. The enactment and revision of the implementing ordinances of the Swissmedic Agency Council (ordinances of a technical nature) is however among the competences of Swissmedic.

Activities

- The changes to legislation adopted by Parliament on 18 March 2016 as part of the regular revision of the Therapeutic Products Act (TPA 2) necessitate numerous modifications of the implementing legislation. In March 2016, Swissmedic and the FOPH jointly launched a legislative project for the associated ordinances of the Federal Council and an in-house revision project for the ordinances of the Agency Council under the designation "Therapeutic Products Ordinance Package IV (TPO IV)". The public consultation period for the draft ordinances affected by TPO IV began on 21 June 2017 and ran until 20 October 2017. More than 200 opinions were submitted regarding the three new and six fully or partly revised ordinances. The opinions are being evaluated with the aim of submitting the Therapeutic Products Ordinance Package IV to the enacting bodies, the Federal Council and the Agency Council for a decision in autumn 2018.
- On 29 September 2017, Parliament adopted the proposal to approve and implement the Medicrime Convention in the final vote. Adaptation of specific aspects of the Therapeutic Products Act (TPA) and the Criminal Procedure Code (CrimPC) were part of the proposal. The implementing provisions in the ordinance concerning the Medicinal Products Licensing Ordinance (MPLO) are currently being adapted. The consultation on the revision of the MPLO is scheduled to begin in spring 2018.
- The EU began the revision of its medical devices legislation in 2012, and on 5 April 2017 it approved new regulations governing medical devices (MDR) and in vitro diagnostic agents (IVDR). Switzerland has to integrate the new regulations into Swiss law in good time if it wants to continue participating in the European internal market for medical devices and avoid technical trade barriers. In adapting its legislation to the European regulations, Switzerland is also seeking to increase the safety and quality of medical devices, and one of the ways in which this will be done is by monitoring the market more stringently. Laws and ordinances will require far-reaching modifications and the MRA (agreement between Switzerland and the EU on mutual recognition of conformity assessments) will also have to be modified to maintain the equilibrium between European regulations and Swiss legal foundations. The FOPH is developing the Swiss legal framework in close cooperation with Swissmedic, the State Secretariat for Economic Affairs (SECO) and the Directorate for European Affairs (DEA). A partial revision of the Medical Devices Ordinance (MedDO) entered into force at the end of 2017, with the full revision of Switzerland's medical devices legislation scheduled for 2020.

Human resources deployed to work on legislation (hours worked)



- Active work on legislation (not related to projects)
- Projects involving the implementing legislation for the revision of the TPA (TPA IV), revision of the Medicinal Products Licensing Ordinance (MPLO) in the context of Medicrime and the revision of the legal foundations for medical devices (revision of MD regulation)

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 and for certain medical devices. The requirements are drawn up in the light of current science and technology and are legally binding.
The pharmacopoeia contributes significantly towards ensuring that all patients receive therapeutic products whose quality is of an equally high level. It therefore constitutes a key prerequisite for safe and effective therapeutic products. Swissmedic takes part in the elaboration of the Ph. Eur. on the basis of a state treaty, and through the Ph Helv. it publishes supplementary requirements that are important on a national level. The Pharmacopoeia Division of the Agency is Switzerland's national pharmacopoeial authority.

Activities

- Switzerland made a major contribution to the production of the 9th edition of the Ph. Eur. and to its translation into German. The main volume, edition 9.0, came into effect on 1 January 2017, with supplements 9.1 and 9.2 following on 1 April and 1 July 2017. Once again, various texts in these three volumes were harmonised with the Japanese Pharmacopoeia and the Pharmacopoeia of the United States of America, making the Ph. Eur. part of the basis of a global quality standard.
- Problems were identified with the testing of "related substances" in the monograph for erythromycin ethylsuccinate that was newly published in volume 9.0; these problems led to incorrect results. In order to ensure an unbroken supply of the active substance erythromycin ethylsuccinate to the European market, a revised monograph was produced and came into effect as a temporary measure on 1 May 2017 following an urgent change.
- Various text sections in the Ph. Helv. were updated to reflect the state of the art in science and technology. Swissmedic deployed a specialist working group to develop a chapter of the Ph. Helv. on GMP for small quantities of radiopharmaceuticals with the aim of ensuring quality in this area too in the future.
  The future elaboration and revision of product monographs for the Ph. Helv. was optimised with the involvement of the user community.
- Swissmedic – together with Swiss experts from industry, universities, pharmacies (in the community and hospitals) and other authorities – performed the specialised work necessary for the Ph. Eur and Ph. Helv. 59 % of this work was done by the Swiss Agency for Therapeutic Products.
- A total of 133 people from Switzerland were mandated to work in the various national and European committees and groups employed on the pharmacopoeia. This is a clear indication not only of the value placed on the pharmacopoeia but also of the expertise that Switzerland can provide in the pharmaceutical sector.

Technical standards for medical devices

Swissmedic is the competent authority for registering technical standards that are suitable for specifying the fundamental requirements that medical devices must fulfil (as stipulated in TPA Art. 45 para. 4 and MedDO Art. 4 para. 3). Swissmedic registers internationally harmonised standards wherever possible.

The list of registered technical standards is updated regularly and promptly in the Federal Gazette and on the Swissmedic website.
The Agency also works in various national standards committees (SC) and technical committees (TC). These committees analyse the effects of new or revised international standards on medical devices with regard to Switzerland, and issue comments on them where needed.

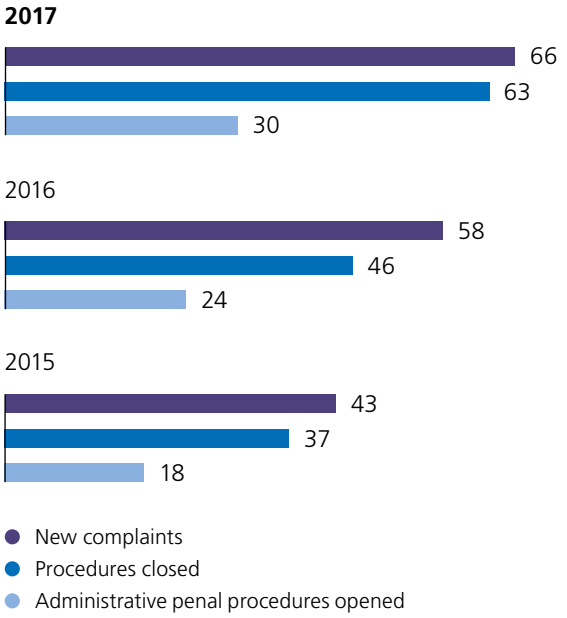
Activities

- In 2017, Swissmedic was active in two national standards committees and one technical committee.

Penal law

General developments

Swissmedic is mandated to carry out a considerable proportion of the penal prosecutions in connection with offences against the Therapeutic Products Act. The Agency may carry out penal investigations and (as long as fines or financial penalties are involved), may impose sanctions. In cases where a custodial sentence is sought or if a conviction handed down by Swissmedic is contested, the Agency represents the prosecution before the courts or appeal bodies.



Activities

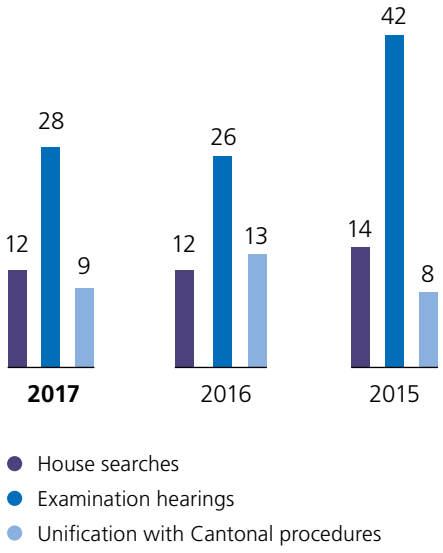
- The Penal division received 66 new complaints and closed 63 cases. It opened administrative penal proceedings against 30 individuals. The workload and complexity of these proceedings remain at a stable, if high, level. Apart from the illegal import of, and trading in, medicinal products, the proceedings also involved non-compliant medical devices, unauthorised clinical trials and failure to comply with the duty to cooperate.
- The Swiss parliament has accepted the ratification of the Council of Europe's Medicrime Convention. Work continued on its implementation and its revision. Specifically, discussions concerning future collaboration were conducted between the customs authorities and the Office of the Attorney General of Switzerland.
- In compliance with the strategy for publicising decisions issued by Swissmedic in criminal matters, three lists of decisions were communicated to accredited journalists, one for the period from October 2016 to February 2017 and two for the periods from March to June and July to November 2017. This publicity prompted 22 consultation requests relating to the decisions and to several articles that helped prevent violations of the Therapeutic Products Act.

Investigative measures

The Federal Act on Administrative Penal Law grants Swissmedic's investigators-in-charge competences that are similar to those of a Cantonal or Federal prosecutor. They may notably carry out house searches, seize goods or conduct examination hearings. Within the framework of an investigation, individuals affected by investigative measures may submit complaints to the Director of Swissmedic or to the Federal Criminal Court.

Activities

- In 2017, Swissmedic carried out 12 house searches and 28 hearings.
- Coercive measures had to be taken at the homes of two doctors, the office of one of these doctors and at the home of a lawyer. These cases required the intervention of the Cantonal Medical Officer and the head of the cantonal lawyers' association.
- The Federal Criminal Court (FCC) admitted a request, submitted in 2016, to challenge an employee of the Penal Division after he had refused a request to extend a time limit. At the same time, the FCC annulled the latter decision, against which an appeal had also been pending since 2016. A new employee took over this case and, once again, the request to extend the time limit was refused. The appeal submitted to the Director of Swissmedic was rejected, as was the appeal lodged with the FCC. Two appeals submitted to the Director of Swissmedic, one requesting a rejection of an individual and the other a refusal to inspect the file, have become irrelevant and were dismissed. Two appeals concerning coercive measures against doctors were lodged with the FCC and are still pending.
- Swissmedic received four requests for international cooperation in criminal matters from Lithuania, Kazakhstan, France and Germany and submitted two requests to Germany.
- Nine cases were the subject of procedural unification, i.e. the association of the prosecution with Cantonal proceedings.

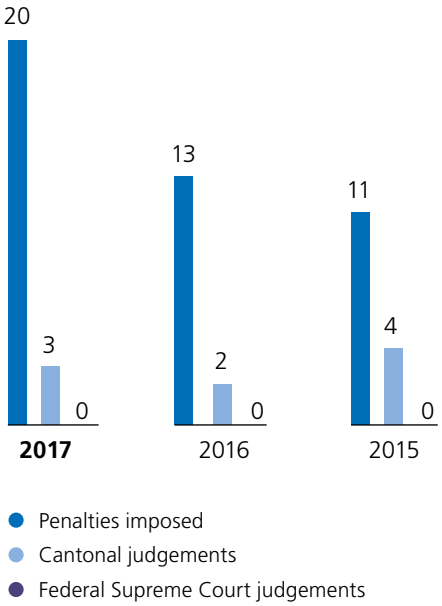


Decisions / judgements by Swissmedic and by courts

After the investigation phase, cases are subject to a decision regarding a penalty, or they are transmitted to the competent court, or the procedure is closed. For cases that are brought before a court, Swissmedic represents the prosecution.

Activities

- A total of 18 natural persons and 11 legal entities were affected by the 20 penalties that were imposed.
- Fourteen cases concerned illegal manufacture and trading, including illegal import, export and wholesale trading. Two cases involved illegal advertising and the conferring of illegal economic benefits on doctors. Four cases concerned violations of the duty to report non-compliance, one involved violations of due diligence obligations and another violations of the duty to cooperate.
- Three criminal orders were issued following objections submitted against imposed penalties, two concerning illegal trading and one concerning illegal advertising and the conferring of illegal economic benefits on doctors. Swissmedic also dismissed one case in which the suspicions were not confirmed.
- Of particular interest was the fact that three hospitals were fined for failing to report serious quality problems observed for medical devices.
- A cantonal court of second instance confirmed another 2017 judgement concerning the placing on the market of a medical device promoted for indications not covered by the certificate of conformity supplied by the competent certifying body. Qualification as a non-compliant medical device, which was defended by Swissmedic, was thus confirmed in this case. In another case, this time involving the diversion of medicines purchased at reduced prices for humanitarian purposes, but sold in Switzerland without a wholesale trading permit, a court of first instance acknowledged the guilt of the offender, but decided not to impose damages, which would have amounted to several million Swiss francs. Swissmedic has filed an appeal against this decision.



Stakeholder management

Information

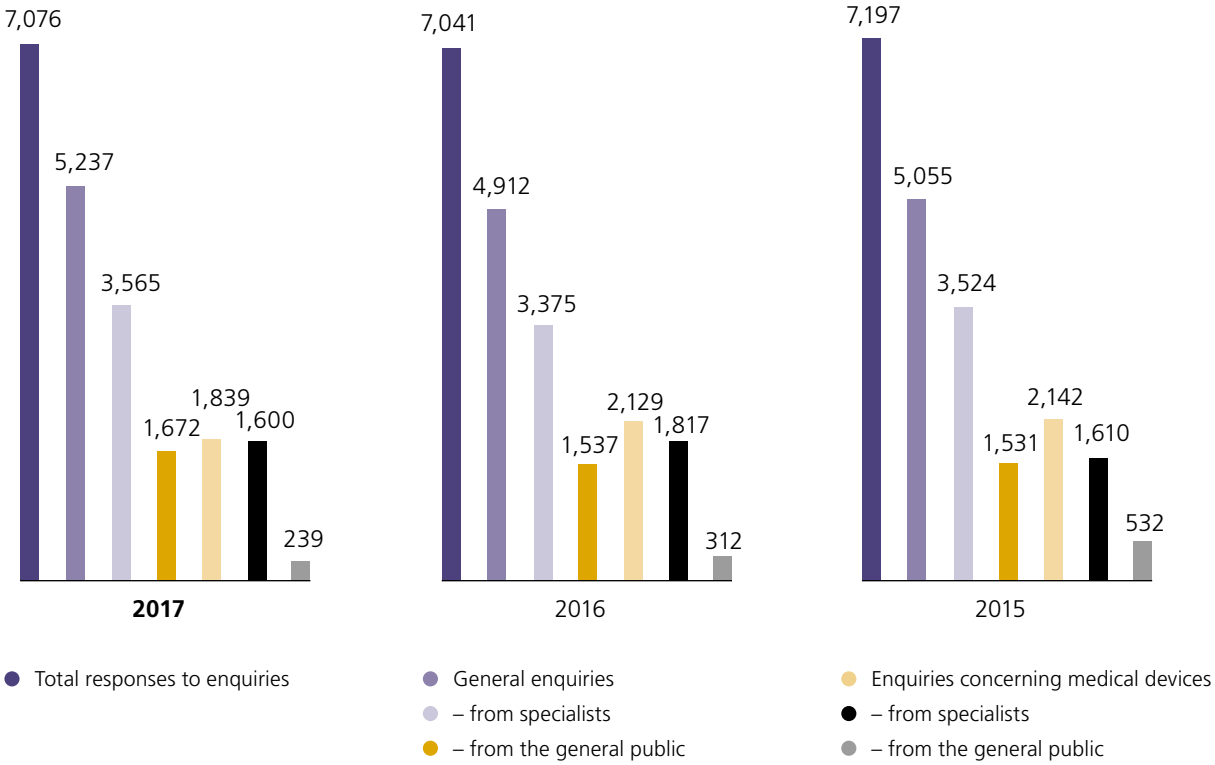
Swissmedic provides fast, targeted information on new findings concerning therapeutic products that could constitute health hazards. In addition to safety-relevant information, new authorisation decisions or major changes to medicinal product information are of considerable interest.

General enquiries

Swissmedic responds to general enquiries submitted by consumers, patients and specialists on a wide range of subjects associated with therapeutic products. Generally speaking, these general enquiries are answered within ten days. Enquiries related to specific applications or cases and information and advice provided by Swissmedic's Legal Affairs staff do not fall under this category.

Activities

- There was a slight increase in the number of enquiries in the year under review compared with 2016.
- Among the general enquiries, there was a larger number of enquiries related to the form for manufacturers' details and CBD.
- The main topics of the enquiries related to medical devices were marketing and delimitation. The website redesign has led to a decrease in the number of enquiries related to medical devices.
- 97 % of all general enquiries were answered within ten calendar days.



Performance indicator

General enquiries: percentage of responses sent within 10 days

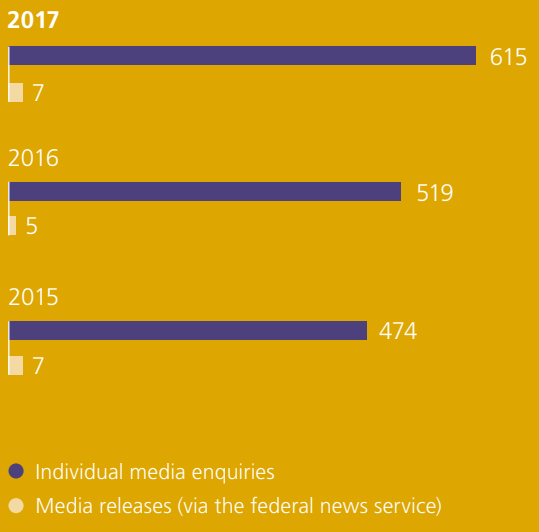
Target Result

Press relations

As "information service providers", the media managers at Swissmedic are responsible for a large proportion of the Agency's public relations work. The Media Unit responds to enquiries from media representatives, puts them in touch with the right experts for background information or interviews and publishes releases for the media and the public. Within the boundaries of the law, Swissmedic provides open, transparent information that medical lay people can understand about the benefits and risks of therapeutic products and about the Agency's tasks and areas of competence.

Activities

- The annual statistics on imports of illegal medicinal products published in early March, the results of the PANGEA X project and the approval of the Medicrime Convention by the Council of States generated a wide-ranging response in the media. Swissmedic drew attention on various occasions to the dangers associated with ordering medicinal products online.
- In the year under review, Swissmedic decided to approve an application from the Swiss Transfusion SRC to no longer exclude MSM (men who have sex with men) indefinitely from donating blood. The announcement of this change in practice met with a considerable media response from mid-2017.
- Both the electronic and print media reported regularly on the boom in products containing cannabidiol (CBD) in Switzerland. Swissmedic took the opportunity to draw attention to an information sheet produced jointly with the FOPH, FSVO and FONES that provides an overview of the legal situation regarding the various raw materials and products available.
- Attention focused repeatedly on experiments performed with medicinal products in Swiss psychiatric clinics in the period from the 1950s to the 1980s. Swissmedic staff gave interviews explaining patients' rights and the approval requirements that exist nowadays.
- Reports on the risks associated with medicinal products based on the active substance valproate appeared in various media. If used during pregnancy, these products can cause malformations and subsequent developmental disorders in children. Swissmedic experts publicised new measures designed to limit the number of exposures during pregnancy.
- In June the Federal Council initiated the consultation procedure for the implementing provisions of the revised Therapeutic Products Act. The restructuring of the dispensing categories used to date was a particular subject of media enquiries.



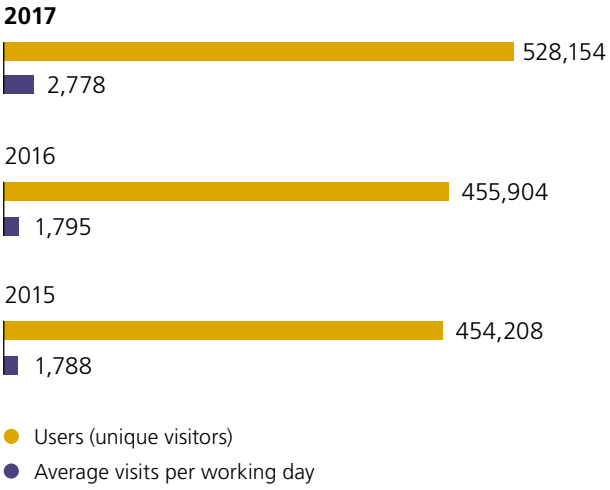
Publications

Swissmedic has a legal mandate to inform the public about specific events relating to therapeutic products. Announcements about new first authorisations of medicines, authorisation withdrawals, and amendments to regulatory requirements are published monthly in the Swissmedic Journal, the Agency's official periodical. Updates of medicinal product information for healthcare professionals and patients as well as safety notices and recommended behaviours for therapeutic products are distributed by circular.

Activities

- In addition to periodicals, the Communication Department in the Market Surveillance Division produced new brochures including "Good practice in the processing of medical devices" and "Guidelines on quality assurance in the transfusion chain". The layout of the "Swissmedic Vigilance News" that appears twice a year was restructured and given a typographical overhaul to improve accessibility.
- Swissmedic publishes safety-related notices on medicinal products (mainly Direct Healthcare Professional Communications, DHPC) on its website and via electronic newsletter
- The updated Swissmedic website (www.swissmedic.ch) went online in mid-November with a new design, a topic-oriented structure and additional navigation in the footer. The redesign was necessitated by the changeover to a new software used to operate the federal government's websites. The new Internet platform provides the basis for future upgrades in terms of content and functionality in order to satisfy the modified requirements arising from the ordinary revision of the Therapeutic Products Act and the implementing regulations.
- The application used to publish safety notices relating to medicinal products (fsca.swissmedic.ch/mep) was completely revised. Notices can now be published automatically on an ongoing basis instead of being manually updated once a week. The search results can also be exported and saved as a link.
- As in 2016, roughly 20 % of visitors now access the website from mobile devices.

Website statistics www.swissmedic.ch



Events

Swissmedic organises events, information sessions and workshops with the objective of enhancing cooperation with stakeholders and disseminating information. Most specialised addresses are prepared and presented by Swissmedic employees. Depending on the topic, guest speakers from other authorities or from industry are also invited.

Activities

The information sessions organised by Swissmedic are an important element of stakeholder management. Every year, numerous individuals use these opportunities to ask questions, meet Swissmedic staff, discuss their concerns in person or exchange views with others. In 2017 Swissmedic organised 15 events where this was possible.

- The focus of the workshop for users of blood products in 2017 was a presentation of the new guidelines on quality assurance in transfusion practice. The workshop was held once in German and once in French.
- Users of the IT solutions that monitor the commercial flow of narcotic substances attended the international NDS and I2ES User Group Meeting. The main topics were solution updates and the drafting of recommendations for future developments. This event was held in conjunction with the UN.
- Swissmedic presented the new guidelines on quality assurance in transfusion practice at the national "Swisstransfusion" conference. Swissmedic staff also chaired some of the sessions at this conference.
- In 2017, the training course for GMP inspectors organised annually by Swissmedic focused on the inspection of manufacturers of medicinal products faced with the problem of cross-contamination. Three Swiss GMP inspectors and around 25 foreign (primarily European) inspectors also participated in the two-day seminar. The presentations were delivered both by inspectors and representatives of the pharmaceutical industry. A third half-day reserved for Swiss inspectors was devoted to subjects specific to Switzerland, for example the technical interpretation of a document concerned with the duties and responsibilities of the Responsible Person employed by the holder of an establishment licence.
- Scientific and technical developments in the field of medicinal products necessitate continuous adaptation of the regulatory environment and, consequently, the requirements for the authorisation of medicinal products. This year's "Regulatory News from the Authorisation Division" event, attended by some 440 participants, focused on the revised Therapeutic Products Act (TPA 2) and the modifications made to the implementing ordinances (TPO IV). To the extent possible at the time, Swissmedic presented the most important practical consequences of the implementation of this revised law. This year for the first time there were breakout sessions on specific topics relating to veterinary medicinal products, complementary medicine and herbal medicinal products.

Transparency

The Federal Act on Freedom of Information in the Administration (FoIA), which entered into force on 1 July 2006 together with the related Ordinance, grants every individual the general right to access public documents. This includes documents which relate to public mandates and were drawn up or received by Swissmedic after 1 July 2006. An application to consult such documents does not need to be substantiated. The right of access to official documents can be restricted or refused in order to protect overriding public or private interests.

Activities

- The number of requests falling under the FoIA decreased compared with 2016 from 19 to 11.
- In one case a verbal mediation was held before the Federal Data Protection and Information Commissioner (FDPIC).

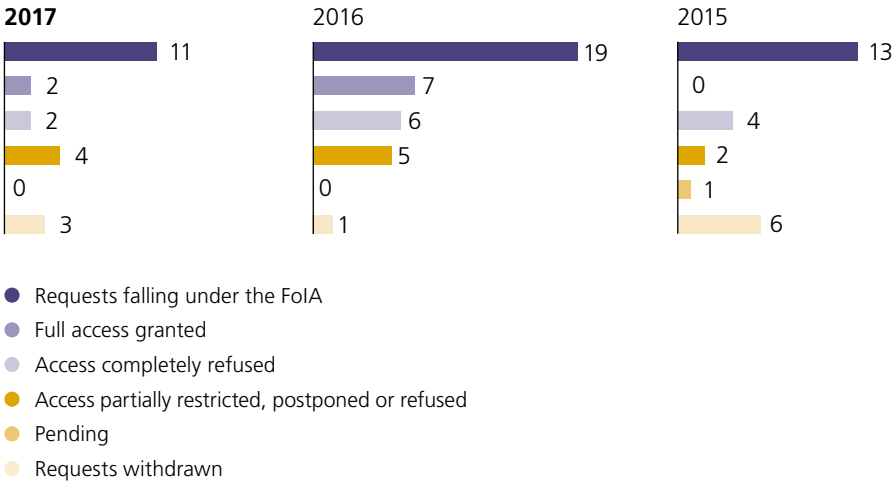
Appeals procedure regarding access to official documents

Appeals against decisions in connection with access to official documents may be lodged with the Federal Administrative Court within 30 days. A judgement by the latter court may in turn be contested before the Federal Supreme Court.

Activities

- No appeals were lodged with the Federal Administrative Court against an official decision of the Agency in connection with access to official documents.
- Of the appeals already pending before the Federal Administrative Court, one was approved in part. The appealing party subsequently took the appeal to the Federal Supreme Court. The decision is outstanding.

Appeals procedure regarding access to official documents



Collaboration

In accordance with its legal mandate, its service mandate and the strategic plan, the Agency pursues a policy of including external stakeholders, with their often diverging interests, in Swissmedic's various fields of activity as a fundamental principle. Collaboration is structured in such a way as to preserve Swissmedic's independence as an authorisation and supervisory authority. It is based on a relationship that creates long-term trust and fosters mutual understanding.

National collaboration

National network

Collaboration on a national level is a fundamental factor that enables Swissmedic to achieve the objectives laid down in its legal and strategic foundations. These objectives are geared first and foremost to guaranteeing the safety of therapeutic products. The following stakeholder groups are part of Swissmedic's national network:

- 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 parliament
- Media representatives (see section headed Press relations)

Activities

- The annual meeting between Swissmedic and the cantonal pharmacists took place on 17 March. As in past years, it provided a platform for a frank exchange and a discussion of current topics affecting therapeutic product regulation such as the revision status of the Therapeutic Products Ordinances, regulatory classification of mixed sets containing medicinal products and medical devices, the new food legislation, the new EU regulations governing medical devices and in vitro diagnostics (MDR and IVDR) and the project to reallocate dispensing categories.
- On 23 March Swissmedic, the FOPH and SECO supported the conference organised by SWISS MEDTECH and the Swiss Association of the Diagnostics and Diagnostic Equipment Industry SVDI on the topic of the entry into force of the new EU regulations on medical devices (MDR) and in vitro diagnostics (IVDR) that are intended to further increase patient safety. The 420 attendees were given an overview of these regulations and the planned adaptation of the Swiss regulations in this field.
- Three Regulatory Affairs round table meetings with industry association representatives took place during the year under review. On each occasion Swissmedic provided information on current authorisation-related topics, including experience with the eGov project and the implementation of TPO IV. This forum is also an opportunity to discuss questions and challenges relating to operative business and to define problem-solving approaches.
- A round table meeting with companies from the veterinary pharmaceuticals industry took place in June 2017. The topics discussed included stem cell therapy in animals in Switzerland, e-submission and the impact of the Therapeutic Products Act revision on veterinary medicinal products. A round table meeting of this kind is planned to take place once a year in future, with an option to meet more frequently if needed.
- The patient/consumer organisations working group continued its work as usual. The working group met four times, on one occasion at the first ever full-day workshop focusing on patient information and a possible model for a summary of the SwissPAR (Swiss Public Assessment Report) in language accessible to lay people.

External further training initiatives and specialist presentations

Swissmedic is engaged in the initial and continuing training of therapeutic product specialists at institutions of tertiary education, conferences and expert meetings. Staff give presentations on regulatory issues relating to the entire spectrum of Swissmedic's service mandate. The main organisational points of the presentations are published on the Agency website.

Activities

- As in 2016, Swissmedic continued to play an active part in the Middle European Organisation for Regulatory Affairs (MEGRA) further training courses in Switzerland and in the Master of Drug Regulatory Affairs programme of the German Society for Regulatory Affairs (DGRA).
- Swissmedic also gave presentations for the last time for ETH Zurich's master's degree course in Medicinal and Industrial Pharmaceutical Sciences (MIPS). This course was replaced in September 2017 by the master's degree course in Pharmaceutical Sciences, in which Swissmedic will also be involved.

International collaboration

Collaboration among authorisation and supervisory authorities and with international organisations active in the field of medicinal products and medical devices is of great significance for the stakeholders, for Switzerland as a location, and for Swissmedic. At the forefront is the exchange of information on the entire process of authorising medicinal products, market monitoring, and preparing new draft legislation related to therapeutic products. For example, collaboration with authorities from other countries and with international institutions facilitates the identification of risks at an early stage and the initiation of coordinated measures.

International network

In recent years, Swissmedic has consistently networked with partner authorities in line with its strategy and has now concluded information exchange agreements with virtually all internationally recognised therapeutic products authorities of a comparable standard. Bilateral technical collaboration with partner authorities has been stepped up and a system of benefit-driven information exchange established.
International collaboration on the regulation of therapeutic products is not only occurring at the bilateral level between individual authorities, it is increasingly taking place multilaterally on different platforms. Swissmedic is very engaged in the commissions and working groups pertinent to the Agency's role that have been set up by these platforms.

Activities

Bilateral collaboration

- In the year under review, Swissmedic networked with the Austrian Agency for Health and Food Safety (AGES), signing a memorandum of understanding (MoU) on closer cooperation on behalf of the Federal Department of Home Affairs on 13 March. Swissmedic now has agreements to cooperate more closely with all the German-speaking authorities and is continuing its strategy of networking with European therapeutic products agencies and those with a comparable level of therapeutic product control.
- As in previous years, there was an exchange with the existing partner authorities on certain operative and strategic topics during 2017. In March 2017, for example, two staff members from the US FDA visited Swissmedic for discussions on topics including international collaboration between the two agencies and possible intensification of certain activities in the future. The British therapeutic products agency MHRA, with which an agreement on closer cooperation was concluded in 2016, visited Bern in May, and in September 2017 a pilot project was launched with the Korean Ministry of Food and Drug Safety (MFDS) with the long-term aim of mutual recognition of Good Manufacturing Practice (GMP) certificates. A delegation from the Brazilian regulatory authority ANVISA paid a fact-finding visit in November to learn about the implementation of various IT projects.

- Training visits: In January Swissmedic held a training session on authorisation for two experts from the Malaysian therapeutic products agency. A revision of existing practice was initiated in response to an increasing number of requests to Swissmedic from various foreign therapeutic products agencies for training visits. The aim is to achieve better coordination and more efficient organisation of these visits. No training sessions will be held until the new training concept has been established.

Multilateral collaboration

- Cooperation under the mantle of the European Directorate for the Quality of Medicines and HealthCare (EDQM): Swissmedic sits on the Committee of Experts on minimising the public health risks posed by counterfeiting of medical products and related crimes, CD-P-PH/CMED, of which it has held the chair since 2013. During the period under review, the focus was particularly on involvement in one of the Committee's projects that aims to revise and simplify a European database used to record counterfeit medicinal products. Switzerland did most of the work on redesigning this database. A further emphasis in 2017 was the expansion of the network of authorities on the basis of single points of contact (SPOC), and a meeting was held for SPOC in December 2017.
- The Annual Meeting of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring took place in Kampala, Uganda, in November. The focus in 2017 was primarily on medicinal product safety in African countries. Discussions between the numerous delegates from 58 countries revealed great variation in the maturity of pharmacovigilance systems. One thing that they all have in common is the need for closer collaboration. The two Swissmedic representatives played an active role, chairing two working groups and giving a presentation during the plenary session. Their participation also helped to prepare the next conference that will take place in Switzerland and be organised by Swissmedic in close cooperation with the WHO.
- International Generic Drug Regulators Programme (IGDRP) and International Pharmaceutical Regulators Forum (IPRF): Swissmedic actively supported the initiatives of both bodies during the period under review and attended the steering committees' meetings. At the centre of discussion was the implementation plan for the consolidation of IGDRP and IPRF from January 2018. The name of the new initiative, International Pharmaceutical Regulators Programme (IPRP), was decided and draft future guidelines, the organisational structure, operational framework and communication strategies were discussed and refined.
- Swissmedic continued its participation in the working groups of the Australia-Canada-Singapore-Switzerland Consortium (ACSS). The first pilot in the Generic Medicines Work-Sharing Trial (GMWST) was completed successfully in June. An article describing the implementation of and collective experience from the first GMWST is scheduled to appear in the March 2018 issue of the DIA's Global Forum. A package of documents (Notice to Applicants, Expression of Interest Form, Operational Procedures and Questions and Answers) containing information on participation was published on the partner authorities' websites in order to inform the industry about this project and to identify further potential candidates.
- As a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), Swissmedic took part in the evaluation of other GMP inspectorates. The preliminary evaluation of Kazakhstan and the evaluation of the GMP inspectorate in Turkey were completed. Swissmedic was also involved in further PIC/S working groups, among them the Working Group (WG) on Data Integrity and the WG on Revision of GMP Annex 1, and supported discussions between the PIC/S and the European Commission about the new EU GMP Guidelines for Advanced Therapy Medicinal Products.

- Swissmedic is represented in the GMP working group of the International Coalition of Medicines Regulatory Authorities (ICMRA). This working group established a procedural project designed to make the best use of resources in connection with inspections carried out abroad by sharing information generated by trusted inspectorates. This written procedure has been successfully tested: inspection reports have been evaluated and, as a result, certain foreign sites have been exempted from an additional foreign inspection. This procedural project has been forwarded to the PIC/S for consultation among its members.
- Participation in the International Coalition of Medicines Regulatory Authorities (ICMRA) and in its working groups continued. Swissmedic worked closely with the Japanese authority to redesign the ICMRA website (www.icmra.info) and played an active role at the 12th Summit of Heads of Medicines Regulatory Agencies and ICMRA Meeting in Kyoto, Japan. Regenerative medicine, real-world data/real-world evidence, antibiotic resistance and counterfeit medicinal products were the topics discussed at this Summit. Discussion at the subsequent ICMRA Meeting focused on innovation and the future direction of the initiative. The results were then reported at a public symposium. The event was attended by more than 1,500 people.
- Multilateral cooperation is of central importance in the field of medical devices in particular. Swissmedic has been represented in many European technical and working groups for years and consistently works closely and well with the network of European partner authorities. One notable event in the year under review was the establishment of the MDCG (Medical Device Coordination Group), the central European decision-making body under the new regulations. Swissmedic has been awarded observer status in this body.

Development cooperation

Swissmedic has been involved in two development cooperation projects since 2015. This involvement is based on a memorandum of understanding (MoU) with the Bill & Melinda Gates Foundation (BMGF), FDHA and FDFA. The overriding aim of this cooperation is to help improve and expedite access to healthcare and medicines in low-resource countries.

Activities

- The first project focused on support for the East African Community (EAC) and other economic communities in Africa that are seeking to strengthen their therapeutic products authorities and harmonise the requirements for therapeutic product regulation. As in previous years, Swissmedic again supported the Joint Assessments of the EAC in 2017 and also focused on their GMP activities. Swissmedic experts accompanied a joint inspection of the East African Community, for example, gave presentations at GMP training sessions and carried out a test audit for possible PIC/S accreditation of the authorities in Kenya and Uganda. Swissmedic also took part in a WHO benchmarking survey of regulatory authorities in West Africa. This was the first step in expanding activities into other economic communities in Africa, namely the Economic Community of West African States ECOWAS.
- The second project makes it possible to include African regulatory authorities and the WHO in an evaluation process carried out by Swissmedic for products to treat diseases that disproportionately affect people in southern Africa. Known as the Marketing Authorisation Procedure for Global Health Products (MAGHP), this procedure was presented at numerous events last year and discussions were held with interested stakeholders. The submission of an application at the end of 2017 marked the start of the pilot phase that is expected to last until the end of 2018.

Special activities and events: Stakeholder management

ICH meeting in Geneva

The International Council for Harmonisation (ICH) met in Geneva, Switzerland from 11 to 16 November 2017. This was the first ICH meeting held in Switzerland, and it was organised and run by Swissmedic in close cooperation with the ICH Secretariat. The ICH brings together regulatory authorities and pharmaceutical industry associations with the aim of discussing globally the harmonisation of scientific and technical aspects of medicinal product authorisation. The meeting takes place twice a year. The conference in Geneva lasted five days and was attended by 360 people from all over the world.

Realignment of cooperation with associations and organisations of healthcare professionals

Healthcare professionals are an important stakeholder group for Swissmedic. Depending on the topic and current relevance, the respective divisions of Swissmedic have been in contact with the associations and organisations that represent healthcare professionals in Switzerland since the Agency was founded and collaborate with them on an ad hoc basis. This ad hoc situation was placed on a structured footing in 2017 with the aim of intensifying collaboration overall and promoting dialogue. Two events were held to provide information about the planned approach and its implementation.

Telematics / Information

IT management

IT management handles the strategic and operational planning and provision of IT and telecommunications services. Important instruments in this area are the IT strategy, the IT architecture, and the portfolio of projects, processes, products and services. IT management is responsible for cost-effective, legally compliant procurement, sustainable development, and the stable, secure availability of IT resources and services.

Activities

- New technologies for the evaluation of large, partly unstructured data sets from heterogeneous sources (big data) are being used increasingly in the pharmaceutical industry as well to obtain evidence in both pre- and post-marketing processes. The terms real-world data (RWD) and real-world evidence (RWE) refer to data and information originating from many and varied sources outside of the usual clinical trials. The findings derived from analysing RWD/RWE are gradually appearing in the scientific documentation submitted with authorisation applications and in signal detection. In 2017 Swissmedic began to look at the implications for its own processes, systems and competences.
- The development of approaches to implementing the new ISO standard Identification of Medicinal Products (IDMP) was intensified. Swissmedic is aligning the content of and timetable for this work with the approach taken by the European Medicines Agency (EMA).

Solution development

Implementation of the projects road map represents an important foundation for the achievement of Swissmedic's strategic objectives. Building on the investments in renewals made in recent years, additional project support functions are continually developed and upgraded.
Investments continue to be focused not only on internal process automation projects, but also on expanding options for communicating electronically with the authorities via the Internet (eGovernment).

Activities

- Priority was given to adapting processes and information systems to the revised Therapeutic Products Act, the corresponding ordinances and the requirements of the Medicrime Convention. Technical implementation will continue to tie up much of the IT organisation's capacity in 2018.
- The eGovernment solution for the full electronic processing of applications, reports and correspondence that was piloted in 2016 went into regular operation in mid-2017. The proportion of applications submitted in hard copy dropped to below 15 % within a matter of months. More than 50 % of the related correspondence can already be signed electronically and sent with legally valid digital signatures as needed.
- The Swissmedic website was updated and transferred to the new content management service platform of the Federal Office of Information Technology, Systems and Telecommunication (FOITT). The publication of recalls and safety information about medical devices was made more user-friendly. The intranet was also redesigned and adapted technically to the corresponding FOITT platform.
- The implementation of a new, future-ready information system to process and analyse adverse drug reactions is almost complete and is expected to come into operation in the first half of 2018.

IT operations, use, maintenance and ongoing improvements

Deriving a benefit from IT solutions requires trained, informed users, easily accessible, secure and well-maintained infrastructures, the constant exploitation of potential efficiency drivers, and rapid, simple access to support services. Service and application management plays a vital part in the delivery and oversight of these support capabilities. The operating and support services for Swissmedic's entire system infrastructure and office automation solutions are provided by the FOITT, and other service and software suppliers are brought in for the maintenance and further development of IT resources.

Activities

- The information systems used for business administration and document management were further optimised for the core business processes. As a result, internal job handling for these processes is now largely paperless.
- The functionality of the solution used to manage specification documents was revised, updated and transferred to a modern technology platform in the course of quality management.
- All public tenders issued in accordance with the PPA/PPO (Federal Act on Public Procurement / Ordinance on Public Procurement) were completed within the stipulated deadline and without encountering any objections.
- The IT organisation was reconfigured with the aim of enabling it to meet the challenges posed by the increasing digitalisation of regulatory activities, the pharmaceutical industry and Swissmedic's operating processes both now and in the future. The solution development, innovation and operation and maintenance functions were systematically unbundled and their focus was sharpened, advisory services to the divisions were expanded and medium- and long-term IT architecture management was reinforced.

Corporate Governance

Organisation

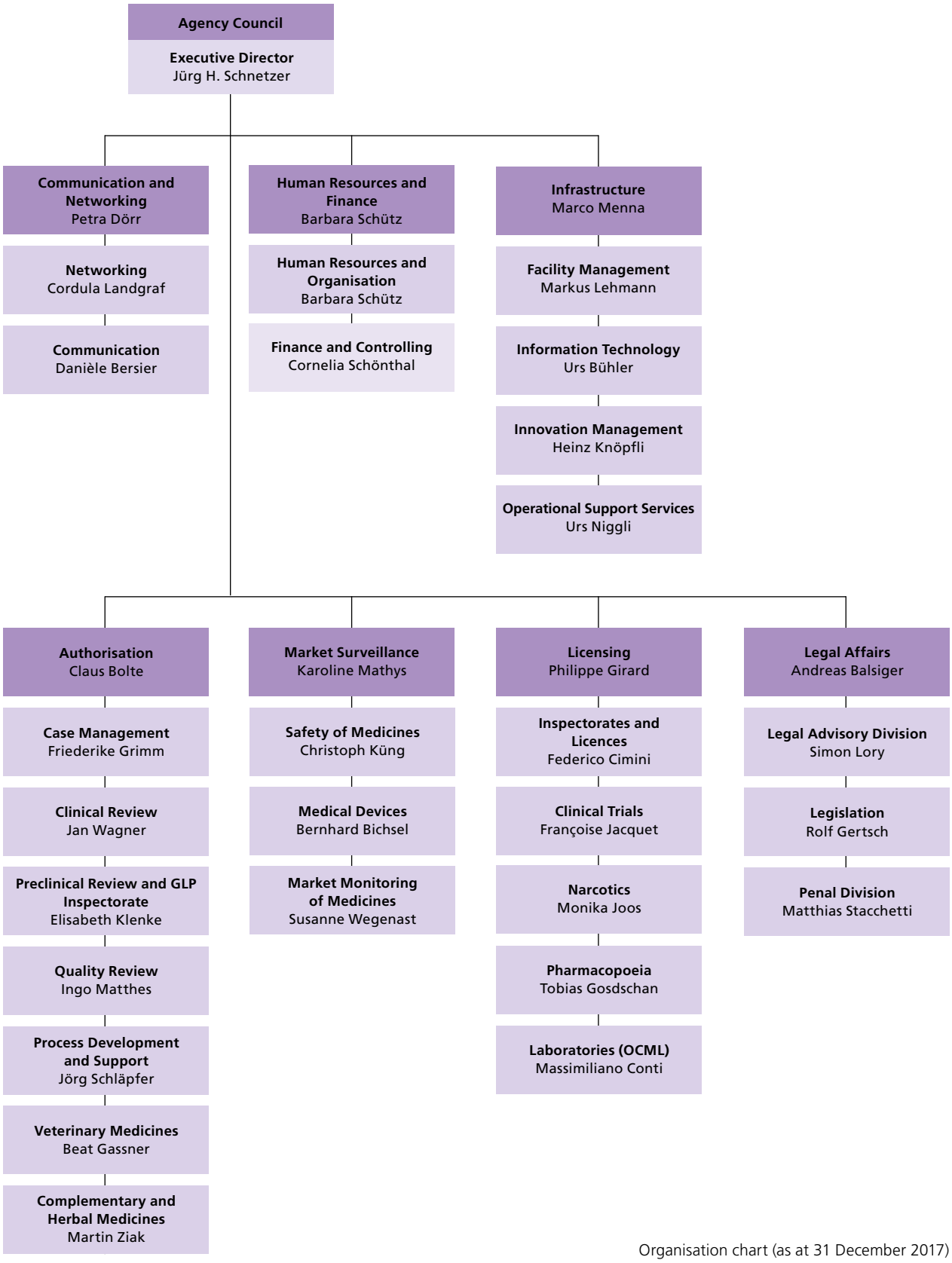
Swissmedic is the Swiss regulatory and control authority for therapeutic products. Its activities derive from therapeutic products legislation. The principal legal basis is the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA). Swissmedic is attached to the Federal Department of Home Affairs. As a federal public institute based in Bern, the Swiss Agency for Therapeutic Products, Swissmedic, is independently organised and managed, and has its own budget.

Swissmedic commenced operation on entry into force of the Therapeutic Products Act on 1 January 2002. The Agency was formed from the merger of the Intercantonal Office for the Control of Medicines and the Main Unit Medicines of the Swiss Federal Office of Public Health.

The services of public interest are described in a service mandate issued by the Federal Council and in the service level agreement concluded each year with the Federal Office of Home Affairs. Swissmedic's strategic plan consists of the guiding principles and the strategic objectives. The strategic plan is adopted by the Agency Council and is based on the legal provisions (Therapeutic Products Act / Ordinances) and the mandate from the owner (service mandate and service level agreement).

Tasks

- Authorisation of medicinal products
- Issuing licences for manufacturing and wholesale trading, and conducting inspections
- Market surveillance of medicinal products and medical devices
- Criminal prosecution
- Licensing and monitoring of clinical trials
- Laboratory testing of the quality of medicinal products
- Drawing up standards
- Information
- National and international cooperation



Organisation chart (as at 31 December 2017)

Revenues

Swissmedic is financed through fees and levies, payments from the federal government for services of public interest and through payments received for 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.

	Revenues in 2017	As a percentage of total revenues
Fees	32,256	35
Levies	44,891	49
Payments from the federal government	14,346	16
Payments received for services rendered to third parties	155	0.17

Agency Council

The Agency Council is Swissmedic's supervisory body. It is comprised of a maximum of seven members and is appointed by the Federal Council, which also designates the chair. Three members may be proposed by the Cantons. The term of office is four years. The duties of the Agency Council are similar to those of the board of directors of a public limited company.

In its capacity as a strategic body, the Agency Council represents Swissmedic's interests vis-a-vis the Federal Office and the Federal Council. It also tasked with approving the Swissmedic budget, annual accounts and Annual Report. Further information can be found in the Agency Council's business regulations (in German and French) on the Swissmedic website.

The Agency Council is comprised of the following members (as at 31 December 2017):

Member	In office since
Christine Beerli (C)	2006
Dr. iur. Lukas Engelberger	2017
Prof. Reto Obrist	2010
Prof. Peter Suter	2010
Prof. Olivier Guillod	2014
Giovan Maria Zanini	2015
Ms. Vincenza Trivigno (VC)	2016

C = chair; VC = vice-chair

In its present composition, the Agency Council satisfies the requirements of language community and gender representation.

Chairwoman Christine Beerli, lic.iur., attorney-at-law

Attorney-at-law, Vice-President of the International Committee of the Red Cross (ICRC)

Olivier Guillod, Prof. Dr. iur.

Director of the Institute of Health Law, University of Neuchatel

Peter M. Suter, Prof. Dr. med.

Honorary professor, University of Geneva, former President of the Swiss Academy of Medical Sciences (SAMS)

Giovan Maria Zanini, Pharmacist

Cantonal Pharmacist, Department of Health and Social Services, Canton of Ticino

The CVs and details of the vested interests of the individual members of the Agency Council can be found on the Swissmedic website. .

Lukas Engelberger, Dr. iur., attorney-at-law

Chair of the Department of Health and Member of the Executive Council of Canton Basel-Stadt

Reto Obrist, Prof. Dr. med.

Former chief physician for oncology, Valais Health Network

Vincenza Trivigno, lic. rer. pol.

State Chancellor, Cantonal Chancellery, Canton of Aargau

Management Board

The Management Board is an advisory body tasked with assisting the Executive Director. It is comprised of members selected by the Agency Council at the request of the Executive Director (Art. 72 para. 1 h TPA). The Management Board is comprised of the following members (as at 1 January 2017):

Jürg H. Schnetzer
Executive Director

Philippe Girard, Dr.
Head of Licensing –
Member of Management Board

Andreas Balsiger Betts
Head of Legal Affairs –
Member of Management Board

Karoline Mathys Badertscher, Dr.
Head of Market Surveillance –
Member of Management Board

Claus Bolte, Dr. med.
Head of Authorisation –
Member of Management Board

Marco Menna, Dr.
Head of Infrastructure –
Member of Management Board

Petra Dörr, Dr.
Head of Communication and Networking – Deputy Director;
Member of Management Board

Barbara Schütz Baumgartner
Head of Human Resources and Finance –
Member of Management Board

The CVs, other occupations and public offices of the individual members of the Management Board can be found on the Swissmedic website.

Remuneration

The expenses approved by the Federal Council for the Agency Council are capped at CHF 200,000 per year. In 2017 the remuneration paid to the Agency Council amounted to CHF 189,000, of which CHF 42,000 was paid to the Chair. Details of the remuneration for the members of the Agency Council are contained in the latter's business regulations, which are published on the Agency website.

The total remuneration paid to the Management Board was CHF 1,850,905. The Executive Director's salary was CHF 301,538.

Supervision by the owner

As a rule, three meetings (owner discussions) are held each year between the Federal Department of Home Affairs (FDHA) and the Swissmedic Agency Council. These meetings are chaired by the Head of the FDHA. They are also attended by the chair and vice-chair of the Agency Council, the Executive Director and individual members of the Management Board.

Swissmedic submits a report to the FDHA on the attainment of the objectives specified in the service level agreement for 2017 and prepares an Annual Report. On the basis of these reports and the auditors' report, the Head of the FDHA ratified the actions of the Agency Council for the 2017 financial year. The (entire) Federal Council takes note of the auditors' report and briefs parliament on Swissmedic's attainment of the objectives specified in the service level agreement.

Auditors

The Agency Council has mandated the Swiss Federal Audit Office to conduct the audit in accordance with Art. 74 of the Therapeutic Products Act (SR 812.21; TPA).

Information policy

Taking account of the requirements (and constraints) of the law, the Agency's information policy is designed for maximum transparency. Swissmedic has a mandate to provide information, as defined in Art. 67 TPA. Accordingly, the Agency ensures that the public is informed of occurrences specifically relating to therapeutic products which endanger health, and issues appropriate recommendations. It publishes information of general interest about the therapeutic products sector, in particular regarding authorisation and revocation decisions as well as about amendments to professional and patient information concerning medicinal products.

The main information platform is the website www.swissmedic.ch, on which all relevant information is published, including the monthly Swissmedic Journal and all safety-relevant communications on therapeutic products. Swissmedic also publishes media releases via the federal news service and responds to stakeholder inquiries received by telephone, in writing or online via the website. In addition, Swissmedic stages events directed at specific expert groups or entire stakeholder groups.

Internal control system

Swissmedic has an internal control system (ICS). The ICS identifies the operational risks posed by finance-related business processes, defines suitable control measures to minimise these risks, and implements the measures. The ICS is reviewed annually in terms of the risks identified and assessed as well as the effectiveness of the risk-minimising controls conducted. It is part of the Agency›s comprehensive risk management matrix.

Organisation

Swissmedic Agency Council

Current as at December 2017

Chairwoman: Beerli Christine, barrister
Engelberger Lukas, Dr. iur.
Guillod Olivier, Prof. Dr.iur.
Obrist Reto, Prof. Dr. med.
Suter Peter M., Prof. Dr. med.
Vincenza Trivigno, lic. rer. pol
Zanini Giovan Maria, pharmacist

Members of the Human Medicines Expert Committee (HMEC)

Current as at December 2017

Chairman: 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.
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.
Borner Markus, Prof. Dr. med.
Buser Katharina, Dr. med.
Caldelari Reto, Dr. phil. nat.
Cavin Frédy, phil. nat.
Cerny Thomas, Prof. Dr. med.
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.
Kraenzlin Marius Edgar, Prof. Dr. med.
Ludwig Christian, Prof. Dr. med.
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.
Pfeifer Dina, Dr. med.
Pittner Heribert, PD 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.
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.
Hofmann Heinrich, Prof. Dr. ing.
Hunger Robert Emil, Prof. Dr. med.
Lämmle Bernhard, Prof. Dr. med.
Rabe Thomas, Prof. Dr. med.
Saller Reinhard, Prof. Dr. med.
Streuli Isabelle, Dr. med.

Members of the Veterinary Medicines Expert Committee (VMEC)

Current as at December 2017

Chairman: Knutti Barbara Katharina, Dr. med. vet.

Ordinary members

Brunner Katharina, Dr. med. vet.
Glaus Tony, Prof. Dr. med. vet.
Meylan Mireille, Prof. Dr. med. vet.
Naegeli Hanspeter, Prof. Dr. med. vet.
Perreten Vincent, Prof. Dr. sc. tech.

Extraordinary members

Hemphill Andrew, Prof. Dr. phil. nat.
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

Auditors

Swiss Federal Audit Office (SFAO)

Our staff – our capital

Current as at December 2017

Executive Director

Schnetzer Jürg H.

Management Board

Balsiger Betts Andreas, Bolte Claus, Dörr Petra, Girard Philippe, Mathys Badertscher Karoline, Menna Marco, Schütz Baumgartner Barbara

Our staff

Abegglen Julia, Aebischer Kathrin, Aeschbacher Monique, Albayrak Mehmet, Amsler Lorenz, Amstutz Yann, Appenzeller Campana Katrin, Arnheiter Larissa, Bachmann Beat, Baeriswyl Gerda, Bailat Sylvie, Balli Sandra, Balsiger Betts Andreas, Bapst Astrid, Bärtsch Martin, Baumann Yvonne, Begert Beat, Bellac Caroline Laetitia, Bellwald Patricia, Berger Christoph, Bersier Danièle, Bertholet Josiane, Bichsel Bernhard, Bill Helena, Bitschnau Monika, Blanco Philippe, Blaser Béatrice, Blum Markus, Bögli-Schlüchter Franziska, Bögli-Stuber Katja, Böhlen-Walther Caroline, Böhm Steffen, Bolli Richard, Bolte Claus, Borner Stefan, Boschung Andrea, Boschung Livia, Boss Doris, Brockmann Silke, Brunner Stefan, Büchi Jacqueline, Büchler Monika, Buchs Renato, Buchter Linda, Bühler Urs, Bur Kathrin, Bürge Michaela, Burgener Julia, Burgener Roger, Burkhalter Gabriele, Burri Michael, Carrel Nadja, Carulli Amico Sabina, Cavaliero Tania Cecilia, Chadha Santuccione Antonella, Chatelain Barbara, Chodup Piotr, Christen Tobias, Cimini Federico, Cina Susanne, Cipolli Francesca, Cokoja Adisa, Colangelo Elena Conti Massimiliano, Coso Marija, Crottet Pascal François, Dalla Torre Simon, Damke Beat, De Luigi Lucia, Decoudre Julia, Déverin Olivier, Dexheimer Petra, Diel Carolin, Diethelm Markus, Diggelmann Joy, Ditesheim Véronique, Djonova Julia, Dogan Nurhak, Dörr Petra, Drapela Aurélie, Drechsel-Weiss Bettina, Driess Stephanie, Dunkel-de Raad Saskia, Dupasquier Thierry, Dürr-Kammer Eva, Eggenschwyler Doris, Egger Franziska, Ehrensperger Edmund, Ehrensperger Murri Eva, Endress Eva-Maria, Endrich Michael, Engel Marie-Helene, Erne Franz, Escandari Markus, Essen Renate, Essers Dirk, Eugster Urs, Eyal Eva, Fahrni Ursula, Faller Claudine, Federer-Oetliker Martina, Felber Hanspeter, Feldmann Danila, Ferbitz-Scheurer Simone, Filgueira David, Fischer Bernt, Fischer Lisa, Flechtner Olivier, Fotinos Nicolas, Franscini Nicola, Frêche Barbara, Fritzsche Constanze, Fuchs Sebastian, Fuhrer Therese, Fürer Andreas, Gaber Linda, Gafner Verena, Gamma-Lauber Madeleine, Gassner Beat, Gaudesius Giedrius, Gautschi Matthias, Geluk Charlotte, Gertsch Rolf, Gilgen Bernadette, Gilgen Michael, Giovannangelo Céline, Girard Philippe, Glauser Daniel, Gloor Eveline, Gobet Magali, Gosdschan Tobias, Gottofrey James, Graber Angelika, Grimm Friederike, Gross Bruno, Grüter Eric, Grütter Daniela, Guggisberg Stefan, Gugler Claudia, Gürtler Rolf, Gysin René, Häberli-Airoldi Isabelle, Haenggeli Christine, Hahn Spielmann Véronique, Haldemann Silvia, Hammel Mario, Häni Brigitte, Hatibovic Maja, Häuptli Daniel, Häuptli Thomas, Hausammann Georg, Häusermann Monika, Heckenmeyer-Probst Clara, Hediger Ronald, Heneka Bilkis, Hernandez Perni Maria Engracia, Herren Daniel, Herrli Stefan, Hildebrand Pius, Hofmann Linda, Hofstetter Christiane, Horn-Lohrens Ottmar, Hottiger Thomas, Hotz Rolf, Huber Cornelia, Huber Elisabeth, Hügli Muriel, Hug-Michel Christine, Hürlimann Daniel, Hürlimann Maria Gertrud, Jaccottet Aline, Jaggi Lukas, Jahn Katrin, Jaquet Françoise, Järmann Stephan, Jaus Alexandra, Jentzsch Christoph, Jéquier Martine, Jermann Ronald, Johner Regula, Joos Monika, Joye Laetitia, Jungo Jacqueline, Junker Christian, Juritz Stephanie, Käser Sandra, Käsermann Donald, Keller Michael, Keller Michel, Kemmler Hans, Kempná Bukovac Petra, Keusen-Weyermann Katrin, Kindler Adrian, Kläy Barbara, Klenke Elisabeth, Kleppisch Thomas, Knöpfli Heinz, Kocher-Guggisberg Beatrice, Koeninger Franziska, Köhli Michael, Kopp Lukas, Krayenbühl Jean Christian, Krebs Franziska, Krebs Michael Oliver, Kühni Martin, Kummer Robert, Küng Christoph, Kunz-Greub Marianne, Künzle Werner, Kuster André, Lack Adena, Landgraf Cordula, Langenkamp Anja, Langos-Mabboux Manuela, Lany Catharina, Lapke Conwitha, Lauer Gabriele, Lavanchy Vincent, Le Stanc Pascale, Lehmann Markus, Lehmann Thomas, Leidreiter Kirsten, Leist Roman, Leu Martin, Leuenberger Alice, Leuenberger Hansjürg, Leuenberger-Bischoff Monika, Leyens Lada, Lichtsteiner Ronja, Liechti Claudine, Linder Ursula, Liniger-Thommen Andrea, Lippmann Hans-Georg, Löhr Ingrid, Lory Simon, Lottaz Daniel, Lucas Christine, Ludwig Ljubica, Luginbühl-Weber Karin, Lüthi-Wyss Nicole, Lütolf Natalie, Maier Ralph, Manolio Silvana, Marrer Edith, Marti Andreas, Mathys Badertscher Karoline, Matthes Ingo, Meier Ines, Meier Roger, Meincke Ricarda, Menna Marco, Méroz Jean-Christophe, Meseguer Georges, Messerli Nicole, Messi Mara, Meusburger Madeleine, Meyer Rita, Meyer Simon, Meyer Ulrike Ursula, Meyer Urs, Mion Alexander, Mooser Guido, Morciano Julie, Moreno Rafael, Mosimann Lenzin Ruth, Müller-Mook Renate, Müntener Cedric, Munz Thomas, Mutti Sven, Nava Gabriela, Neeser Zaugg Rosmarie, Netsch Marco, Nick André, Niggli Urs, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli

Simon, Op den Camp Roel, Osswald Tschan Marco, Özsahin Hülya, Pagan Madrid Jose Francisco, Paniga Nicoletta, Pavelic Ferretti Danijela, Pecaric Petkovic Tatjana, Pereira Claudia, Perez Eugenio Daniel, Pernusch Jenny, Petitpierre Claude-Philippe, Petkovic Vibor, Pfäffli Chantal, Pfefferkorn Anita, Pinsard François, Plüss Ruth, Polatti Daniela, Porporini Lucio, Prisching Andrea, Puliafito Anita, Pürro Michel, Rached Eva, Ramelli Monica, Ramseier Isabelle, Rätz Katerina, Remund Thomas, Renaudin Michael, Renftle Wolfgang, Rethage Janine, Reusser Daniel, Rickenbacher Nadja, Rieder Barbara, Riesen-Beer Sabine, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Rohr Ulrich-Peter, Roost Matthias, Rosolen Joël, Roth Daniel, Roux Catherine, Ruch Claudia, Rüfenacht Francine, Rumo Anton, Rüst Chantal, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sänger Michael, Satarasinghege Don Sandya, Schaffner Nils, Schärer Christian, Schäublin Martina, Scheidegger Michelle, Scheidegger René, Schläpfer Jörg, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Eggler Dorit, Schnetzer Jürg Heinz, Schnyder Benno, Schochat Thomas, Schöni Damian, Schönthal Cornelia, Schumacher Thérèse, Schütz Andrea, Schütz Baumgartner Barbara, Schwab-Stampfli Rebekka, Schwartz Thomas, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Senessie Charles, Sieg Anna, Sommer Andrea, Sorg Regula, Spohn Margot, Spörri Bernhard, Spring Andrea, Stacchetti Matthias, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stämpfli Ursula, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Steinle Patrizia, Stoller Rudolf, Strack Guido, Straub Andrea Katharina, Sulser Mario, Tanner Soland Eveline, Tanner Yvonne, Terkovics Attila Leo, Teuscher Françoise, Thiess Maria, Thürig Soltermann Eva, Toma Valeriu, Tonarque Liechti Gabriele, Tromp Jan, Tschalär Yolanda, Tschanz Lara Timea, Tschirren Markus, Tschui Janie, Utiger Christoph, van den Ouweland Frank, Vihertola Mari, Vilei Edy, von Mühlenen Eva, Vonlanthen Bianca, Wacker Christoph, Wagner Jan, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Wälti Markus Wälti Rudolf, Waser René, Wassmer Karin, Weber Heidi, Wegenast Susanne, Wegmann Barbara, Weissmahr Richard, Weix Janine, Werder Carine, Weyermann Andrea, Weyermann Philipp, Whitehead Frances, Whitehead Margaret, Wieland Christa, Wiget Jasmine, Wildner Oliver, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wullschleger Stefan, Wüthrich Cinderella, Wüthrich Karin, Wyss Brigitte, Wyss Kaspar, Wyss Martin, Wyss-Romanello Sabine, Zaugg Kunz Sandra, Zbinden Raphael, Zemp Markus, Ziak Martin, Ziehli Salvisberg Mariette, Zimmermann Esther, Züger Dominik, Zurbuchen Andreas, Zürcher Jasmin, Zurkinden Tanja

Income statement

(in KCHF)

	2017	2016
Procedural fees and income further to Art. 69 TPA	41,173	39,129
Levies on sales	44,891	43,321
Other income	230	296
Federal contribution	14,346	13,899
Other operating income	89	29
Loss of revenues from procedural fees	-8,917	-7,484
Net income	**91,812**	**89,190**
Services for third parties	-1,220	-2,059
Personnel	-63,110	-63,220
Rental, maintenance, energy, transport and insurance	-2,702	-2,672
Administration	-4,377	-4,460
IT	-9,934	-8,672
Other expenditure	-283	-277
Amortisation	-5,742	-5,563
Total operating expenditure	**-87,368**	**-86,923**
Operating income	**4,444**	**2,267**
Financial income	5	10
Financial expenditure	-157	-220
Financial result	**-152**	**-210**
Gain / Loss	4,292	2,057

Statement of comprehensive income (in KCHF)	**2017**	**2016**
Gain / Loss	**4,292**	**2,057**
Other income Actuarial losses (gains)	17,921	-1,589
Total comprehensive income	22,213	468

The full, detailed annual accounts can be ordered by telephone or downloaded from our website www.swissmedic.ch (under the section "About us/Publications").

Balance sheet

(in KCHF)

	per 31.12.2017	per 31.12.2016
Cash and cash equivalents	863	416
Receivables from sales and service	20,894	19,144
Other receivables	0	676
Prepaid expenses	46	79
Current assets	**21,803**	**20,315**
Fixed assets	4,207	3,644
Immovable property	71,650	74,897
Intangible assets	4,473	6,267
Capital assets	**80,330**	**84,808**
Total assets	**102,133**	**105,123**
Commitments on sales and services	5,088	5,828
Other commitments	11,892	19,589
Deferred income and short-term provisions	3,812	3,834
Short-term commitments	**20,792**	**29,251**
Firm advances	10,000	10,000
Provisions for loyalty bonuses	2,675	2,597
Provision for pension fund commitments (net)	56,134	72,956
Long-term commitments	**68,809**	**85,553**
Gain/Loss	4,292	2,057
Reserves	3,094	1,037
Endowment capital	14,500	14,500
Accumulated actuarial losses	-9,354	-27,275
Own capital	**12,532**	**-9,681**
Total liabilities	**102,133**	**105,123**

Products funded mainly by the Confederation

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result-based product accounting
Legal foundations	-6,541	0	-6,541
Information for the general public	-3,909	295	-3,614
Medical devices vigilance	-3,283	0	-3,283
Market monitoring of medical devices	-3,398	108	-3,290
Penal law	-2,356	230	-2,126
Total products funded mainly by the Confederation	**-19,487**	**633**	**-18,854**
Total Federal contributions			**14,346**
Expenditure surplus			**-4,508**

swissmedic

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

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