



Annual Report 2018

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Stéphane Rossini, President of the Agency Council

Taking action in the interests of the general public

In an environment marked by evolving health policies, a globalised economy in which the quest for profit causes a growing number of ethical issues, the coexistence of contradictory healthcare expectations – such as those of the authorities, patients and the industry – and political uncertainty on an international scale, the role of a regulatory body such as Swissmedic is both exciting and increasingly complex.

However, the new legislation on medicinal products and medical devices leaves no room for doubt. We have a great responsibility and clearly-defined competencies. This is confirmed by the legislator's choice of terms: protecting the health of human beings and animals, and ensuring that safe, efficient and high-quality therapeutic products are placed on the market. This is the essence of our mission. We aim to fulfil it independently, competently, rigorously and with a spirit of innovation.

By devising its 2019–22 Strategic Goals, the Agency Council has identified the challenges it faces and presented its priorities. These have been legitimated and recognised as relevant by the Federal Council. With conviction, our aim is to assume efficient, independent oversight of therapeutic products, participate in the development of international standards and cooperate even more closely with national and international regulatory authorities, rise to the challenges posed by digitalisation in order to become more efficient, provide optimal information for the general public

and strengthen our communication with health authorities and stakeholders and contribute our expertise to poorly-equipped countries to ensure the health security of their populations.

These goals form part of our long-term strategy and are based on the solid foundations of our experience. They aim to enhance the Agency's credibility and will be achieved through cooperation with all relevant partners. This is our commitment.

The 2018 annual report eloquently demonstrates the extent of Swissmedic's range of activities. It reviews the development of a sensitive sector from both a quantitative and a qualitative viewpoint. Indeed, this sector deals with the most personal aspect of human beings – that is, our health and our need for healthcare services – as well as material interests that risk giving rise to illegal practices. Above all, however, it is a story of success and technological progress that strives to improve the population's wellbeing.

The close cooperation between the Federal Department of Home Affairs and the Agency Council, the constructive dialogue with health authorities, industry stakeholders and beneficiaries, and the commitment of Swissmedic employees have enabled us to accomplish these various missions successfully. I would like to address sincere thanks to you all for your commitment.



Raimund Bruhin, director

“Not too small to make a difference!”

The Annual Report contains a collection of figures, data, facts and reports which together sum up Swissmedic's performance, its activities and the priorities of its various departments. The format of our 2018 report has remained unchanged from previous years.

We look back on what in many ways was an unusual year. The year was unusual in that the start of the year saw two parallel changes at the top (new President of the Agency Council and new Director). It was also unusual because of the scale of the demanding challenges that arose in addition to the routine daily tasks, such as finalising the extensive and complex Ordinance documents, the complex implementation project running in parallel to the drafting of the new legislation, and the planning and communication of the implementing measures, which included two information events for more than 550 attendees from across the whole spectrum of stakeholders.

Among other things, the end of 2018 saw Swissmedic successfully complete the aforementioned extraordinary activities while also accomplishing the strategic objectives set out in the service level agreement with the Federal Office of Home Affairs. The financial result was also encouraging.

The experience I have gained with staff members and management has confirmed to me that I can count on motivated, professional and hardworking employees at all

levels and in all areas. An exemplary case in point was our laboratory (OMCL), which – by developing a new method for detecting another carcinogenic substance – made Swissmedic the global leader in the handling of the valsartan scandal. With this achievement and the overall performance mentioned above, Swissmedic showed that it bears comparison even with the large agencies (“Not too small to make a difference”).

The new legal framework, the new strategy and the new management regulations – through which the new governance is now also being implemented – have created a broad set of clearly defined operating conditions. With implementation through the project roadmap, transparent planning for several years ahead has been established. Despite the accelerating pace of change, therefore, Swissmedic is well positioned and ready to meet the challenges that lie ahead. In doing so, it is making a crucial contribution to the federal administration's health strategy for 2030.

Medicinal products recalled because of nitrosamine contamination. What is still to come?

The “valsartan scandal”: How Swissmedic dealt with the issue of an impurity in the antihypertensives.

In early July 2018, there was a global recall of medicinal products containing Chinese-manufactured valsartan because they contained the nitrosamine NDMA, an impurity that is probably carcinogenic. In the course of investigations, unacceptable amounts of NDMA and other nitrosamines were found in other sartans. Swissmedic’s laboratory – the Official Medicines Control Laboratory or OMCL – was, and continues to be, involved in testing.

The fact that antihypertensives had been found to be contaminated with nitrosamines startled the pharmaceutical industry, regulatory authorities and public alike. During the initial phase, there were a lot of questions: Is the impurity really NDMA, and are the concentrations likely to be a health risk? Is the NDMA only in the active substance or in the finished drug product too? Are any other active substance manufacturers affected?

Scale unclear

It quickly became clear that the problem would develop into a major worldwide challenge. High blood pressure is a widespread condition, and antihypertensives are therefore among the most commonly prescribed medicines. Consequently, it was necessary to assume that a large number of patients could have taken a contaminated preparation. There was constantly growing media pressure, coupled with ever more frequent questions from worried patients.

Different levels and areas of the Swissmedic organisation were affected, and it soon became apparent that internal coordination of activities would be key in enabling the Agency to act and react in a prompt, efficient manner. The cross-departmental “valsartan task team” was set up and tasked with amalgamating and coordinating tasks within the Agency and managing information sharing with foreign authorities.

As soon as the first recalls had taken place, the Swissmedic laboratory immediately began precautionary testing of all valsartan products on the Swiss market in a bid to gauge the

extent of risk exposure. Active substances and finished drug products were tested for contamination with N-nitrosodimethylamine, also known as NDMA. Testing was extended to medicinal products containing losartan, olmesartan, candesartan and irbesartan, all active substances that are related to valsartan. Like valsartan, they contain a specific ring system, known as a tetrazole ring. Depending on the manufacturing process, contamination with nitrosamines can occur during the formation (synthesis) of this system. Since other sartan-based active substances do not have this ring system, they are not affected by nitrosamine contamination.

After further cases of contamination came to light in autumn 2018, the Swissmedic laboratory wrote to all holders of authorisation for sartans in Switzerland, requiring them to supply samples from all batches of all preparations, including the corresponding active substance batches. Over 1,000 samples were analysed.

In the weeks that followed, the recalls were found to be justified, as confirmation emerged that all the valsartan batches that had been recalled in Switzerland contained the impurity. However, no NDMA was found in the irbesartan, olmesartan, losartan and candesartan products that were tested.

Fast response by Swissmedic

Just as the situation seemed to be calming down somewhat, traces of another nitrosamine, N-nitrosodimethylamine, or NDEA, were found in active substances from certain manufacturers. The Swissmedic OCML responded quickly, developing an analytical method for NDEA and starting once again to test all the sartans on the Swiss market. During its investigations, the laboratory became the first in the world to discover that valsartan sourced from the Indian manufacturer Mylan Laboratories Limited was contaminated with NDEA. Since the quantities in question were above the safety threshold, a further recall campaign was launched first in Switzerland, then internationally.

The situation subsequently calmed down. Over recent months, Swissmedic has continued to test for NDMA and NDEA, and has now analysed all finished drug products available in Switzerland that contain valsartan, losartan, irbesartan, olmesartan and candesartan for the impurities. All the products that are available in Switzerland can be considered safe.

Swissmedic lab plays pioneering role

Detecting very low concentrations of nitrosamines by analytical chemistry is a challenging task. Since there were no sufficiently sensitive, validated methods capable of testing for tiny quantities of NDMA and NDEA at the same time, Swissmedic's lab first had to develop and validate appropriate tests. At the time, no laboratory outside Switzerland was able to detect such small concentrations of NDEA impurities using existing test methods. The pioneering role that the Swissmedic laboratory played in the field earned it international acclaim.

To facilitate and speed up the roll-out of sensitive tests to manufacturers, Swissmedic decided to publish its analytical method. The method was also made available to the European Directorate for the Quality of Medicines (EDQM), a

Directorate of the Council of Europe that plays a key role in monitoring active pharmaceutical substance quality.

Although Swissmedic's investigations and actions have defused the situation, the problem has not yet been fully resolved. New findings are still emerging. The fact that the flood of reports of impurities is subsiding only slowly indicates that Swissmedic will have to continue testing sartans for some considerable time to come. Swissmedic will also have to hold discussions with its international partner authorities on how to prevent a repetition of such cases, for example by addressing the way active substance manufacturers are supervised.

Sartans



The sartan group of medicinal products include preparations containing the active substances valsartan, losartan, olmesartan, candesartan and irbesartan, as well as a number of other active substances. These medicinal products are also known as angiotensin II receptor antagonists.

Sartans have antihypertensive and vasodilatory effects, and are used for the treatment of high blood pressure, heart failure or kidney disorders. Most sartans are available as tablets or film-coated tablets, alone or in combination with other active substances.

According to the WHO's International Agency for Research on Cancer, animal testing has shown that nitrosamines such as NDMA, NDEA, NDELA and NMOR can cause cancer. The Agency therefore suspects that they will do the same in humans, even though there have been no epidemiological studies of the subject. Exposure to nitrosamines should be minimised as a precautionary measure, not least because they are present in many other sources, including foodstuffs, alcoholic beverages, tobacco products, certain cosmetics and rubber products.

Swissmedic spreads the word

In November 2018, 19 people from seven different countries visited Swissmedic to learn about the way we work, our processes and our methods. It was an opportunity for the Agency to demonstrate its commitment to improving health and proved to be a learning experience for everyone.

In partnership with the World Health Organization (WHO), Swissmedic devised a training course for regulatory authorities in low- and middle-income countries. Such courses are part of the WHO's programme to improve its member states' regulatory systems. The aim of the programme is to develop the knowledge available within authorities in such a way that they can function effectively and perform their regulatory duties. The pilot course took place in Bern from 19 to 22 November 2018.

“The achievement of any State in the promotion and protection of health is of value to all.”

From the Constitution of the World Health Organization, 1946

By specialists, for specialists

The training course was structured as a “peer learning” event, i.e. learning goals are achieved primarily through interaction with other specialists and colleagues.

The pilot course was an enriching opportunity to learn from each other about working methods, processes, methods, people and cultures. Simply taking account of the various countries' eating habits brought fresh perspectives and broadened horizons. When we in Switzerland hear how longstanding traditions can hinder or slow down regulatory authorities' work, we find it difficult to grasp. Nevertheless, hosting people from faraway countries in Bern was a hugely valuable experience.

“Swissmedic's openness and willingness to share information is overwhelming.”

Julius Mayengo, NDA, Uganda



Basis for development cooperation

The foundations for Swissmedic's involvement in development cooperation were laid in 2013, when the Federal Council expanded the Agency's service mandate to include this activity. This paved the way for the signing of a Memorandum of Understanding (MoU) between the Bill & Melinda Gates Foundation (BMGF), the Federal Department of Home Affairs (FDHA) and the Federal Department of Foreign Affairs (FDFA) in January 2014. The aim of this MoU is to improve regulatory procedures and systems in Sub-Saharan countries so as to speed up access to high-quality, life-saving medicinal products in these low-resource states.

"WHO needs help to help the countries."

Mike Ward, WHO



Representatives of the following authorities attended the Swissmedic training course:

- Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA)
- Food and Drug Authority, Ghana
- Pharmacy and Poisons Board (PPB), Kenya
- Tanzania Food and Drugs Authority (TFDA)
- National Drug Authority (NDA), Uganda
- Saudi Food and Drug Authority (SFDA)
- Ministry of Health – Pharmaceutical Division, Israel

WHO and Swissmedic: A partnership for better health

According to the WHO's Constitution, the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. Properly functioning authorisation and control of medicinal products are essential parts of a country's healthcare system. Conversely, a non-functioning regulatory framework is a barrier to access to safe, effective, good-quality medicinal products and provides plenty of scope for abuse and criminality. The WHO is supporting its member states' efforts to strengthen their healthcare systems and has initiated the "regulatory system strengthening" programme.

"The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States."

From the Constitution of the World Health Organization, 1946

The WHO's request to Swissmedic concerning cooperation came at an opportune moment, since there was strong demand for support and training from foreign authorities. Thanks to the new training programme, the Agency can respond positively to requests and provide efficient support.

Swissmedic now intends to hold training courses in partnership with the WHO twice a year. Eight authorities will be invited to send three experts to each course. Six of these authorities will be chosen by the WHO, two by Swissmedic itself.

To ensure the long-term sustainability of the project, the foreign authorities are required to submit an action plan to the WHO, setting out how they intend to implement the knowledge acquired by participants.

Is medical device safety guaranteed in Switzerland?

Can patients be confident that implants have been adequately tested before they are used? This was the question at the heart of the "Implant Files", a large-scale investigation by an international network of journalists that started to make headlines in November 2018. The global investigation focuses on defective medical devices. Publication of the first results was preceded by several years of research by more than 250 journalists from 36 countries, including representatives of Swiss media outlets.

In contrast to the USA, medical devices are not subject to official authorisation either in Switzerland or the European Union (EU). Medical devices undergo a conformity assessment by notified bodies. Switzerland is in the European system. Swissmedic's primary goal with reference to medical devices is to ensure effective market surveillance.

Weaknesses identified

One of the examples used by the Implant Files to illustrate the weaknesses within the system is the Cadisc-L, a spinal disc implant manufactured by a British company. The case caused considerable consternation, particularly in Switzerland and Germany. Some time after implantation, several patients' implants disintegrated. This had serious consequences: the fragments caused the affected patients severe health problems and had to be removed in painstaking surgery.

It transpired that a European conformity assessment body (CAB) had CE-certified the implant, even though it had not undergone adequate clinical trials. As a result, it was launched throughout Europe and implanted into a large number of patients. A small number of these patients were in Switzerland.

It is indisputable that the current regulatory system has weaknesses. However, a new, stricter EU Regulation, which will also be adopted in Switzerland, should close many of the gaps in the system identified by the Implant Files.

Under the new Regulation, the basic system that is currently in place will be retained. Furthermore, medical devices will continue to be certified by a CAB rather than approved by a regulatory authority like medicinal products. Official

oversight of CABs has been stepped up in recent years, and there will be an overall shift towards proactive market surveillance by regulatory authorities. Surveillance and coordination will be improved across Europe. Systematic implementation of the new requirements will be key. This will involve giving the authorities responsible for implementation adequate resources with which to enforce the requirements. Swissmedic too will have to substantially augment its competencies and resources.

New Regulation brings stricter control

The new Regulation will subject high-risk products such as implants to stricter controls in terms of clinical evaluation and clinical trials. Until now, manufacturers have often been able to rely on clinical data for existing products, and have not had to submit their own trials in order to obtain certification. In the future, however, companies will have to better demonstrate the benefits and safety of their products by means of clinical data. Products will also have to be labelled with a Unique Device Identification (UDI) to make it easier to trace them.

CABs will also be subject to stricter requirements so that they can review clinical evaluations appropriately during the certification procedure. To enable them to examine the dossiers in the necessary depth, they will therefore have to provide the relevant competencies. Furthermore, the experts they consult will have to satisfy tougher neutrality criteria. The responsible authorities will also inspect dossiers at random as part of their supervisory role, and attend CABs' manufacturer inspections.

While doubtlessly tragic for the patients affected, the cases described in the Implant Files are no longer current, since some of the products in question were placed on the market over ten years ago.

Supervision has already been improved in the years following the PIP breast implant scandal in 2012, and surveillance has been intensified. CABs have had to satisfy substantially more stringent requirements since 2013, and they are audited by international inspection teams, as well as national authorities, before they are accredited.



Better protection against defective medical devices for patients

The new EU Regulations provide a pan-European response to the critical points in the current system. Under the revised provisions, a new European Database for Medical Devices will be created, in which all economic operators and medical devices will be registered. EUDAMED, the new database, will provide a central repository for the data needed to ensure effective and efficient surveillance. The public will also have transparent access to relevant data in EUDAMED.

Swiss therapeutic products legislation is under revision, and the new rules are due to enter into force in Switzerland in May 2020, at the same time as the new Regulations take effect in the EU.

Conformity Assessment Bodies



Conformity Assessment Bodies (CABs) verify medical devices' compliance with legal requirements at the manufacturers' premises. They carry out what are termed conformity assessment procedures for all devices in any but the lowest risk classification. Once the procedure has been successfully concluded, manufacturers are issued with an EC certificate empowering them to place their conforming devices on the market in contracting states.

Swissmedic accredits Swiss CABs. The Agency inspects CABs as part of its accreditation, accreditation extension and surveillance activities. Swissmedic's assessment and surveillance activities also include reviewing CABs' quality systems, inspecting randomly selected conformity assessment procedures carried out by CABs, and audits under observation.



Combating medicinal product crime more efficiently

Two pharmaceutical company executives falsify the expiry date of a cancer medicine used primarily in children by extending it. As a result, the medicine only contains part of the original quantity of active substance, and is proportionally less effective. The culprits are simply fined or given a fine plus a suspended financial penalty. Too light a punishment? Courts at all levels of recourse refused to acknowledge any specific risk to health. Swissmedic even took the case to the Federal Supreme Court – and lost.

Efforts to combat crime involving therapeutic products are now being stepped up. At the beginning of 2019, amended legal provisions entered into force to enable Switzerland to enact the Medicrime Convention. Contracting states are committed to expanding the range of offences.

Effective criminal prosecution

The Therapeutic Products Act (TPA) has been in force since January 2002. Since that date, Switzerland has had modern resources with which to combat therapeutic product crime. The Act incorporated penal provisions that were pioneering at international level. By giving Swissmedic wide-ranging penal powers in its area of competence, it guaranteed effective prosecution in complex cases.

Nevertheless, it became apparent that there was a need for optimisation in practice. The Federal Supreme Court defined the conditions for proving a risk to health in two decisions. In the light of the Supreme Court's interpretation, the lower courts rarely ruled that the conditions for an aggravated offence under the terms of Article 86 TPA (Misdemeanours) had been fulfilled.

The different ways in which therapeutic product offences and banned narcotics offences were treated under criminal law proved to be a further stumbling block. For example, Swissmedic's investigators-in-charge were unable to make

undercover investigations in one case of medicinal products dealing. On three occasions in 2010, former National Councillor Guy Parmelin submitted parliamentary proposals aimed at improving legislation.

Several highly publicised, headline-making cases created awareness of the issue, particularly among the public, and helped prompt the Council of Europe to draw up the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention). The Convention has now been signed by 28 countries, and ratified by 15. Switzerland is one of the countries to have done both, having been among the first states to sign in 2011.

Easier to prove a risk to health

The ordinary revision of the Therapeutic Products Act and the ratification of the Medicrime Convention have now brought about several improvements to the law. In particular, it is easier to prove a risk to health. Even an offence that might endanger human health is punishable by a prison sentence of up to three years (Art. 86 para. 1 TPA). Harsher penalties have also been introduced. Aggravated offences (high-volume commercial trading or commercial trading for substantial gain, gang-based trafficking or putting the health of a large number of people at specific risk) are punishable by up to ten years in prison (Art. 86 para. 2 TPA).

Furthermore, counterfeiting is now an offence under the Therapeutic Products Act. In addition, compulsory measures can be ordered in proceedings being conducted under the Therapeutic Products Act, for example phone tapping or putting a post office box under surveillance. In such cases, the Office of the Attorney General takes control of the proceedings.

Closing loopholes

The amendments described above took effect on 1 January 2019, and close a large proportion of the loopholes identified in the Therapeutic Products Act during the 18 years it has been in force. The greater emphasis afforded to the prosecution of therapeutic products and banned narcotics offences is a reflection of the risk associated with this form of crime and will act as a deterrent in both specific and general deterrent activities.

Under a further criminal-law provision due to take effect on 1 January 2020, offering or accepting material benefits (currently Art. 33 TPA) will no longer be punishable just by a fine, but by a prison sentence of up to three years or a financial penalty (future Art. 55 TPA and Art. 86 para. 1 let. h TPA).

Key issues in 2018

Medicinal products dispensing liberalised

As part of the revision of the Therapeutic Products Act, the government decided to abolish dispensing category C (pharmacy only) and to liberalise medicinal products dispensing in such a way as to avoid endangering patient safety. Consequently, all medicinal products assigned to dispensing category C had to be evaluated and reclassified, while some medicinal products in dispensing category D had to be reassessed to ascertain their suitability for reclassification in category E (unrestricted sale in all outlets).

The scientific criteria by which products were reassigned to dispensing categories were reviewed with the assistance of external experts.

Of the 650 medicinal products in dispensing category C that were evaluated, only 15 % had to be reassigned to category B for the following scientific reasons:

- Potential for abuse: Two thirds of the medicinal products contain opiate derivatives (codeine or dextromethorphan) as active substances. Many of these medicinal products also harbour a significant risk of serious side effects.
- The other reasons were severe interactions with prescription-only medicines and special dispensing documentation that necessitate expert advice from medical personnel.

Of the almost 1,800 medicinal products in dispensing category D, around 540 were evaluated to establish whether they could be reclassified for self-service sale. This process involved applying the strict legal requirements to which dispensing without expert advice is subject.

One of the key criteria in determining whether a medicinal product can be reassigned to dispensing category E is whether patients can correctly assess the symptoms treated by the product.

17 % of the category D products assessed satisfied the criteria for reassignment to category E. As a result, dispensing category E has now grown by 60 % to 240 medicinal products.

Simplified procedure for combating illegal imports

Working closely with the Federal Customs Administration, Swissmedic developed a simplified procedure for dealing with illegal imports during 2018, and tested it in a pilot project. It did so in response to the government requirement to use available resources to combat illegal shipments more efficiently.

For eight weeks, a new simplified procedure for confiscating shipments was trialled, focusing primarily on erectile stimulants. Shipments were assessed using a calculation geared to the active substance. Digitally transmitting the data from the customs office to Swissmedic meant they could be employed in proceedings. As a result, expense per shipment was substantially reduced, while significantly more illegal shipments were destroyed.

The new process developed by Swissmedic in partnership with the Customs Administration fulfilled the expectations of both. It has therefore been extended to other medicinal product categories, added to standard operating procedures for customs inspections and routinely applied as of 2019.



Autologous transplant products

The legislation that was amended at the end of 2017 requires all institutions that prepare, distribute, stock, import or export cells or tissues destined for autologous transplantation to notify Swissmedic in advance.

This specific field comprises a wide range of products and diversified uses, including adipose tissue grafts for cosmetic purposes or umbilical cord blood, and involves a large number of economic operators. It became clear that several of these institutions were not familiar with the legal requirements, and had difficulty classifying their products, or even did not know how to classify them. Consequently, Swissmedic ran a large-scale information campaign during 2018 to raise awareness of what the law demands. This sensitised the organisations concerned to the requirements in force and gave them an overview of the associated activities in Switzerland. Furthermore, quality management systems often fall short of the standards demanded of them. Efforts to establish a unified basis for product classification will therefore continue. These will focus particularly on adipose tissue-based products in a bid to guarantee compliance with quality assurance requirements.

European Paediatric Formulary

The English-language European Paediatric Formulary is a free, easily accessible online collection of scientifically reliable, child-appropriate formulations. Its aim is to help users around the world promote children's health where there is no authorised alternative.

Published by the European Directorate for the Quality of Medicines & HealthCare (EDQM), the Formulary is a pan-European collection of monographs on magistral formulations that are already described in national formularies or are well established in European countries. It is compiled by 17 experts from hospital pharmacies, universities and national authorities in 14 countries. Swissmedic is an active contributor to the collection.

In 2018 it compiled two general texts and the first two pilot monographs in the Formulary and published them for public comment.

Outlook

CAR-T cell therapy

In CAR-T cell therapy, a patient's own T cells are harvested and genetically engineered with chimeric antigen receptors (CARs). This is done with the aid of viral vectors, which transfer the genetic information in the CARs to the T cells and insert them stably into the T cells' genome. This ensures that the genetic information from the CARs is transmitted to the cells even when they divide or are activated.

Although research has been in progress for over 30 years, CAR-T cell-based products are only just starting to reach a stage of development where they can be administered to patients. While these products represent a beacon of hope for cancer patients, they can also cause serious adverse reactions. Some have already been authorised for international marketing. However, more than 500 clinical trials are currently underway in a variety of indications, as efforts continue to further study and verify the products' risk-benefit ratio. Swissmedic holds a leading position in these innovative treatments and is closely following developments in the field. Since CAR-T cell-based products look set to usher in a new era in cancer treatment, a large number of institutions intend to submit applications for authorisation to administer their products to patients.

New variations structure

With the entry into force of the revised Therapeutic Products Act, the legal and regulatory requirements for submitting, reviewing and approving variations for authorised medicines have been aligned with EU.

Two full-day information events were held to accompany the introduction of this new variation structure. A list of the questions asked at these events was published on the Swissmedic website along with the associated answers.

The following types of variation now exist:

- Type IA/IA_{IN} variations – minor variations that have to be notified within no more than one year of implementation in the case of type IA or within 30 days in the case of type IA_{IN} ("do and tell" procedure)
- Type IB variations – minor variations that have to be notified prior to implementation ("tell and do" procedure)
- Type II variations – major variations that could have a substantial impact on the quality, safety and efficacy of the medicinal product and which must be notified prior to implementation
- Extensions

Swissmedic applies more liberal requirements for submitting multiple applications than the EU. For example, it accepts multiple applications covering quality and clinical aspects. It is important to note here that it will be possible in the future to submit extensions as a type II variation and thus obtain a shorter time limit than before.

All these measures aim as far as possible to harmonise regulatory processes with the EU, as well as to simplify them and, where feasible, to accelerate them.

Temporary authorisation: rapid access to medicinal products to treat life-threatening and debilitating diseases

Temporary authorisation provides a way of giving affected patients and animals access to medicinal products for the treatment of life-threatening diseases as quickly as possible, provided certain legal requirements are met (Art. 9a TPA). It thus equips Switzerland with a new mechanism for giving innovative medicinal products the fastest possible route to market after only a short development time.

Under the temporary authorisation procedure, the submitted clinical documentation does not have to be as complete as for a normal procedure. Temporary authorisation is limited to two years. If the conditions are met during this period, a temporary authorisation can be transformed into an ordinary authorisation.

According to Art. 18 TPLO, a medicinal product may be temporarily authorised if:

- it serves to identify, prevent or treat a disease that could lead to serious invalidity, cause severe suffering possibly resulting in death, or swiftly result in the death of a patient;
- no alternative and equivalent medicinal product is authorised or available in Switzerland;

- its use is likely to deliver major therapeutic benefit;
- the applicant is likely to be able to supply the necessary data in due course;
- it would take so long to compile all the required data, and to process and evaluate that data under an ordinary authorisation procedure, that irreversible damage would ensue or be aggravated, or severe suffering would result for the patient.

The temporary authorisation procedure was devised to give patients get rapid access to highly promising medicinal products that meet the legal requirements. It follows similar lines to Swissmedic's successfully established fast-track authorisation procedure, which is in itself very fast by international standards.

The option of temporary authorisation is only available for human medicinal products containing new active substances. Temporary authorisation is contingent on the timely fulfilment of conditions. These conditions generally involve submitting the results of ongoing clinical trials.



Facts and figures

Business statistics as at end 2018

Firms with a Swissmedic licence

The licences below were attributed to a total of 1,099 firms.

Manufacturing of medicinal products	
Manufacturing of medicinal products (with a licence for wholesale distribution)	236
Manufacturing of medicinal products (without a licence for wholesale distribution)	93
Institutions with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	27
Wholesale distribution of medicinal products	
Import of medicinal products	536
Wholesale trade of medicinal products	817
Export of medicinal products	428
Foreign trade with medicinal products	377
Microbiological laboratories	
Laboratories that carry out microbiological tests for the identification of transmissible diseases under a Swissmedic licence or FOPH recognition (according to the old Epidemics Act)	115
Controlled substances	
Establishment licences for handling controlled substances	358

Number of authorisations by type of product as at end 2018

Therapeutic products code	Number of authorised medicinal products
Synthetics	5613
Biotechnologicals	362
Vaccines	62
Blood products	66
Antivenins/antidotes	41
Radiopharmaceuticals	54
Generators	4
Bacterial and yeast products	23
Allergens	293
Transplants: tissue products	2
Transplants: gene therapy products	2
Transplants: cell therapy products	1
Phytopharmaceuticals	566
Medicinal sweets	52
Homeopathics	660
Ayurvedic medicinal products	1
Anthroposophics	424
Tibetan medicinal products	6
Other complementary medicinal products	27
Total	8259

Number of authorisations by dispensing category as at end 2018

Dispensing category/ Authorised medicinal products		Number of authorised medicinal products
A	Dispensed once only on medical or veterinary prescription	1730
B	Dispensed on medical or veterinary prescription	3818
B/C	Dispensed on medical or veterinary prescription/after expert advice from medical personnel	33
B/D	Dispensed on medical or veterinary prescription/after expert advice	48
C	Dispensed after expert advice from medical personnel	587
C/D	Dispensed after expert advice from medical personnel/after expert advice	30
D	Dispensed after expert advice	1848
E	Dispensed without expert advice	165
Total		8259

Homeopathic and anthroposophic medicinal products without indication authorised by the notification procedure as at end 2018

Single products	11 041
Combined products	1008

Swissmedic as an agency

Staff headcount at year end	425
Full-time positions at year end	350
Total women	58.3 %
Total men	41.7 %
Staff working part time (part time is defined as working up to 89 % of a full-time post)	49.2 %
Average age of staff	47,9
Women	46,5
Men	50,0
Fluctuation rate	4.7 %

Language distribution	
German	82.7 %
French	12.5 %
Italian	4.8 %
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 of examining and approving authorisation applications for all medicinal products to be placed on the domestic market or destined for export. 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.

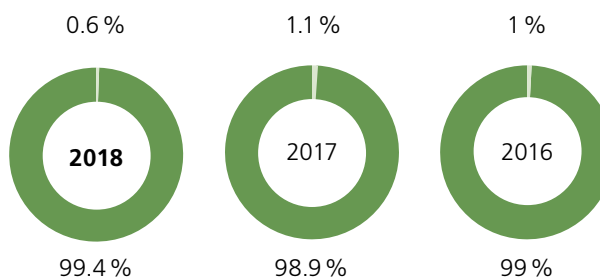
Activities

- A total of 13,397 applications were submitted in 2018, while 13,562 applications were completed.
- Of the 16 scientific advice meetings, 27 pre-submission meetings and 25 clarification meetings requested during the year, 38 were answered in writing, while face-to-face meetings took place in 30 cases.
- The Clinical Trials (CT) division submitted 25 queries to the Preclinical Review (PCR) division, and 45 to the Quality Review (QR) division. In this context, 14 initial preclinical reviews were undertaken for the notification of clinical trials, while QR issued 51 reports with licences.

Time limits

In 2017, 99.4 % of all applications were completed within the prescribed time limits. For innovative medicinal products, the time limits were respected in 99.7 % of cases; for non-innovative medicinal products, the figure was 94.3 %.

Time limits respected for all completed applications for human and veterinary medicines



- Completed within the time limit (as stipulated in the Administrative Ordinance on time limits for authorisation applications)
- Time limit not respected

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 substances or major variations thereto) and non-innovative medicinal products (medicinal products with known active substances 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

- 352 applications for first authorisations of or major variations to innovative medicinal products were received in 2018.
- 377 applications for first authorisations of or major variations to innovative medicinal products were completed.
- Of the 32 medicinal products with new active substances that were authorised, four were authorised under the fast-track procedure.
- 245 applications for first authorisation of non-innovative medicinal products were completed (including rejections, non-admissions and withdrawals). 40 of them concerned co-marketing products.
- No requests for the parallel importation of a medicinal product were completed in 2018.

Human medicinal products with a new active substance authorised in 2018

Therapeutic area (ATC)	Active substances	Product name	Application
Alimentary tract and metabolism	Telotristatum	Xermelo, film-coated tablets	Carcinoid syndrome diarrhoea
	Rolapitantum	Varuby, film-coated tablets	Prevention of chemotherapy-related nausea and vomiting
	Acidum obeticholicum	Ocaliva, film-coated tablets	Primary biliary cholangitis (PBC)
	Eluxadolinum	Truberzi, film-coated tablets	Irritable bowel syndrome with diarrhoea (IBS D)
	Ertugliflozinum	Steglatro, film-coated tablets	Type 2 diabetes mellitus
	Semaglutidum	Ozempic, solution for injection	Type 2 diabetes mellitus
Anti-infectives for systemic use	Letermovirum	Prevymis, film-coated tablets	Prophylaxis of cytomegalovirus (CMV) infection
Antineoplastic and immunomodulating agents	Carmustinum	BiCNU, powder and solvent for solution for injection	Gliomas, Hodgkin's lymphoma, Non-Hodgkin's lymphomas
	Sarilumabum	Kevzara, solution for injection in prefilled syringe	Rheumatoid arthritis
	Guselkumabum	Tremfya, solution for injection in prefilled syringe	Plaque psoriasis
	Niraparibum	Zejula, capsules	High-grade undifferentiated ovarian, fallopian tube or peritoneal cancer

Therapeutic area (ATC)	Active substances	Product name	Application
	Venetoclaxum	Venclyxto, film-coated tablets	Chronic lymphatic leukaemia (CLL)
	Durvalumabum	Imfinzi, concentrate for solution for infusion	Non-small-cell lung cancer (NSCLC)
	Darvadstrocelum	Alofisel, suspension for injection	Perianal fistulas associated with Crohn's disease
	Tisagenlecleucelum	Kymriah, cell suspension for infusion	Acute lymphatic B-cell leukaemia (B-cell ALL and diffuse large B-cell lymphoma (DLBCL))
Blood and blood-forming organs	Vonicogum alfa	VEYVONDI, powder and solvent for solution for injection	Von Willebrand disease
	Emicizumabum	Hemlibra, solution for injection	Haemophilia A, factor VIII deficiency
Dermatologicals	Deoxycholic acid	Belkyra, solution for injection	Treatment of submental fat
Nervous system	Cariprazinum	Reagila, capsules	Schizophrenia
	Brexipiprazolum	Rexulti, film-coated tablets	Schizophrenia
	Stiripentolum	Diacomit, capsules	Severe myoclonic epilepsy of infancy (SMEI, Dravet's syndrome)
	Methoxyfluranum	Penthrox, liquid to produce a vapour for inhalation	Pain management
	Opicaponium	Ongentys, capsules	Parkinson's disease
	Erenumabum	Aimovig, solution for injection in prefilled syringe	Migraine prophylaxis
	Pitolisantum	Wakix, film-coated tablets	Narcolepsy

Therapeutic area (ATC)	Active substances	Product name	Application
Respiratory system	Armoraciae radices pulvis Tropaeoli majus herbae pulvis	Angocin, film-coated tablets	Acute inflammation of the upper respiratory tract and urinary tract infections
	Benralizumabum	Fasenra, solution for injection	Severe eosinophilic asthma
Sensory organs	Cenegermin	Oxervate, eye drops	Neurotrophic keratitis
	Lifitegrastum	Xiidra, eye drops	Treatment of the signs and symptoms of dry eye disease (DED) in adults
Miscellaneous	HYNIC-[D-Phe(1), Tyr(3)-octreotidi]trifluoroacetum, acidum ethylenediamini-N,N'-diaceticum	Tektrotyd, labelling kit	Diagnosis of neuroendocrine tumours (GEP-NET)
	Oxodotreotidum	Netspot, kit for radiopharmaceutical preparation	Diagnosis of neuroendocrine tumours (NET)
	Tilmanoceptum	Lymphoseek, kit for preparing a radiopharmaceutical	Diagnosis/detection of lymph nodes

Human Medicines Expert Committee (HMEC)

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

Activities

- The HMEC advisory panel issued 71 recommendations regarding marketing authorisation applications at its twelve meetings. The majority of them concerned new authorisations or additional indications for medicinal products. Furthermore, the panel was informed of 42 authorisation decisions and invited to comment on them.
- In addition, HMEC experts provided 13 expert reports for the purpose of full assessments and 33 reports on individual aspects.

A Number of HMEC recommendations relating to marketing authorisation applications



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 are still met, 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 has to be amended.

Activities

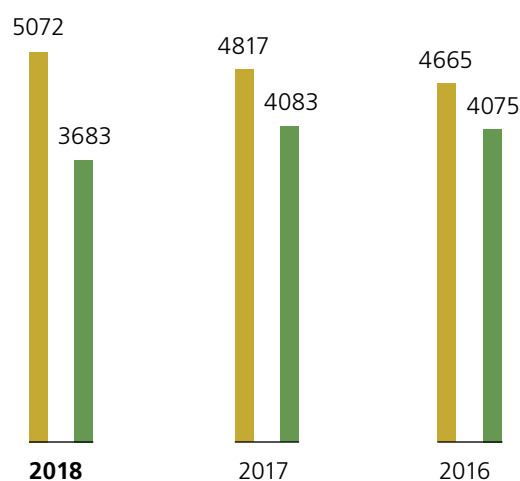
- 1,479 applications for an extension of marketing authorisation were completed.
- 274 applications for the discontinuation of a product and 16 applications for the discontinuation of a dosage strength of a product were completed. The authorisations of 65 preparations were not extended.

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. Collective applications and multiple applications are counted as one application.

Activities

- A total of 5,048 variations requiring notification were submitted, and 5,072 notifications were completed.
- 3,683 variations requiring approval with scientific evaluation were submitted and completed.



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

The fast-track authorisation procedure

Applicants may request adoption of the fast-track procedure for human medicinal products or major variations to such products, provided that three conditions are met:

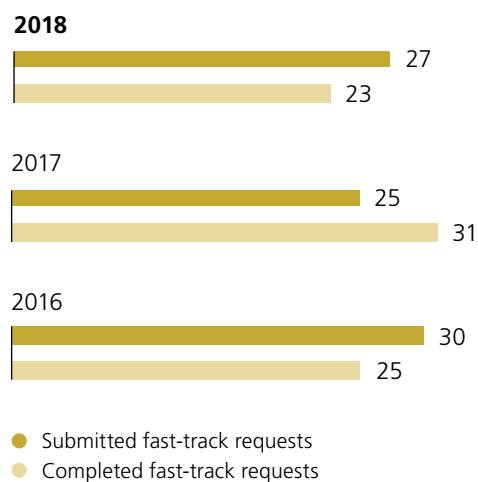
- Expected successful treatment in the case of a serious illness,
- Lack of other treatment possibilities with medicinal products or unsatisfactory treatment option,
- The use of the medicinal product indicates a significant therapeutic benefit.

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

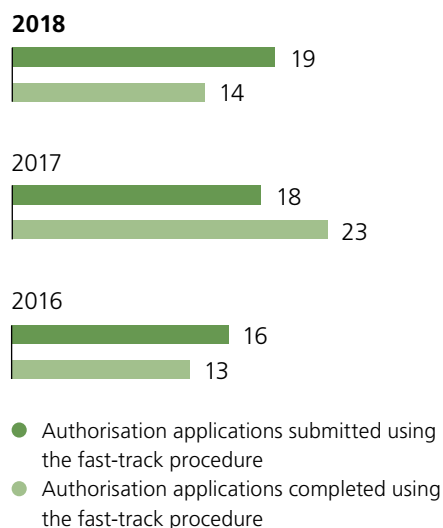
Activities

- 27 requests for the fast-track procedure to be applied were submitted, and 23 fast-track requests were approved.
- 19 authorisation applications were submitted for the fast-track procedure, and 14 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)

Swissmedic offers applicants the option of having the assessment carried out 20 % more rapidly if 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. Interim analyses 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 has been reached. Full documentation must also be submitted.
- Swissmedic must have the necessary human resources available to be able to complete the assessment of the application within the required time and by the date foreseen.

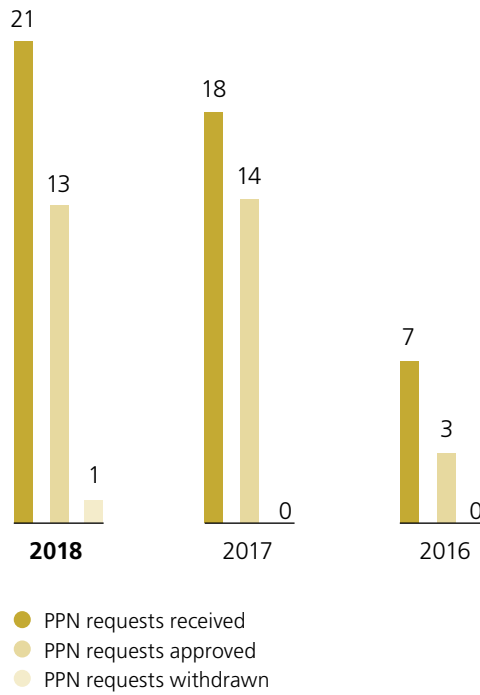
If these conditions are met, the PPN request is approved and the application can then be submitted using the procedure with prior notification. For Swissmedic, the time limit for processing the authorisation application is reduced from 330 to 264 days.

A request for a PPN procedure can be submitted at the same time as an FTP application. This means that if the FTP application is rejected, the applicant does not need to wait for notification of rejection before submitting a PPN request, but can confirm that it intends to pursue the PPN option in its response to the preliminary decision.

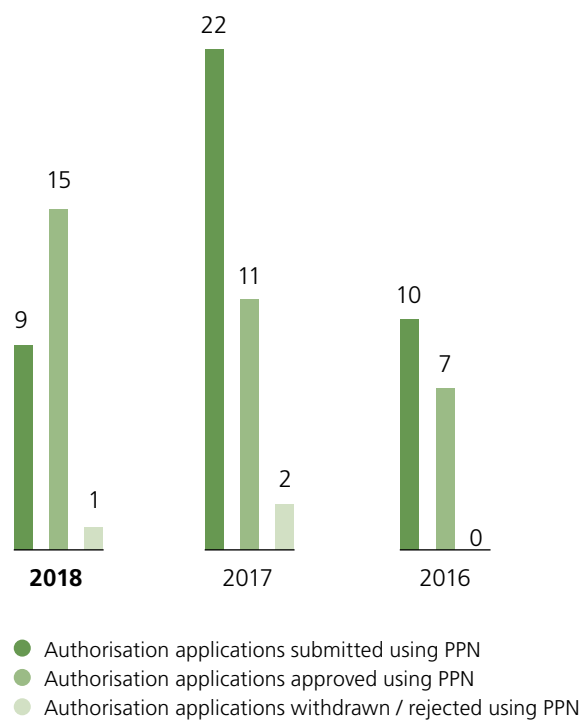
Activities

- Of the 21 PPN requests made in 2018, 13 were approved, one request was withdrawn and seven are still being processed.
- Nine authorisation applications using PPN were submitted and 15 were completed; four further submissions were planned for the end of 2018.

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 provided 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 116 authorisation applications completed and authorisation conditions fulfilled under Art. 13 TPA in 2018, 108 (93 %) were approved, two applications were withdrawn, two were rejected and four applications were not admitted.
- These 116 applications comprised three new notifications of a new active substance, eleven known active substances with innovation, 54 known active substances without innovation, seven major variations, including four additional indications, 39 variations requiring approval and two applications in other categories.



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

Human medicinal products

	2018		2017		2016	
	Appr.	Rej.	Appr.	Rej.	Appr.	Rej.
New notification of a new active substance	3	0	0	2	4	0
Known active substances with innovation	9	2	10	2	12	2
Known active substances without innovation	50	4	38	1	26	1
Known active substances of complementary and herbal medicines	0	0	0	0	8	0
Changes requiring approval	39	0	49	0	27	0
Additional indications	4	0	3	0	4	1
Other major variations	3	0	2	0	3	0
Other applications	0	2	7	0	9	0
Total	108	8	109	5	93	4

- Approval
- Rejection / withdrawal of the application

Special categories of human medicinal products



Orphan drugs

Swissmedic may, upon application, recognise the status as a medicinal product for a rare disease (orphan drug). Applicants 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 five out of 10,000 people in Switzerland, or that it has been granted this status by a country with comparable medicinal product control. Most applications are based on 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 to or, more usually, as the result of recognition of the orphan drug status. The authorisation procedure for orphan drugs is exempt from processing fees.

Activities

- 27 applications for recognition of orphan drug status were received, and 30 applications were completed.
- Orphan drug status was granted 28 times, distributed across 25 preparations.
- 14 preparations were authorised as new orphan drugs, while additional orphan indications were approved for 13 existing orphan drugs.
- The status was discontinued for five products.

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 permits 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 2018, the submission of PIPs once again proved helpful in the notification of paediatric clinical trials. A total of 29 paediatric trials was 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

- Two blood transfusion services were granted simplified authorisation for the use of a pathogen inactivation process.
- In addition, a variation requiring approval was reviewed and approved.
- A submission for main authorisation of a new blood pathogen inactivation process was received and is still under review.

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

- Five applications for marketing authorisation were received during 2018, specifically two gene therapy products and three tissue engineering products. Two products – one gene therapy product and one product based on mesenchymal stem cells – were authorised. The others are still in the review process. One application relating to a tissue engineering product was withdrawn.
- Two FTP applications were submitted. One was approved and the other is still under review.
- Five applications for orphan drug status were submitted for two products (covering five indications) and approved.
- Five PSURs were submitted.

- 16 variations requiring approval were reviewed, 12 of which were completed. In addition, three variations requiring notification were also completed.
- Two clinical restrictions were approved, as were two quality restrictions.
- Two presubmission meetings were held.

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. All complementary and herbal medicines are essentially eligible for the simplified authorisation procedure 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

- Compliance with the processing time limits was 95 % for applications completed in 2018.
- Swissmedic employees spoke on the subject of complementary and herbal medicinal products at several international congresses.
- Five new guidance documents were created for the authorisation of complementary and herbal medicines.

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 greatly simplified authorisation procedure is usually applied. In addition to quality and safety, the focus is above all on tolerability.

Activities

- Swissmedic completed twelve applications for the first authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication.
- No preparation without an indication according to Art. 17 para. 2 of the Complementary and Phytotherapeutic Products Ordinance (CPTPO) was approved under a simplified authorisation procedure.
- Official decisions were issued for 155 products without an indication under the notification procedure. 102 of these were single products, 53 were combined products.
- 35 applications for simplified authorisation with a reduced dossier were completed. 26 of these products were authorised, and nine applications were rejected or withdrawn.

Herbal medicinal products

Herbal medicinal products contain only herbal substances or preparations. Under the simplified authorisation procedure, proof of efficacy and safety can be provided in the form of bibliographic evidence. No simplification is possible for the quality documentation. It is possible to apply for conventional authorisation of herbal medicinal products that have been used for medicinal purposes for at least 30 years, of which at least 15 must have been in Western European cultures.

Activities

- Twelve applications for non-innovative first authorisation of herbal medicinal products were completed. Two of them 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

- A meeting with stakeholders operating in the field of traditional Chinese medicine was held during 2018.
- The list of traditional Asian substances (TAS list) was revised.

Authorisation of veterinary medicinal products

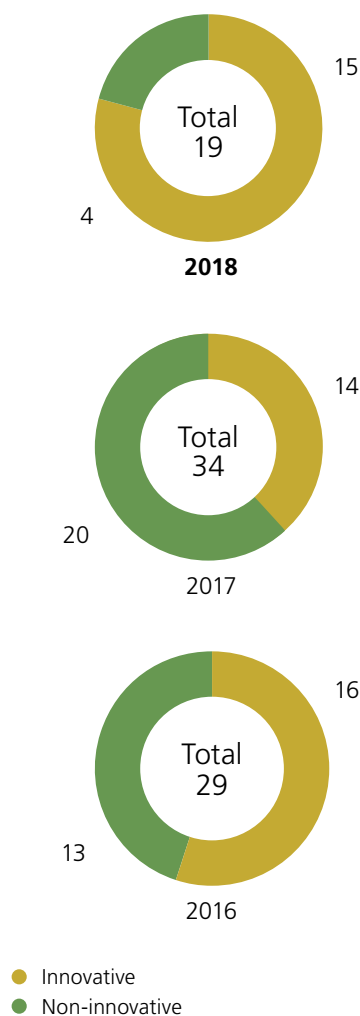
Authorisation of veterinary medicinal products

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 substances or major variations thereto) and non-innovative medicinal products (medicinal products with known active substances 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 in 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 levels 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.

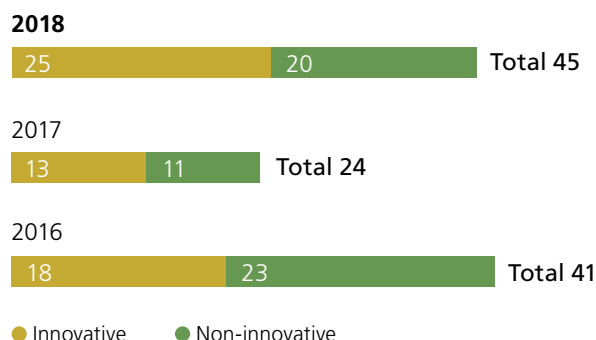
Activities

- 15 applications for innovative first authorisation and major variations were submitted, and 25 applications were completed.
- 20 applications for non-innovative first authorisation were completed,
- All of these applications were processed within the prescribed time limits.
- Cytopoint ad us.vet. became the first highly innovative medicinal product to be authorised for dogs. It is a monoclonal antibody therapy for canine atopic dermatitis that targets and interrupts IL-31.

Number of applications for first authorisation submitted:



Number of applications for first authorisation completed:



Veterinary medicinal products with a new active substance authorised in 2018

Therapeutic area (ATC)	Active substances	Product name	Application
Cardiovascular system	Torasemidum	UpCard ad us. vet., divisible tablets	Treatment of clinical signs, including oedema and effusion, related to congestive heart failure in dogs
Other dermatologicals	Lokivetmab	Cytopoint 10 mg/ml ad us. vet., solution for injection for dogs	Treatment of clinical manifestations of atopic dermatitis in dog.
Systemic ectoparasiticides	Lotilaner	Credelio 56 mg ad us. vet., chewable tablets for dogs	Treatment of flea or tick infestation 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 three meetings in 2018, the VMEC assessed eight applications for authorisation or a variation of the authorisation.
- Since the issue of anthelmintic resistance is gaining in significance in Switzerland, as elsewhere, the VMEC examined the reflection paper on anthelmintic resistance (EMA/CVMO/EWP/573536/2013) published by the European Medicines Agency (EMA) and discussed the need for warnings and appropriate labelling on the affected products.
- Thanks to Swissmedic's agreement with the EMA, the VMEC was able to follow online broadcasts of eleven meetings of the EMA Committee for Medicinal Products for Veterinary Use (CVMP).
- The Committee gave its views on the new requirements that the EMA intends to introduce for Summaries of Product Characteristics (SPCs) for veterinary antimicrobials.

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 ceases.

Activities

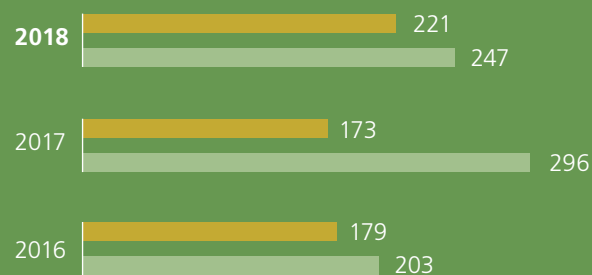
- Authorisation was extended for 157 veterinary medicinal products.
- Authorisation holders discontinued the marketing of 23 products.
- Applications for discontinuation were completed for nine preparations. The authorisations of 15 preparations were not extended.

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

- 221 variations requiring approval with scientific assessment and 247 variations requiring notification were completed.



- Variations requiring approval
- Variations requiring notification

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 applications are waived.

Activities

- One product was awarded MUMS status for the first time.
- One application for the authorisation of a product with a known active substance was approved for a minor species (hedgehogs).

Applications under Article 13 TPA for veterinary medicinal products

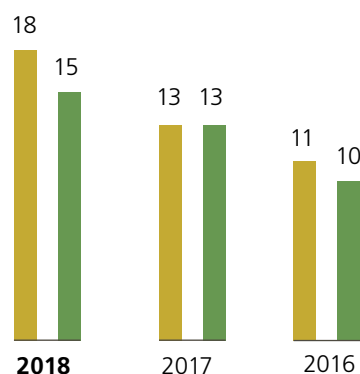
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose provided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

- 15 out of 18 completed authorisation applications for veterinary medicinal products under Art. 13 TPA were approved.
- Of the 15 completed applications, nine involved known active substances without innovation, two major variations and four variations requiring approval.



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

Veterinary medicinal products

	2018		2017		2016	
	Appr.	Rej.	Appr.	Rej.	Appr.	Rej.
Known active substances with innovation	0	0	2	0	1	1
Known active substances without innovation	9	1	5	0	5	0
Changes requiring approval	4	0	4	0	2	0
Additional indications	1	1	0	0	1	0
Other major variations	1	1	2	0	2	0
Total	15	3	13	0	11	1

- Approval
- Rejection/withdrawal of the application

Authorisation of human and veterinary medicinal products

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. That Court's judgement may in turn be contested before the Federal Supreme Court.

Activities

- One appeal was lodged with the Federal Administrative Court against an official decision taken by the Agency in connection with product authorisations. The appeal was not admitted.
- Of the appeals already pending before the Federal Administrative Court, one was rejected. One appeal was dismissed. One appeal was approved in part. This involved the restriction of an authorised indication. The authorisation holder is appealing the decision in the Federal Supreme Court. The appeal is pending.
- Of the appeals pending before the Supreme Court, two were rejected.

Table of performance indicators for human and veterinary medicinal products

The key figures for respecting time limits encompass all medicinal products, both human and veterinary.

Performance indicator	Target	Result
	2018	Total 2018
Application category		
Marketing 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 %	94 %
Extensions / discontinuations of marketing authorisations (ZL2); proportion of procedures completed within the prescribed time limits	95 %	100 %
Scientific variations (ZL3A); proportion completed within the prescribed time limits	95 %	100 %
Administrative variations (ZL3B); proportion completed within the prescribed time limits	95 %	100 %

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

- In preparation for the entry into force of the revised therapeutic products legislation on 1 January 2019, Swissmedic held information events on 25 October and 9 November 2018. Each was attended by about 550 stakeholders. On 30 September 2018, some 340 specification documents were published in four languages on the Swissmedic website in anticipation of the events. The entry into force of the revised therapeutic products legislation marked the provisional high point of a project that had been driven forward with great energy for two and a half years.
- Swissmedic presented the changes to quality documentation necessitated by the implementation of the revised therapeutic products legislation at an international workshop held by the Drug Information Association (DIA) in Basel in June 2018.
- In a comprehensive study¹, Swissmedic authors analysed the extent to which the Agency's authorisation decisions diverge from the decisions made by the EMA and US FDA. The results shed an interesting light on regulatory authorities' decision making.
- The Head of the Market Authorisation sector took part in two panel discussions. The first was organised by Forum Gesundheitswirtschaft Basel (Basel healthcare business forum) and was entitled "Value & values of medicinal product authorisation", while the second, at ETH Zurich, was on the topic of "Digital Health".

¹ A Comparative Review of Marketing Authorization Decisions in Switzerland, the EU, and the USA, Therapeutic Innovation & Regulatory Science, 2018, sagepub.com/journalsPermissions.nav, DOI: 10.1177/2168479018764660

Licensing

Medicinal and transplant products

Establishment licences for medicinal 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 2018, 1,099 companies held an establishment licence for the manufacture, wholesale, import, export and trade in foreign countries of medicinal and transplant products. Some companies carry out several of the activities mentioned. The number has been stable for several years.
- Once again, more establishment licences were issued, extended, modified or revoked. There were 844 decisions in 2018. Owing to the change in establishment licence format (total revision of the Medicinal Products Licensing Ordinance, MPLO, SR 812.212.1), a large number of renewals were completed prematurely at the end of 2018 using the old format.

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 for importing 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

- The number of special licences increased on 2017. The protracted unavailability in Switzerland of a veterinary medicinal product for the prevention of bovine mastitis (antibiotic-free prevention of ascending intramammary infections throughout the dry period) resulted in a large number of requests to import the product in packaging authorised in EU countries. Turning to human medicinal products, the unavailability of certain vaccines contributed to the increase in the number of special licences issued.

A Total number of 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 give foreign customers or authorities confirmation in an internationally standardised format that a valid establishment licence exists. Companies that export medicinal or transplant products can apply for confirmation of the current authorisation status in Switzerland in French, English or Spanish.

Activities

- Ordering certificates for pharmaceutical products using the online portal proved effective and simplified checking. The solution will be rolled out for GMP/GDP certificates during 2019.
- Looking at the multi-year trend, the number of certificates ordered remained stable, even if there was a slight fluctuation compared with 2017.

2018



2017



2016



- GMP/GDP certificates issued
- Product-specific certificates issued

Performance indicator



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



Product-specific certificates; proportion of procedures that were completed within 28 days

- Target
- Result

Control of the flow of narcotics

Swissmedic issues establishment licences to companies and individuals that handle controlled substances. Every import and export of controlled substances must be licensed in advance by Swissmedic. Swissmedic must be notified of domestic deliveries of narcotics in Lists A, B and D. Accounts must be kept by the licence holder of all transactions involving controlled substances. Corresponding annual accounts must be prepared and submitted to Swissmedic. The Agency 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 2018, 358 companies held an establishment licence for handling controlled substances. The number of processed applications for modifications, renewals or the start of operations fell to 153.
- Swissmedic examined the annual accounts submitted by 474 company sites for the purpose of reporting to the INCB in accordance with international agreements.
- The Agency reviewed the group listing of fentanyl derivatives and 15 new psychoactive substances, and applied to the FDHA for their inclusion in the Narcotics Lists Ordinance (NarcLO-FDHA)
- Five events were held on issues related to narcotics legislation and controlled substances.

Import and export permits granted for controlled substances



2018

2017

2016

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 180 applications for clinical trials with medicinal products in 2018. However, it was only possible to process 176 of these because the rest were either incomplete or fell outside the remit of the Clinical Trials division.
- In total, 176 clinical trials were approved, including 25 in category B and 151 in category C. Four of the applications in the latter category concerned a first-in-human trial. One clinical trial was rejected, and two were withdrawn by the sponsor during evaluation. The other applications are currently being processed. The trend observed in 2016 and 2017 towards more complex products and, as a result, more complex dossiers continued during 2018.
- On the other hand, 2,866 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 128 reports of suspected unexpected serious adverse reactions (SUSARs).
- Swissmedic continued to work with the FOPH and swiss-ethics, the Association of Swiss Ethics Committees, on research involving humans, with the aim of coordinating and harmonising the three bodies' interpretation of certain legal provisions. In connection with these efforts, Swissmedic took part in four meetings organised by the FOPH's Coordination Office for Human Research. The new Clinical Trials Symposium started in 2017 was successfully repeated during 2018, and will now become an annual fixture. The aim of this form of information dissemination is to provide training to one or two individuals in each organisation (e.g. clinical trial units) so that they can then train others at local level. The symposium will replace the numerous presentations that used to be given to these organisations.

2018



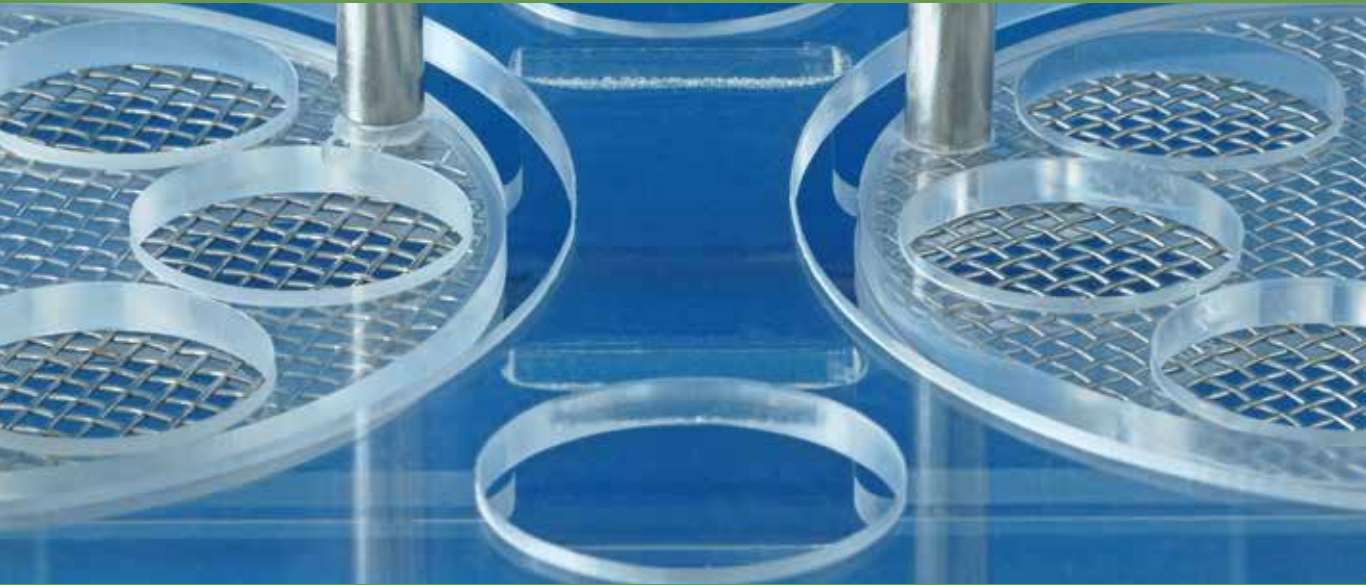
2017



2016



- 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

- Swissmedic received 13 applications for clinical trials of transplant products, four of which involved gene therapy products. It is notable that the majority of these trials (n=7) were for cancer therapies intended for use after all standard treatments had failed.
- A total of ten clinical trials were approved.
- 59 out of a total of 77 submitted variations were approved during the year.
- 15 Development Safety Update Reports (DSURs) were assessed.
- With over 300 reports, the biovigilance reporting system has become a firmly established part of daily practice. One transplant product safety signal was identified.

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

- The Swissmedic inspectorate carried out 58 GMP/GDP inspections of manufacturers and wholesale companies, while the regional inspectorates carried out 615. This makes a total of 673 inspections.
- The Swissmedic inspectorate carried out inspections in the following areas: transplant products 29 %, blood transfusion services 16 %, pre-approval inspections 7 %, "for cause" inspections 14 %, pharmaceutical sector inspections 34 %.
- In 2018, Swissmedic once again took part in international inspection programmes run by partner authorities outside Switzerland. One active substance manufacturer in China was inspected in conjunction with the European Directorate for the Quality of Medicines (EDQM).
- The Agency also took part in ongoing assessments of partner authorities within the framework of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).
- The national focus area chosen for special attention during GMP/GDP inspections in 2017 was continued during 2018. This involved random checks during inspections of marketing authorisation holders to verify whether the manufacturer information in authorisation dossiers was correct and up-to-date, and whether the companies in question were fulfilling their obligation to monitor and qualify foreign suppliers.
- Once again there was a sharp increase (from 54 to 62) in reports of major changes to installations (in accordance with Art. 30 para. 2 MPLO).
- Swissmedic commenced monitoring of institutions that work with tissues and cells for autologous transplantation and received 39 notifications. In the course of two inspections, the Agency carried out random checks of compliance with legal quality assurance requirements relating to cells and tissues.

2018



2017



2016



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 carries out random inspections of clinical trials of medicinal products in Switzerland. Good Clinical Practice (GCP) 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. Inspections may examine circumstances relating to one or more clinical trials. They can focus both on the way trial centres are conducting a trial (trial centre inspection) and on the way pharmaceutical companies, contract research organisations (CROs), pharmacies and research organisations or units are managing it.

After it has approved a human medicinal product in Switzerland, Swissmedic conducts pharmacovigilance inspections of authorisation holders (pharmaceutical companies), as well as of CROs and organisations contracted by authorisation holders to carry out pharmacovigilance-related activities on their behalf. These inspections assess whether the pharmacovigilance processes operated by the companies, CROs or organisations being inspected comply with applicable national laws, international Good Vigilance Practice (GVP) directives and Swissmedic requirements.

Activities

- In 2018, Swissmedic carried out 22 GCP inspections of clinical trials involving medicinal products authorised in Switzerland, including one trial in Germany and one in the UK.
- Swissmedic also carried out 12 GVP inspections in Switzerland.
- Within the framework of the Geneva-based PIC/S (Pharmaceutical Inspection Co-operation Scheme) convention, Swissmedic participated in two GCP inspection programmes (in Norway and Germany) and one GVP inspection programme (in Lithuania). One of the 12 GVP inspections conducted in Switzerland was also part of the PIC/S programme.
- Swissmedic's GCP/GVP inspectors participated in the EMA's Inspectors Working Groups once again in 2018.
- One GCP inspection was carried out in the transplant products sector during 2018.

Performance indicator



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

● Target ● Result

GLP inspections

For authorisation in Switzerland, non-clinical assessments for notification or authorisation procedures must, with the exception of pharmacodynamic testing, 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 other authorities, such as those for medical devices imposed by the Food and Drug Administration (FDA) in the USA, are also taken into account.

Activities

- Swissmedic's specialist GLP unit inspected GLP compliance at a total of seven assessment facilities and one service provider.
- One assessment facility left the Swiss GLP monitoring programme at its own request, while a further facility scaled back its activities substantially.
- Cooperation with the GLP units at the FOPH and FOEN were further stepped up, particularly as regards inspector training and inspection planning.

Performance indicator



GLP inspections; degree to which the annual plan was fulfilled

● Target ● Result

Inspections for third parties

Swissmedic can provide services for third parties subject to payment of a fee. On behalf of the 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 performs some of the inspection activities in the therapeutic products sector for the Principality of Liechtenstein.

Activities

- Swissmedic carried out 16 inspection procedures 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

- No problems occurred in connection with the implementation of the new rules governing inspections by foreign authorities in Switzerland that entered into force on 1 January 2018. While Swissmedic is notified beforehand of inspections by foreign authorities, such inspections no longer require SECO approval. However, foreign authorities are required to send a copy of their inspection report to Swissmedic, a condition that was largely respected.
- Foreign authorities carried out 82 GMP inspections at pharmaceutical companies in Switzerland. The inspecting authorities concerned were from the USA (39 inspections), Russia (21), Turkey (5), Mexico (3), Brazil and Belarus (2 each), and Taiwan, Korea, Kazakhstan, Yemen, Iran, Saudi Arabia, Libya, Colombia, the Gulf Cooperation Council¹ and Eurasian Economic Union² (one each).
- Furthermore, Swissmedic provided specialist support during one GVP inspection conducted in Switzerland by BfArM, the German Federal Institute for Drugs and Medical Devices.

Monitoring of the blood transfusion service

Swissmedic monitors Swiss blood transfusion activities by means of inspections, licences, market monitoring 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

- To minimise the risk of transmitting the hepatitis E virus (HEV) in blood transfusions, Swiss Transfusion SRC adopted the recommendation of a working group of which Swissmedic was a member, and started testing all donated blood for HEV on 1 October 2018.
- Other risks were addressed by continually adapting donor suitability criteria to the epidemiological situation (e.g. in response to the spread of transmissible diseases such as dengue fever and Chagas disease, or cases of West Nile virus (WNV) and Chikungunya disease in nearby countries).
- The special provisions applicable to blood and blood products were also overhauled as part of the complete revision of the Medicinal Products Licensing Ordinance (MPLO).
- New provisions governing testing for the hepatitis B virus, improving the information given to donors and alignment with European GMP requirements have been applied since 1 January 2019.

A Inspections by foreign authorities in Switzerland



¹ GCC Golf Council Cooperation, including the members Saudi Arabia, Kuwait, Oman, Qatar, Bahrain and the United Arab Emirates (UAE)

² EAEU Eurasian Economic Union, including the members Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia

Licensing of microbiological laboratories

Establishment licences for microbiological laboratories

The introduction of the revised Federal Act on Combating Communicable Human Diseases (Epidemics Act, EpidA; SR 818.101) brought a new task to Swissmedic. Since 1 January 2016, laboratories that conduct, or wish to start conducting, microbiological tests for the identification of communicable diseases have required an establishment licence from 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 2018, 95 microbiological laboratories held a microbiological laboratory licence issued by Swissmedic under the revised Epidemics Act that has been in force since 1 January 2016. This leaves 18 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.
- During 2018, as part of the MPLO/Medicrime project, suitable IT tools were developed to increase the level of automation in licence processing. Preparations were also made for similar tools for microbiological laboratory licences. The change took effect on 1 January 2019.

Inspections of microbiological laboratories

Microbiological laboratories must satisfy the requirements defined in the Ordinance on Microbiological Laboratories (LaborVO, 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 inspected 33 licensed laboratories. These inspections took account of whether or not a laboratory possesses an accreditation issued by the Swiss Accreditation Service (SAS).
- 2018 also saw the first laboratory inspections associated with licences for examining samples from B-incidents (threat from genetically modified or pathogenic organisms). The laboratories' work is coordinated by the FOPH under the auspices of the Regional Laboratory Network.
- Further discussions with the SAS made it clear that this Service will not take on any additional monitoring tasks on behalf of Swissmedic until further notice. To avoid duplicated effort at accredited laboratories, certain elements of the Microbiological Laboratories Ordinance (LaborVO) were identified that the SAS can assess as part of the accreditation activities it performs in accordance with the Ordinance.

A Inspections of microbiological laboratories





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 carrying out laboratory analyses and developing and assessing methods.

Activities

- 14 % more batches and 17 % more plasma pools were tested and released as part of Official Control Authority Batch Release (OCABR) activities. Despite the increase in assignments, automation and process optimisation ensured timeline-compliant release.
- The laboratory plays a key role in compiling standards. During 2018 it worked on the revision of Directive ICH Q2(R2) and on drafting new Directive ICH Q14. It also helped prepare or revise European and Swiss Pharmacopoeia monographs. The laboratory represented Swissmedic's interests and made a valuable expert and scientific contribution.
- The majority of unauthorised medicinal products analysed by the laboratory were erectile stimulants, biotechnological medicinal products and various samples from house searches.

Analyses completed for new marketing authorisations and market monitoring

	2016	2017	2018
Authorisation procedure: Number of medicines examined	39	16	20
Market surveillance: Number of medicines examined	1187	686	1682
Other (pharmacopoeia, round robin tests)	479	522	366
Total	1705	1224	2068

Batch assessments and plasma pool analysis

	2016		2017		2018	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU and WHO)	712	64	703	40	782	48
Notifications	357	157	406	172	354	137
Plasma pool analyses	2467	–	2680	–	3213	–
Product analyses as WHO reference laboratory	–	9	–	–	–	15

Performance indicator



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

● Target ● Result

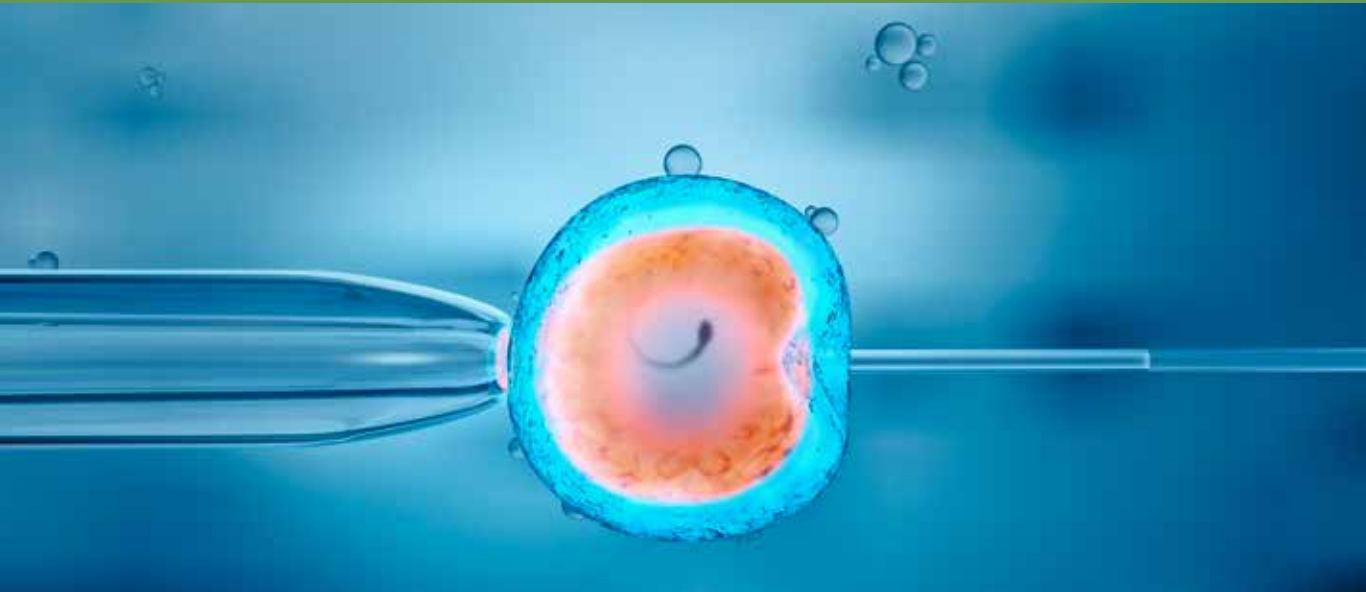
Appeals procedures regarding licences

Appeals against official decisions taken by Swissmedic 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

- Three appeals were lodged with the Federal Administrative Court against official decisions by the Agency in connection with licences. One of these was dismissed, while the other two were still pending at the end of 2018.
- Of the appeals already pending before the Federal Administrative Court at the beginning of the year, two were dismissed.
- Appeals against two decisions by the Federal Administrative Court were lodged with the Federal Supreme Court. These were still pending at the end of 2018.

Special activities and events: Licensing



PIC/S reassessment of the Swiss GMP control system

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) carried out a one-week assessment of Switzerland's GMP control system between 15 and 19 October 2018. The Swiss system passed this external assessment by our partner authorities, and its equivalence is thus confirmed. The PIC/S delegation, comprising auditors from the US FDA, the UK's Medicines and Healthcare products Regulatory Agency (MHRA), Health Canada and Germany's Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG), examined whether Switzerland's licensing and GMP inspection system still satisfies PIC/S standards. The positive outcome also extends to all four regional inspectorates. Certain activities performed by the Swissmedic laboratory were also examined, as was Market Surveillance's approach to processing quality deficiencies.

Furthermore, the audit provided a basis for continuing mutual recognition of inspection results and certificates under Switzerland's Mutual Recognition Agreements (MRAs) with the EU and Canada, and will help facilitate a future agreement with the FDA.

Market monitoring

The quality, safety and efficacy of medicines and medical devices continue to be monitored by Swissmedic even after they have obtained marketing authorisation. This entails evaluating reports from Switzerland, international safety signals and reports of quality problems. Swissmedic also takes action when illegal therapeutic products are imported into Switzerland.

Medicinal products

Medicinal products vigilance

Swissmedic records safety signals associated with medicinal products, vaccines, labile blood products and veterinary medicinal products based on reports of adverse drug reactions (ADR) from within Switzerland.

If investigation confirms a new risk, Swissmedic initiates the necessary action 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

- A new database for recording and assessing adverse drug reactions was introduced.
- In an important step in efforts to improve efficiency and encourage paperless working, a further four authorisation holders were connected to the electronic ADR reporting gateway.
- To improve reporting quality, Swissmedic systematically evaluates the quality of the reports submitted by companies and uses the finding to help plan and conduct GVP inspections.

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

2018



2017



2016



- Regional pharmacovigilance centres
- Firms

Performance indicator



Adverse reactions:

Proportion of assessments carried out and transmitted to the firms within 15 calendar days

- Target
- Result



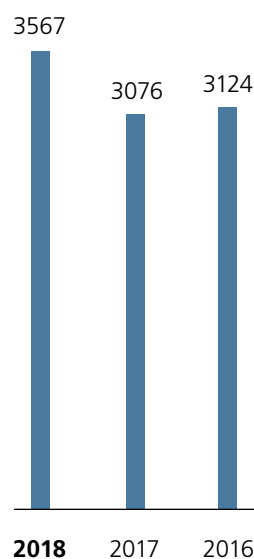
Haemovigilance

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

Activities

- While cooperation was increased, so was enforcement of the haemovigilance reporting obligation. Two working visits were made to hospitals for the purpose of improving existing quality assurance processes.
 - Drawing on the results published in the Haemovigilance Annual Report 2017, information and preventive actions relating to the following focus areas were issued during 2018:
 - Transfusion-associated circulatory overload (TACO)
 - Near misses associated with shift changes in hospitals
- www.swissmedic.ch/haemovigilance-report

Adverse events involving blood products: Number of reports



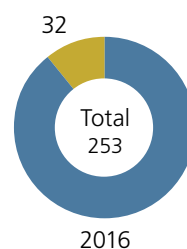
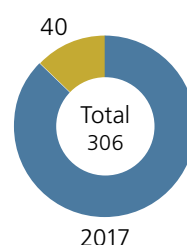
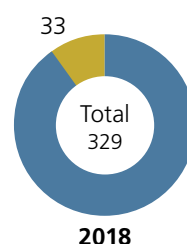
Vigilance for veterinary medicinal products

Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich to collect and assess reports on adverse reactions to veterinary medicinal products. Reports on vaccines for animals are recorded by the Institute for Virology and Immunology (IVI) of the Federal Food Safety and Veterinary Office (FSVO). Swissmedic has no evaluations of these reports.

Activities

- A report on the evaluation of adverse drug reaction (ADR) reports relating to veterinary medicinal products was prepared for and accepted by the journal Swiss Archive of Veterinary Medicine. The report was published in February 2019.
- 329 reports of adverse drug reactions involving veterinary medicinal products were received. This is an increase of 5 % on the previous year. 33 of the reports submitted to Swissmedic by Tox Info Suisse were also recorded.
- Once again, the ADR reports primarily involved dogs (201) and cats (77), followed by cattle (26) and horses (9). The medicinal product categories most frequently involved were antiparasitics (174 reports), products containing hormonally active substances (20), anti-inflammatories (22) and antibiotics (20). This distribution is virtually unchanged from previous years.
- Seven signals were generated from the 329 reports and from the analysis of the periodic safety update reports (PSURs). Six of them involved products for use in small animals.

Adverse drug reactions, veterinary medicinal products



- Number of reports
- Of which reports from Tox Info Suisse

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 and 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 (PSURs) and Periodic Benefit Risk Evaluation Reports (PBRERs).

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

- The number of PVPs and risk management plans (RMPs) assessed by Swissmedic rose once more in 2018, as post-marketing activities continue to grow in importance. Medicinal products are being authorised ever faster and sooner, which means that certain risks are only identified once authorisation has been issued. Specific measures such as post-marketing studies and collecting data on adverse drug reactions once products are on the market are therefore very important.
- Evaluation of post-marketing clinical trials once again resulted in many product information texts being amended and in one product’s authorisation being suspended.

A Pharmacovigilance plans: Number of assessments



PSURs/PBRERs: Number of assessments



- Human medicinal products
- Veterinary medicinal products

Performance indicator



Number of signals identified from reports or international sources

- Target
- Result



Risk mitigation measures

It is mandatory, even after a medicinal product has been 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, DHPCs) and the intended recipients are examined and approved by Swissmedic. These DHPCs and the 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

- The number of signals initially reported by authorisation holders increased significantly in response to our publication on drug safety signals. As a result, risk minimisation measures are being processed and implemented in Switzerland faster and more efficiently.
- Swissmedic was therefore able to complete more signals in significantly less time. Of a total of 175 signals, 41 procedures involving DHPCs were completed.

Performance indicator



Number of completed procedures (including reviews)

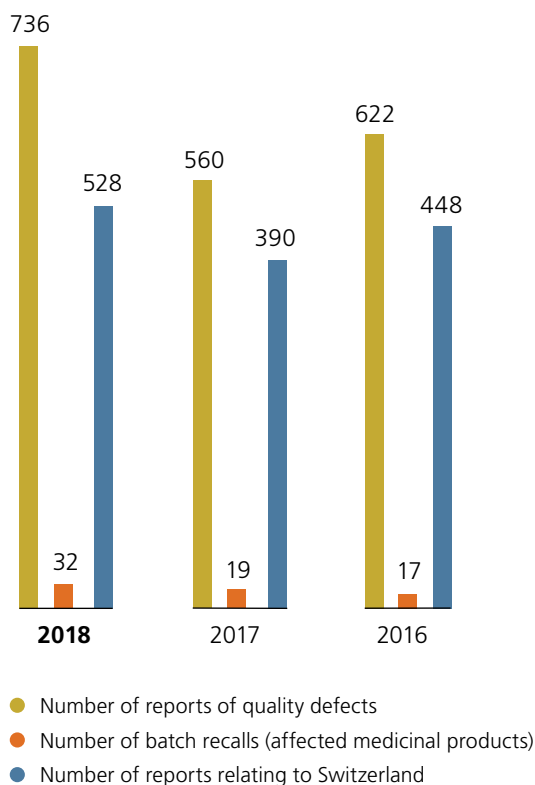
● Target ● Result

Quality defects and batch recalls

Swissmedic records reports on quality defects in medicinal products and takes the necessary actions. The reports are assessed and prioritised; where a potentially high health risk is identified, a batch recall is initiated and professionals and the public are informed. Swissmedic also reviews foreign reports on quality defects specifically to ascertain whether products marketed in Switzerland are affected. It is engaged 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 in cases where the market cannot be served with an equivalent product from a different authorisation holder. The Agency works with the Federal Office for National Economic Supply (FONES) on these applications, since authorisation holders report supply shortages to FONES.

Activities

- A total of 736 reports of quality defects were received in 2018. This represents a 25 % increase on the previous year. The number of batches recalled in the Swiss market also increased.
- Many reports concerned manufacturing incidents, often caused by inadequate compliance with Good Manufacturing Practice (GMP). In spring 2018, several batches of a heparin preparation that is widely used in hospitals were recalled following machinery problems that resulted in leaking ampoules, causing a temporary interruption in supply. Regular supplies of heparins to Swiss hospitals resumed once the machine in question had been modified.
- In the second half of 2018, several batches of sartan antihypertensives had to be recalled after potentially carcinogenic nitrosamines were found in active substance sourced from a Chinese manufacturer.



Measures against illegal medicinal products

Swissmedic increases public awareness of the dangers associated with the use of illegal medicinal products. Professionals and the public are warned of the risks in media releases, interviews and publications. The Agency consults regularly with authorities and organisations as part of this task, and promotes effective national and international networking.

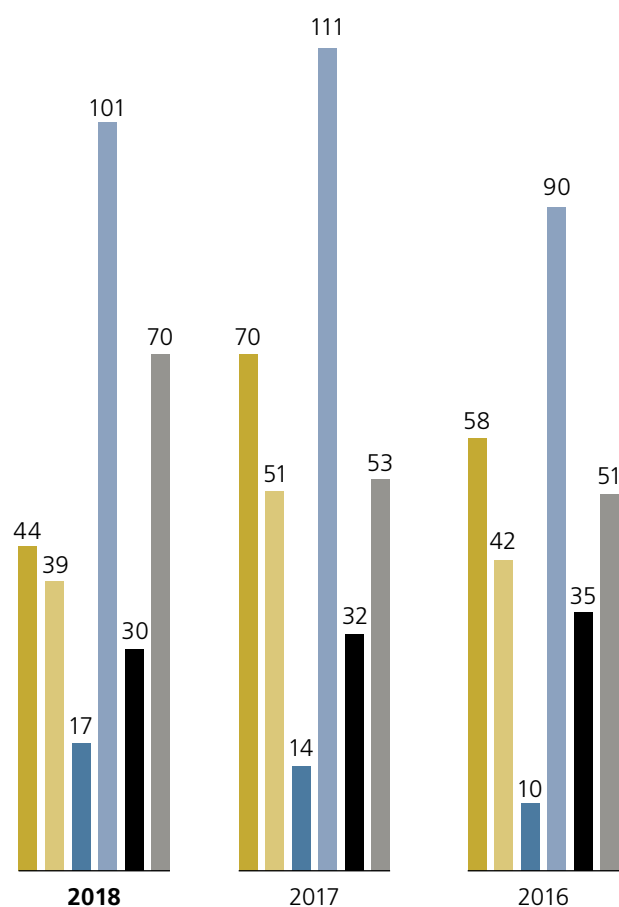
Swissmedic receives reports on illegal products, activities and distribution, reviews them and initiates corrective action as necessary or passes them on to the competent office. The Agency works closely with the customs authorities to monitor imports of medicinal products and orders the return or destruction of illegal shipments.

Activities

- Another national stakeholder meeting with representatives of other authorities (Customs, Federal Office of Police, Cantonal Pharmacists, cantonal police forces and public prosecutors) was held in 2018. The meeting focused on developments and trends in information technology. Illegal online trading and the associated use of cryptocurrencies such as Bitcoin create a challenge for Swissmedic’s market surveillance activities. Various steps are being taken to counteract these trends, including knowledge sharing and identifying synergies in stakeholder meetings.
- An internal working group established that Swissmedic needs to develop its capabilities in IT investigations. Initial measures, regular cross-departmental internal dialogue and meetings with the competent external agencies started in 2018.
- The issue of illegal mail order trading within Europe was addressed on a case-by-case basis with various foreign authorities. This cooperation was instrumental in breaking up the majority of mailing routes between various European countries and Switzerland before they could get fully established.
- In October 2018, Swissmedic took part in Pangea XI, an international week of action against illegal therapeutic products trading. The FCA, Swissmedic and Antidoping Switzerland inspected over 1,000 shipments in the Zurich-Mülligen postal sorting office. 304 packages containing illegal medicinal products or doping agents were confiscated.
- Once again, there was a rise in illegal imports of erectile stimulants. Laboratory testing by Swissmedic confirmed that as in the past, half of these preparations were deficient and therefore represented a risk to health.
- Swiss customs offices notified Swissmedic of 758 incidents involving illegal importing of medicinal products. In most cases, the confiscated items were destroyed under administrative proceedings. Added to the 2,445 packages containing erectile stimulants that were destroyed under the simplified procedure, the total number of cases of illegal importing came to 3,203.
- Isolated incidents of counterfeit medicinal products being trafficked via Swiss licence holders were identified during 2018, but none of these affected the Swiss market. Swissmedic worked with foreign regulatory authorities to identify the source of the counterfeit products.

Product categories of illegal imports dealt with under administrative proceedings:

	2018	2017	2016
Erectile stimulants	54 %	59 %	55 %
Sleeping tablets and tranquilisers	10 %	12 %	13.5 %
Medically important, prescription-only medicines	19 %	16 %	13 %
Slimming preparations	4 %	2.5 %	5 %
Hair growth preparations	3 %	1.5 %	2.5 %
Other	10 %	9 %	11 %



- Illegal distribution (responsibility of Swissmedic)
- Illegal retail trade (responsibility of the Cantons)
- Illegal cosmetics and nutritional supplements (responsibility of the Cantons)
- Counterfeit medicinal products (notifications from abroad)
- Number of evaluations of suspicious products
- Other (notifications from abroad, theft abroad, etc.)

Control of advertising

Swissmedic controls and monitors the advertising of medicinal products. Since the beginning of 2017, official prior control has only applied to advertising for what are deemed to be sensitive medicinal products. These are preparations such as laxatives or sleeping aids which may be dependence-forming or susceptible to abuse according to their product information. Responsibility for ensuring that advertising meets legal requirements lies with the members of licence holders’ staff responsible for compliance with the relevant legislation. The Agency verifies compliance by means of random checks. Swissmedic also investigates reports of breaches of advertising rules, if necessary instigating administrative proceedings or issuing an official objection to the people responsible to oblige them to bring the advertising in question back into line with legal requirements. Publications, information sheets and presentations are used to inform stakeholders of the current legal provisions governing medicinal product advertising.

Activities

- Twelve applications for advertising permits were processed during 2018, as opposed to just two in 2017. Four applications were for advertisements in printed publications, eight for digital media.
- Third-party complaints about medicinal product advertising were addressed using a risk-based approach driven by the potential hazard to health and the need to treat market participants equally.
- Swissmedic continued its proactive post-publication inspections of electronic and printed medicinal product advertising destined for the public. In the majority of cases, the advertising that was inspected met legal requirements. However, a large number of objections concerning the wording of the mandatory warning or the size of the font in which it was printed had to be issued.

Performance indicator



Prior control of advertising: proportion of cases where a preliminary decision was taken within four weeks of receipt of the application

● Target ● Result

The following performance indicators apply to all activities related to medicinal product market monitoring (quality defects, advertising control and illegal activities).



First actions taken within 10 days for priority 1 reports



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



Number of presentations, publications and circulars to raise awareness among stakeholders

● Target ● Result

Appeals procedures regarding medicinal products market monitoring

Appeals against official decisions taken by Swissmedic 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

- Appeals were lodged with the Federal Administrative Court against five official decisions by the Agency concerning medicinal product market monitoring. Four were dismissed, while one is still pending.
- Two appeals that were already pending with the Federal Administrative Court were not admitted. One pending appeal was rejected, but an appeal against this verdict was lodged with the Federal Supreme Court.



Special activities and events: Medicinal product market monitoring

New database launched

The launch of a new database for recording and assessing adverse drug reactions represented a milestone achievement. The changeover was a necessary response to more stringent requirements, the implementation of a global standard and the discontinuation of support by Swissmedic's former long-time provider. Swissmedic has adapted the new Vigilance One Ultimate database to its specific needs to enable it to accurately evaluate data, especially for the purpose of identifying safety risks, and to ensure that it can continue to receive authorisation holders' notifications in the long term. Furthermore, the introduction of the new database means that Swissmedic can receive and process notifications entirely in electronic format, an innovation that will enable it to process a larger volume of notifications.

Medical devices



Market surveillance of medical devices

Medical devices encompass an extremely 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, manufacturers have to carry out and assume responsibility for their own conformity assessment procedure. In the case of higher-risk products, an officially accredited European notified body – a “conformity assessment body” (CAB) – must also examine the product. Products that meet the requirements of the assessment procedure are given CE marking. Swissmedic is responsible both for the surveillance of medical devices that are already on the market and of 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

Swissmedic is integrated into the European system for medical devices. Switzerland has concluded agreements on the mutual recognition of conformity assessments for medical devices with EU Member States, EFTA states and Turkey. Under this

European system, the authorities of the contracting states have access to a shared database (EUDAMED) which acts as a market surveillance information system. CE-marked medical devices are considered to be compliant and may be distributed in all contracting states.

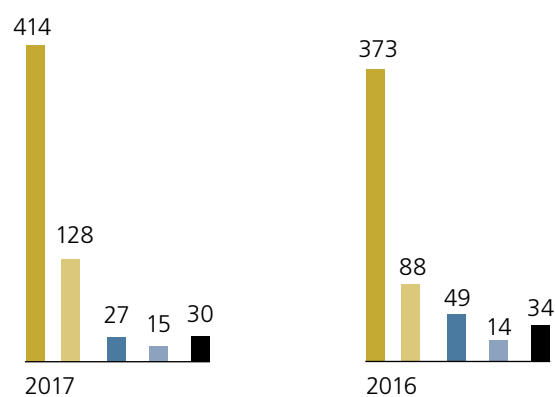
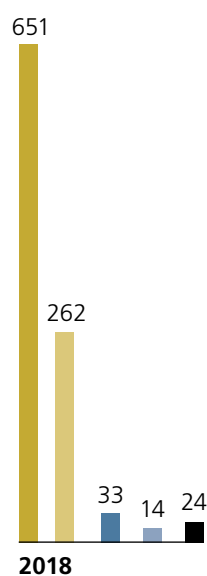
Swissmedic is actively involved in the Competent Authorities for Medical Devices (CAMD) project, the umbrella group for EU Member States, and its working groups. The Agency also sits on the CAMD Executive Group (CEG), and is an observer within the European Commission’s Medical Device Coordination Group (MDCG) and its working groups.

Placing on the market

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

Activities

- 651 notifications under Art. 6 para.1 MedDO were received. The notifications concerned classic Class 1 medical devices, custom-made classic or active implantable medical devices, systems and treatment units. Class 1 products include devices such as reusable surgical instruments, adhesive plasters and rolling walkers.
- A total of 262 notifications under Art. 6 para. 2 and para. 2bis MedDO were submitted for in vitro diagnostic (IVD) devices.
- Eight notifications in accordance with Art. 6 para. 3 MedDO were received for classic and active implantable medical devices made using or containing devitalised human tissue. In addition, 22 change notifications concerning devitalised human tissue were processed.
- In 33 cases, Swissmedic rejected companies' notifications of medical products because the products had been incorrectly categorised or classified, or because they did not fall within its area of responsibility.
- In 2018, Swissmedic took part in 14 EU enquiries on delimitation questions regarding the classification of devices.
- Swissmedic can issue special permits to import non-compliant medical devices if such devices could resolve a life-threatening situation faced by a patient. 24 applications were reviewed.



- Class I notifications
- IVD notifications (Switzerland)
- Notifications rejected
- EU enquiries
- Applications for special permits

European market surveillance activities

Since Switzerland is integrated into the European medical devices system, it carries out market surveillance activities in consultation with partner authorities from contracting states in addition to its national market surveillance activities.

Activities

- The number of requests for mutual assistance from European partner authorities rose from 144 to 180.
- The number of requests made by Swissmedic to European partners remained stable at 32.
- As part of efforts to step up surveillance of CABs and accredit them under the new European Regulations (MDR/IVDR), Swissmedic once again took part in internationally accompanied audits of CABs during 2018.

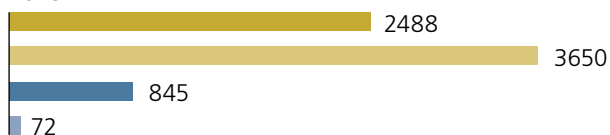
Materiovigilance

Manufacturers and users have an obligation to inform Swissmedic of adverse events that take place in Switzerland. Companies must also inform Swissmedic of measures they have taken, such as product recalls, which the Agency then monitors. Swissmedic is integrated within the European reporting system and also informs affected contracting states about incidents and measures taken in Switzerland.

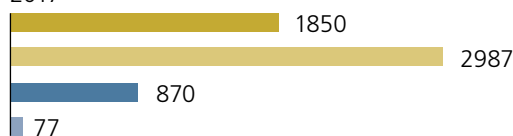
Activities

- A total of 2,488 incidents were reported in Switzerland, a further sharp increase of 36 % on the previous year's figure.
- The implementation of corrective safety measures in Switzerland was monitored in 676 cases. A total of 72 reports on defective medical devices (National Competent Authority Reports, NCARs) were prepared for distribution to foreign authorities, while Swissmedic received 845 NCARs from its European partner authorities.
- In 634 cases, a public safety report was published on the Swissmedic website for the information of users.
- In 2018, Swissmedic again discussed new suspected incidents and concrete action on pending cases during monthly telephone conferences with the other European surveillance authorities.
- With Swissmedic's active participation, the new Manufacturer's Incident Report (MIR) form was drawn up, approved and introduced throughout Europe.

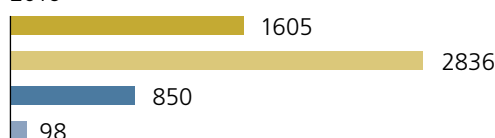
2018



2017



2016



- Incidents; number of reports from Switzerland
- Incidents; number of reports overall: materiovigilance cases opened
- NCARs received
- NCARs issued

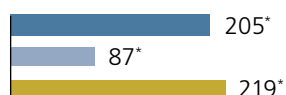
Market monitoring

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

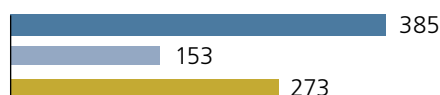
Activities

- Swissmedic received a total of 205 reports of suspected non-compliant medical devices. In view of the persistently high number of reports, processing is based strictly on the potential risk involved.
- Swissmedic imposed corrective measures on market participants in Switzerland in 87 cases.

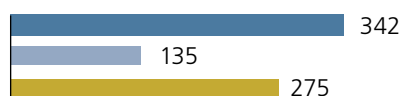
2018



2017



2016



- Reports received
- Corrective measures
- Procedures completed

* compiled using new recording methods; figures not comparable with the two preceding years.

Clinical investigations

Swissmedic approves and monitors clinical investigations of medical devices for human use if the products or intended uses are not yet CE certified. Approval has been mandatory for this type of investigation since 1 January 2014. While the investigations are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events and reports on participant safety. Swissmedic can inspect investigators, sponsors and research institutions throughout Switzerland, and records notifications and measures from the country in EUDAMED. Furthermore, the Agency helps draft international guidelines and design training events for the purpose of enhancing implementation.

Activities

- 36 applications for new trials involving non-CE-marked medical devices were submitted.
- 85 applications for variations were received.
- One clinical trial in progress was inspected.
- The option of submitting documents for clinical trials of medical devices online via the Swissmedic Portal was introduced in autumn 2018.

Monitoring of conformity assessment bodies (CABs) and inspections

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

Activities

- 17 Swiss companies were inspected on an ad hoc basis as part of market control activities.
- Swissmedic inspected reprocessing, maintenance and reporting systems in a total of 20 hospitals.
- The Agency coordinates inspections carried out in Switzerland by foreign authorities and, if needed, accompanies the inspectors on site.

	2018	2017	2016
CAB inspections (excluding ISO 13485)	3	6	3
Number of CABs in Switzerland	2	2	2
Joint assessments	3	2	2
On-site inspections of clinical investigations	1	2	6
Hospital inspections (reprocessing, maintenance and reporting system)	20	26	12
Foreign inspections	45	50	74
Inspections of market controls	17	14	10
Inspections on behalf of the Swiss Accreditation Service (SAS) as specialist inspector	5*	n/a	n/a

Export certificates

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

Activities

- A total of 2,622 export certificates were issued.
- A new practice for issuing export certificates for medical devices was introduced in autumn 2018. Associated with this was the changeover to electronic submission of order documents via the Swissmedic Portal.

2622 **3039** **2677**

2018

2017

2016

Appeals procedure regarding the market surveillance of medical devices

Appeals against official decisions taken by Swissmedic 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

- Appeals were lodged with the Federal Administrative Court against four official decisions by the Agency in connection with the market surveillance of medical devices. One appeal was not admitted and another was dismissed, while the remaining two are still pending.
- Of the appeals already pending before the Federal Administrative Court at the beginning of 2018, one was rejected. One appeal was dismissed.

Special activities and events: Market surveillance of medical devices



Electronic submission of medical device clinical trial and export certificate documents

As part of efforts to optimise processes and digitalise, Swissmedic introduced electronic submission of medical device clinical trial and export certificate documents via the Swissmedic Portal in autumn 2018. At the same time, a new practice was introduced for export certificates.

ELWD 0.3



Standards

Legal framework

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 evolving environment, legislation work that helps enact and maintain legal foundations is one of Swissmedic's key tasks. The lead entity for enacting and revising the Therapeutic Products Act (TPA) and the implementing ordinances (both issued by the Federal Council) at administrative level is the Federal Office of Public Health (FOPH). Swissmedic is integrated within this legislative work as the competent enforcement authority. It is, however, one of Swissmedic's competencies to enact and revise the implementing ordinances (ordinances of a technical nature) of the Swissmedic Agency Council.

Activities

- The changes to legislation adopted by Parliament on 18 March 2016 as part of the regular revision of the Therapeutic Products Act (TPA2) resulted in extensive amendments to the implementing legislation. In partnership with the FOPH, Swissmedic launched a legislative project for the associated ordinances at Federal Council and Agency Council level in March 2016. This project, known as Therapeutic Products Ordinance Package IV or H MV IV, was completed at the end of 2018. The Agency Council approved five ordinances in resolutions passed on 4 May, 7 September and 14 September 2018:
 - Ordinance of the Swiss Agency for Therapeutic Products on the Licensing Requirements for Therapeutic Products (TPLRO)
 - Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO)
 - Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Complementary and Phytotherapeutic Products (KPTPO)
 - Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic)
 - Ordinance on the Personnel of the Swiss Agency for Therapeutic Products (Swissmedic Personnel Ordinance)

On 21 September 2018, the Federal Council passed resolutions on three additional ordinances.

- Therapeutic Products Ordinance (TPO)
- Ordinance on the Assignment of Responsibility for Therapeutic Products Monitoring to the Swiss Agency for Therapeutic Products (Therapeutic Products Monitoring Ordinance)
- Ordinance on the Advertising of Therapeutic Products (TPAO)

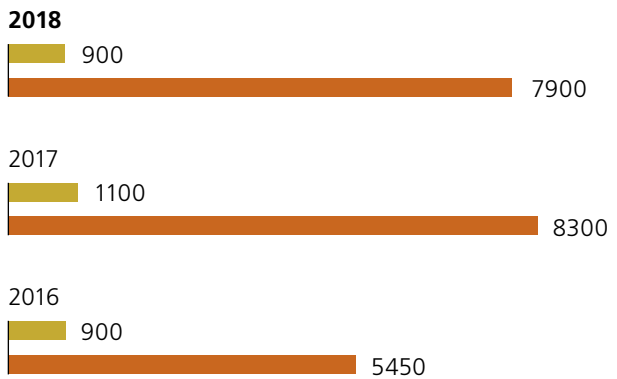
All revised ordinances came into force on 1 January 2019.

- On 29 September 2017, Parliament approved the proposal to approve and implement the Medicrime Convention in the final vote. The proposal included the adaptation of specific aspects of the Therapeutic Products Act (TPA) and the Criminal Procedure Code (CrimPC). In addition to the legal amendments associated with the ratification of the Medicrime Convention, the option of attaching safety features and devices to medicinal products packaging in Switzerland was also approved. The features and devices in question are similar to those provided for in the EU's Falsified Medicines Directive (2011/62/EU). The provisions on safety features and devices are due to be submitted for consultation in the second half of 2019. The Federal Council enacted the implementing provisions of the Medicinal Products Licensing Ordinance (MPLO) on 14 November 2018, and these entered into force on 1 January 2019.
- On 5 April 2017, the EU approved its new Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR). Since Switzerland is a participant in the European single market for medical devices, it has to enact the new Regulations in its national legislation in timely fashion. In adapting its legislation to the European Regulations, Switzerland is also seeking to improve the safety and quality of medical devices. Doing so will also create the framework for Switzerland's continued access to existing and new EU databases and expert groups, which will in turn ensure effective and efficient market surveillance of medical devices in the country. Laws and ordinances will require extensive modification 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 carrying out the legislative work in

close cooperation with Swissmedic, the State Secretariat for Economic Affairs (SECO) and the Directorate for European Affairs (DEA). The project plan maps out a multi-stage procedure that follows the transitional periods applicable to EU Member States. As a first step, revision of the Medical Devices Ordinance (MedDO) was brought forward, and the revised version entered into force at the end of 2017. In connection with the amendments to existing acts, particularly the Therapeutic Products Act (TPA) and Human Research Act (HRA), the Federal Council presented a dispatch to parliament on 30 November 2018. Both chambers will debate the amendments during 2019. The completely revised implementing legislation for medical devices is scheduled to take effect in spring 2020.

Human resources deployed on legislation work

(Hours worked rounded to the nearest 50)



- Active work on legislation (not related to projects)
- Projects involving the implementing legislation for the revision of the TPA (HMF IV), revision of the Medicinal Products Licensing Ordinance (MPLD) connection with Medicrime and 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 quality requirements – appropriate to risk and reflecting the current state of science and technology – for common, known medicinal products and pharmaceutical excipients and for certain medical devices. The pharmacopoeia makes a significant contribution to ensuring that all patients receive therapeutic products of an equally high quality. As such, it constitutes a key prerequisite for safe and effective therapeutic products. Swissmedic participates in the development of the Ph. Eur. under the terms of a treaty and issues the Ph. Helv., which contains supplementary regulations of national importance. The Pharmacopoeia division of the Agency is Switzerland's national pharmacopoeial authority.

Activities

- Switzerland made a key contribution to the production of the 9th edition of the Ph. Eur. and to its translation into German. Supplements 9.3, 9.4 and 9.5 entered into force in 2018.
- To avoid exposing humans and animals to the risk of histamine contamination, the Ph. Eur. general monograph "Products of fermentation" was revised and implemented on 1 April 2018 as an urgent amendment.
- It is essential to ensure the quality of radiopharmaceuticals that are prepared as formula-related medicinal products and are therefore exempt from authorisation. To this end Swissmedic set up a working group to prepare a chapter to supplement the "Rules of Good Manufacturing Practice for medicinal products in small quantities" (GMP small quantities) in the Ph. Helv. In addition, various sections of text in the Ph. Helv. were updated to reflect the current state of the art.
- At the beginning of June, Swissmedic held an experts' meeting for pharmacopoeia specialists. With seven presentations on current issues relating to the European and Swiss Pharmacopoeias, the experts had ample opportunity to obtain information and network

- Swissmedic – together with Swiss experts from industry, universities, community and hospital pharmacies and other authorities – performed the necessary specialist work for the Ph. Eur. and Ph. Helv. The total workload came to 8.5 person years, and 63.5 % of this work was done by the Swiss Agency for Therapeutic Products.
- A total of 131 people from Switzerland held mandates in the various national and European committees and groups working 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 authority responsible for registering technical standards suitable for specifying the fundamental requirements that medical devices must fulfil (as stipulated in Art. 45 para. 4 TPA and Art. 4 para. 3 MedDO). Wherever possible, the Agency registers internationally harmonised standards. 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 one technical committee (TC).

Activities

- In 2018, Swissmedic was active in one national technical committee.

Penal law

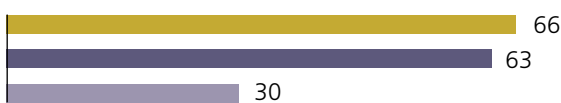
General developments

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

2018



2017



2016



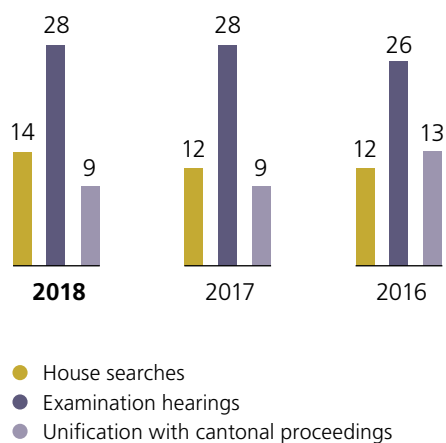
- New complaints
- Procedures closed
- Administrative penal procedures opened

Activities

- The Penal division received 71 new complaints and closed 55 cases. It opened administrative penal proceedings against 41 individuals. The workload involved in these proceedings and their complexity remains at a stable, if high, level. In addition to illegally importing 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.
- Legal work in preparation for the entry into force of the European Council's Medicrime Convention and the ordinary revision of the TPA was completed. Criminal affairs work concentrated primarily on modifications to the Licensing Ordinance (MPLO).
- Collaboration-based processes were established with Swiss Customs wherever possible in preparation for the implementation of the new legal provisions. These will have to be fleshed out and reviewed as necessary as experience is acquired. In-depth discussions were held with representatives of the Office of the Attorney General on the implementation of special surveillance measures (which will be possible from 1 January 2019). This is another area where practices will have to be developed.
- As part of collaboration with the Cantons, training courses were held for the Conference of Swiss Public Prosecutors and members of the Office of the Public Prosecutor of Basel-Landschaft. The same training will be offered to other Public Prosecutor's offices during 2019.
- In line with Swissmedic's practice of publicising decisions issued in criminal matters, two lists of decisions were communicated to accredited journalists. The first covered December 2017 to April 2018, the second the period from May to August 2018. This publicity prompted 21 consultation requests relating to the decisions and resulted in several articles that helped prevent violations of the Therapeutic Products Act. The list for September to December 2018 was communicated in January 2019.

Investigative measures

The Federal Act on Administrative Penal Law gives Swissmedic’s investigators-in-charge powers that are similar to those of a cantonal or federal prosecutor. Specifically, they can carry out house searches, seize goods or conduct examination hearings. Within the framework of an investigation, individuals affected by investigative measures are entitled to submit complaints to the Director of Swissmedic or to the Federal Criminal Court.



Activities

- Swissmedic conducted 14 house searches and 28 hearings.
- Coercive measures were enforced at the home and practice rooms of one doctor. This case required the intervention of the Cantonal Medical Officer.
- Four appeals against coercive measures on the part of Swissmedic were lodged with the Federal Criminal Court (FCC) in 2018. The FCC rejected one and refused to admit another. The third was withdrawn by the plaintiffs, who were obliged to pay costs, and the fourth is still pending. Furthermore, the FCC rejected two appeals lodged in 2017. It also admitted one request to remove the seals affixed to documents submitted by Swissmedic in 2018, and partially admitted one request submitted in 2017, declaring the remainder of the request inadmissible.
- International cooperation in criminal matters centred on Germany, since Swissmedic received one request for cooperation from the German authorities and made six in return.
- Nine cases were the subject of procedural unification, i.e. linking the prosecution to cantonal proceedings.



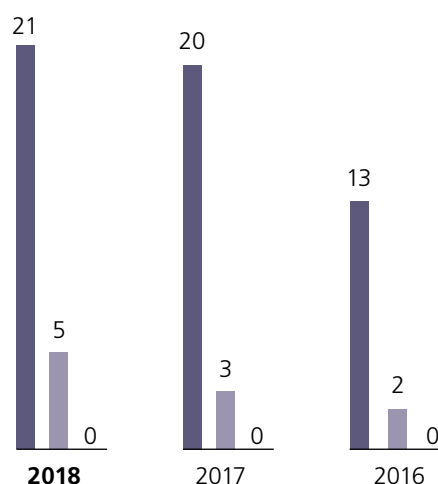
Decisions / verdicts by Swissmedic and by courts

After the investigation phase, cases are subject to a decision on a penalty. Alternatively they may be transmitted to the competent court or proceedings may be closed. Swissmedic represents the prosecution in cases that are brought before a court.

Activities

- A total of 28 natural persons and 17 legal entities were affected by the 21 penalties that were imposed. Thirteen cases concerned illegal manufacture and trading, including illegal import, export and wholesale trading. Three cases involved illegal advertising. There were also three violations of the duty to report non-compliance, two breaches of due diligence obligations and one violation of the duty to cooperate.
- Five sentences were passed following appeals against imposed penalties. Three of these concerned illegal trading, one involved illegal advertising and one was a breach of the duty to cooperate.
- Swissmedic dismissed nine cases in which suspicions were not confirmed. In two cases, the individuals concerned were obliged to pay procedural costs. Furthermore, illegal products were confiscated in two cases in anticipation of their destruction.
- The verdict of the Cantonal Court of Valais in response to an appeal by Swissmedic in a case involving the falsification of expiry dates of cancer medicines is worthy of note. The Court largely confirmed the verdict of the court of first instance. Nevertheless, it increased the penalty imposed on one of the defendants. Swissmedic lodged an appeal with the Federal Supreme Court, primarily in a bid to get the courts to recognise the health risk to patients. However, the Federal Supreme Court adhered strictly to legal precedent and rejected the appeal. Fortunately, the situation will be different in the future in that a potential (abstract) risk will be sufficient to justify a prison sentence.

- A court in St Gallen confirmed the essence of two penalty rulings issued by Swissmedic in 2017, under which a fine had been imposed on a pharmacist who had been trading wholesale in medicinal products for many years despite not having a licence to do so and had also been supplying medicinal products to a doctor who was not licensed to dispense them. The court ruling also confirmed the damages imposed on this pharmacist, which were equivalent to the profit of around CHF 40,000 that had been earned from these activities.



- Penalties imposed
- Cantonal judgements
- Federal Supreme Court judgements

Stakeholder management

Information

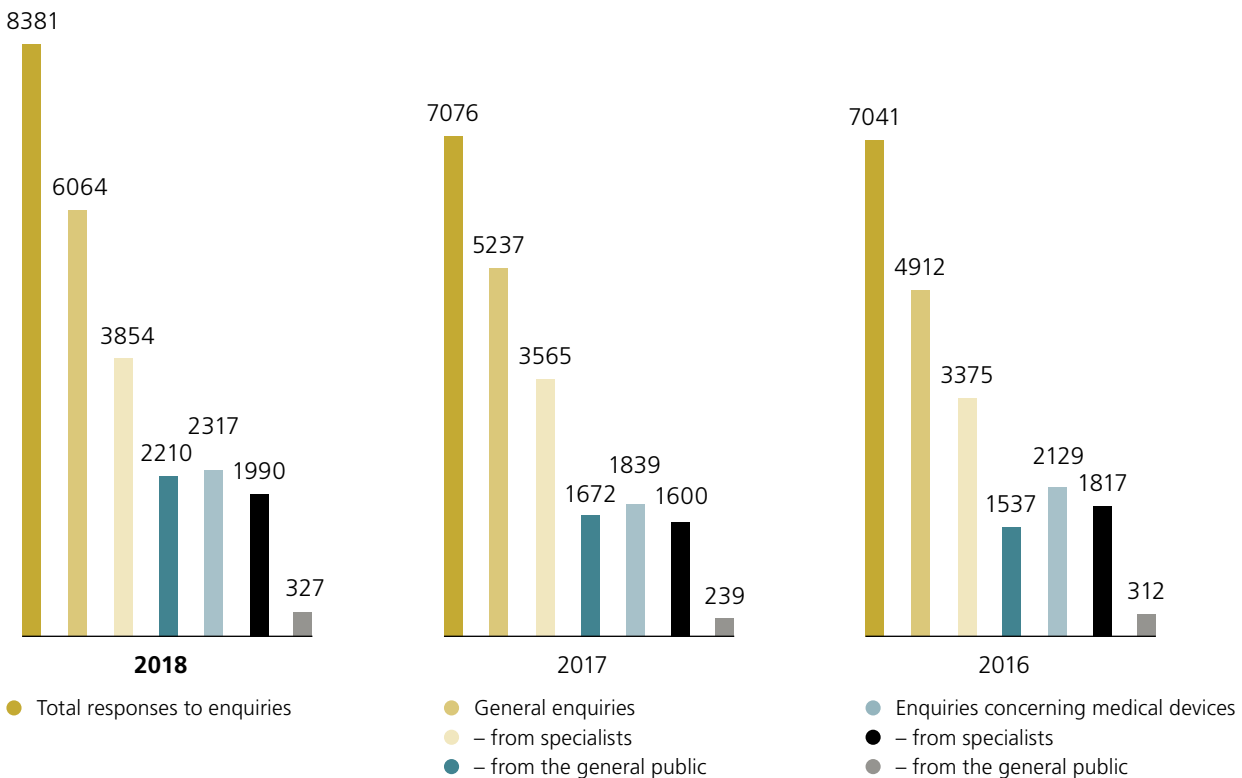
Swissmedic is quick to provide targeted information on new findings concerning therapeutic products if there is a potential risk to health. In addition to safety-relevant information, new authorisation decisions or major changes to medicinal product information are of considerable interest.

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, such 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 within this category.

Activities

- Significantly more enquiries – both general and medical device-related – were received during 2018 than in previous years.
- The most popular subjects were the impurities found in antihypertensives (the “valsartan scandal”), cannabis products and the associated accountabilities, and information on importing medicinal products for personal use.
- Additional enquiries were sparked by the new EU Regulations on medical devices and in vitro diagnostics, as well as by reporting on the “Implant Files”.
- The uncertainty surrounding the consequences of Brexit for Switzerland created further demand for information.

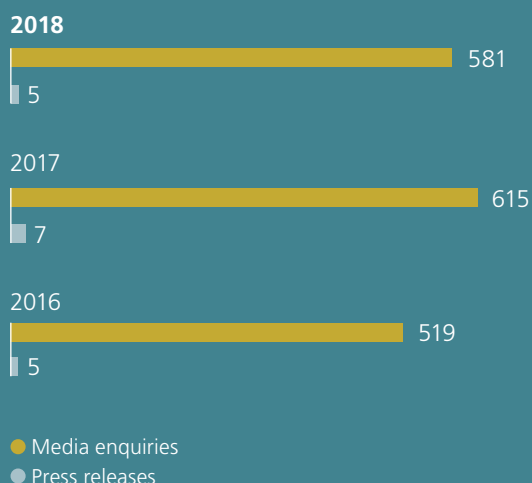


Performance indicator



Press relations

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 to provide background information or give interviews, and publishes releases for the media and the public. Swissmedic provides open, transparent information about the benefits and risks of therapeutic products and about the Agency's tasks and areas of competence in a form that laypeople in medical matters can understand and within the permitted boundaries of the law.



Activities

- Requests for information on the new features of the therapeutic products legislation that entered into force on 1 January 2019 were received throughout 2018. In particular, communications concerning medicines that had been assigned to new dispensing categories as part of the revision of the Therapeutic Products Act received a lot of coverage. There were regular reports on the possible impact of a disorderly Brexit on therapeutic product supplies.
- Cases involving the Penal Division also made the headlines. In addition to reporting on the court proceedings against Alkopharma, which was accused of falsifying the expiry dates on cancer medicines, there was also extensive coverage of certain hospitals' breaches of duty in reporting serious incidents involving medical devices.
- Towards the end of the year, the "Implant Files" became the centre of public interest. New disclosures appeared on an almost weekly basis, and Swissmedic gave several statements and interviews.
- Reporting on medicinal products revolved around the issue of impurities in sartan products.
- Several media outlets reported on the changes in practice regarding HIV self-test kit issuing after Swissmedic approved self-testing on the basis of a recommendation by the Federal Commission for Sexual Health (FCSH).

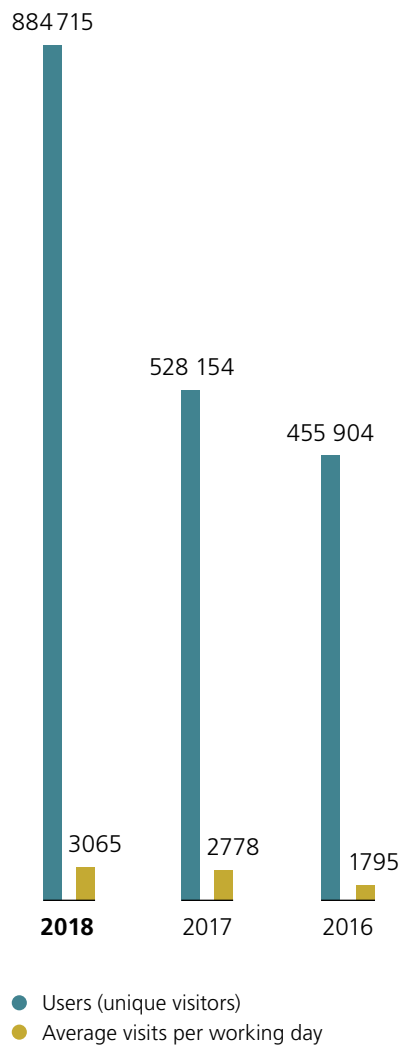
Publications

The Agency has a legal mandate to inform the public about specific events relating to therapeutic products. Announcements about first authorisations of medicines, withdrawals of authorisation, 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 through various channels (on the Swissmedic website, via electronic newsletters, in industry journals and publications by professional associations or even by writing directly to medical professionals).

Activities

- In addition to its regular publications – Annual Report, Swissmedic Journal, Vigilance News and the annual reports on haemovigilance and vaccinovigilance – the Agency produced a printed special edition of Vigilance News to coincide with the WHO's Annual Meeting of Representatives of National Pharmacovigilance Centres in Geneva.
- During 2018, Swissmedic published 31 direct healthcare professional communications (DHPCs) and over 675 safety notices and medical device recall notices. It is possible to subscribe to therapeutic product safety information as either a newsletter or RSS feed.
- The Swissmedic website www.swissmedic.ch scored significantly more page views in 2018. As in 2017, one fifth of these were from mobile devices.
- Once the Federal Council had ratified Therapeutic Products Ordinance Package IV, all the revised Agency Council ordinances and over 600 amended specification documents were published as advance information in a separate section of the Swissmedic website.

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 presentations are prepared and given by Swissmedic staff. Depending on the topic, guest speakers from other authorities or from industry may also be invited.

Swissmedic had contact with over 2,000 stakeholders at various information events, workshops and exhibitions during 2018. It organised a total of 14 events.

Activities

- The annual EuroMeeting of the Drug Information Association (DIA) took place in Basel. The organisers gave Swissmedic, as the host city's national regulatory authority, the opportunity to present itself to attendees at its own stand. With its "Taste the innovation" slogan, the stand attracted a lot of attention.
- Inspector training courses 2018: Two days of presentations and workshops were devoted to a variety of subjects, such as supplier qualification, active pharmaceutical substance and excipient suppliers, and sampling and analytically testing active substances and excipients. One presentation compared the requirements applicable to food industry quality management systems with requirements in the pharmaceutical industry. All in all, 55 participants from some 15 different countries and eight speakers (foreign GMP inspectors and industry representatives) helped make Swissmedic's training activities a success in 2018. A third half-day course for Swiss inspectors delivered insights into the changes resulting from the revised Therapeutic Products Act (TPA) and Medicinal Products Licensing Ordinance (MPLO), which entered into force in January 2019.
- Three years after the 150th anniversary of the Swiss Pharmacopoeia, another conference was held for experts in this particular field. The level of engagement shown by all attendees was impressive. Speakers from inside and outside the Agency talked about their research work, analyses and experiences.
- In conjunction with the Federal Office of Public Health (FOPH) and the Expert Commission for Radiopharmaceuticals (ECRP), Swissmedic organised the first-ever information event for manufacturers and marketing authorisation holders of radiopharmaceuticals. The issues discussed included the regulatory provisions specifically applicable to radiopharmaceuticals.
- The Swissmedic information events on the revision of the Therapeutic Products Act were keenly anticipated by stakeholders. Demand for information was so great that two events covering different subjects had to be organised. In total, more than 1,000 people attended. The results of the post-event satisfaction survey showed that attendees were satisfied to very satisfied.
- The 41st Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring was held in Geneva. Swissmedic organised this international meeting, which attracted over 200 participants from 89 different countries, in conjunction with the WHO. To coincide with the meeting, the WHO also staged a special event to mark the programme's 50th anniversary.
- The Clinical Trials division ran a half-day workshop on current issues during 2018, while the Narcotics division organised another "Narcotics information and news" event.

Transparency

The Federal Act on Freedom of Information in the Administration (FolA), which, together with the related Ordinance, entered into force on 1 July 2006, grants every individual the general right to access public documents. These include documents which relate to public mandates and which Swissmedic drew up or received after 1 July 2006. Applications to consult such documents do 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

- There was a significant year-on-year increase – from 11 to 24 – in the number of requests made under the FoIA.

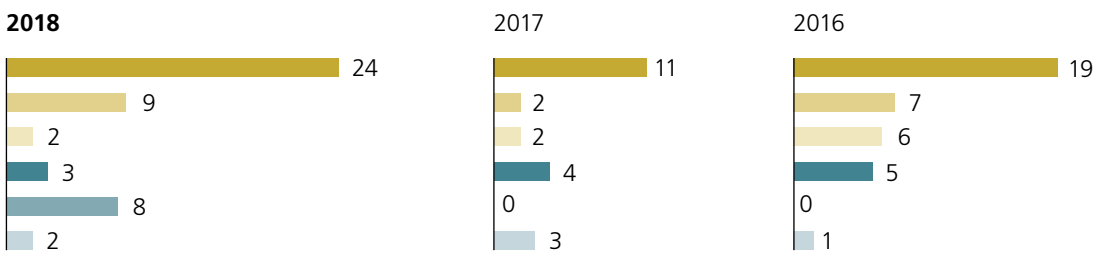
Appeals procedure regarding access to official documents

Appeals against decisions in connection with access to official documents may be lodged with the Federal Administrative Court within 30 days. That Court’s judgement may in turn be contested before the Federal Supreme Court.

Activities

- No appeals were lodged against official decisions issued under Freedom of Information legislation.
- As at the end of 2018, there were no pending appeals before the Federal Administrative Court or the Federal Supreme Court arising from Freedom of Information requests.

Appeals procedure regarding access to official documents



- Requests made under the FoIA
- Full access granted
- Access completely refused
- Access partially restricted, postponed or refused
- Pending
- Requests withdrawn

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

National-level collaboration is fundamental in enabling Swissmedic to achieve the objectives set out 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 Press relations section)

Activities

- *Meetings of the Swissmedic patient/consumer organisations working group*

The patient/consumer organisations working group continued its customary work, holding four meetings during the course of the year. Activities focused on the "Involvement in the assessment of patient information" pilot project, which kicked off on 1 June 2018. By the end of the year, the first candidate for the pilot project had already been identified. In addition, Swissmedic put various issues forward for discussion, including the first draft of a template for layperson-friendly summaries of SwissPARs. The meeting records are published on the Swissmedic website at <https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/national-collaboration/collaboration-with-patient-and-consumer-organisations.html>.

- *Collaboration with the Association of Cantonal Pharmacists (KAV)*

The annual meeting between Swissmedic and the Association of Cantonal Pharmacists (KAV) took place on Friday 16 March. Swissmedic gave KAV representatives a briefing on legal matters (including the status of consultation proceedings for the TPA ordinance package), authorisations (supplying medicinal products to doctors for their own use) and market monitoring (including the issue of distinguishing medicinal products from medical devices, reviewing the status of CBD products and hospital inspections during 2017). In turn, the KAV raised the issue of access to inspection reports. On 29 November, Swissmedic gave Cantonal Pharmacists another full briefing on the changes resulting from H MV IV at their training day in Bern. The briefing focused on the reclassification of medicinal products in different dispensing categories, the changes to the MPLO and other enforcement-related issues.

- *Swiss Medtech conference*

Along with representatives of the FOPH and SECO, Swissmedic participated in the national conference held by Swiss Medtech on 28 March 2018 to discuss the impact of the new EU Regulations governing medical devices and in vitro diagnostics (MDR/IVDR). The conference highlighted the challenges arising from the new Regulations, while the breakout sessions provided an opportunity to discuss specific issues. The attendance figure of 450 is a reflection of the strong interest in the subject.

- *Regulatory Affairs round table meetings with pharmaceutical industry associations*

Three Regulatory Affairs round table meetings with industry association representatives took place during 2018. The round tables are an opportunity to share information on current issues and for each side to ask and discuss questions. The subjects covered included applications for vaccines, the IDMP technical data scheme, the new practice for positive and negative declaration of excipients, and changes resulting from H MV IV.

- *Meetings with complementary and herbal medicine (CHM) stakeholder associations*

The annual meeting between Swissmedic and CHM stakeholders took place on 23 May 2018. It focused mainly on a review of the outcomes of the CHM division's activities during 2017 and the changes associated with H MV IV.

- *Regulatory Affairs round table for veterinary medicinal products*

A delegation from ten veterinary medicinal product distributors headed by Scienceindustries met with Swissmedic in Bern on 14 June 2018. There were briefings and discussions on various topics, including the HMV IV package and the changes it entails for this stakeholder group.

- *Information event for healthcare professionals*

The first information event to be held under Swissmedic's revamped collaboration with associations and organisations representing healthcare professionals took place on 20 June 2018. The event focused on the implementation of the revised Therapeutic Products Act and associated therapeutic products ordinances.

External continuing training initiatives and specialist presentations

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

International collaboration

Collaboration among authorisation and supervisory authorities and with international organisations active in the medicinal products and medical devices field is extremely important for stakeholders, for Switzerland as a location, and for Swissmedic. Efforts focus on exchanging information throughout the medicinal product authorisation process, market surveillance, and preparing new draft legislation related to therapeutic products. For example, collaboration with authorities from other countries and with international institutions makes it easier to identify a therapeutic product's risks at an early stage and to initiate coordinated measures.

International network

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

International collaboration on therapeutic products regulation does not only take place between individual authorities at a bilateral level; increasingly it is occurring multilaterally on different platforms. Swissmedic is heavily involved in the commissions and working groups that have been set up by these platforms where these are pertinent to the Agency's role.

Activities

Bilateral collaboration

- In September 2018, Swissmedic signed a Memorandum of Understanding (MoU) with the Netherlands Medicines Evaluation Board (MEB). Although not legally binding, the MoU creates a formal basis for intensified collaboration and for bilateral initiatives. Both Swissmedic and the MEB will benefit from greater information sharing. The two authorities are also involved in global multilateral initiatives such as the International Coalition of Medicines Regulatory Authorities (ICMRA). Closer cooperation between Swissmedic and MEB therefore benefits both parties and will help them accomplish their mission efficiently.

- As in previous years, there was an exchange with the Agency's current partner authorities on certain operational and strategic topics during 2018. For example, a delegation from the German Federal Institute for Drugs and Medical Devices (BfArM), led by the Institute's President, visited Swissmedic in January. The aim of the visit was to pick up from the last meeting between the two authorities in 2016 and to continue their dialogue on authorisations, market monitoring, IT and international activities. During the visit, there was also a discussion on what effect the new MDR and IVDR would have on the authorities' activities.

In February, the Austrian Agency for Health and Food Safety Ltd. (AGES) visited Swissmedic. Again, discussions centred on the new medical devices regulation.

- Swissmedic continued its dialogue with the Korean regulatory authority on mutual recognition of Good Manufacturing Practice (GMP) certificates.

Multilateral collaboration

- *ICH meeting in Kobe, Japan, and Charlotte, USA*
The International Council for Harmonisation (ICH) met in Kobe, Japan, from 2 to 7 June 2018, and in Charlotte, USA, from 10 to 15 November.

The meeting in Kobe elected additional members to the ICH's Management Committee. In addition to the Founding and Standing Members, the Management Committee now includes the authorities from China (CFDA), Singapore (HSA) and South Korea (MFDS) as regulatory members, as well as BIO and IGBA as industry members. In the course of its decision-making, the ICH Assembly approved the Chinese Taipei Food and Drug Administration (TFDA) as a new Regulatory Member, and the Moldovan (MMDA), Armenian (SCDMTE) and Turkish (TITCK) authorities as new Observers. The Charlotte meeting welcomed Iran's national regulatory authority as a new regulatory observer. The meeting was a clear illustration of the ICH's ongoing development into a global initiative. Three years after the ICH was reformed, all organisational changes have now been implemented. The ICH currently has 16 members and 28 observers. Swissmedic's Dr. Petra Dörr was elected Vice Chair of the ICH Assembly at the Charlotte meeting, while Dr. Theresa Mullin from the US FDA was re-elected Chair of the ICH Management Committee. Dr. Nobumasa Nakashima (MHLW/PMDA, Japan) was elected Vice-Chair of the ICH Management Committee.

- *International Pharmaceutical Regulators Programme (IPRP)*
Following the merger of the International Pharmaceutical Regulators Forum and International Generic Drug Regulators Programme to form the International Pharmaceutical Regulators Programme (IPRP), the first meeting of the IPRP's Management Committee was held in Kobe, Japan, in June. The meeting focused on finalising and adopting the IPRP's terms of reference, developing a standard operating procedure and designing a strategy for the period from 2018 to 2020. The second meeting of 2018, held in Charlotte, USA, in November, completed the operationalisation of the IPRP. The IPRP now has its own website at <http://www.iprp.global/home>.

- In addition, two meetings of the IPRP's Bioequivalence for Generics and Quality for Generics working groups were held during the period under review. One of these took place in Bern. The Bioequivalence for Generics working group's activities focused on completing various publications. The Quality for Generics group worked primarily on the pilot ASMF/DMF database.

- *International Coalition of Medicines Regulatory Authorities (ICMRA)*

The ICMRA plenary meeting held in Basel in April heard reports on the progress made by the individual working groups. The key innovation-related topics addressed by the three working groups and discussed at the ICMRA summit in September 2018 were: "Biosimilars – Ensuring Quality", "The Science of the Patient Voice" and "Regulatory Strategies in a Developing Innovative and Technological Landscape, A Comprehensive Policy Framework for Regenerative Medicine Products". Once again, the individual ICMRA working groups gave progress reports. In addition, there was a resumption of the discussion on the future of ICMRA and its strategic direction.

- *ACSS Consortium*

The heads of the member agencies of the ACSS Consortium met twice during 2018, once in April and again in September. The meetings reviewed progress on ongoing projects and discussed the strategic areas that the Consortium will be focusing on in the future. Top of the agenda here is the issue of work sharing. Swissmedic hosted the 14th meeting of members of the ACSS Generic Medicines Working Group in Bern. Discussions centred on the Generics Medicines Work Sharing Trial (GMWST), experience gained and lessons learned, and on continuing the trial with additional candidates.

- *DIA EuroMeeting, 17–19 April 2018 in Basel*

Swissmedic chaired two sessions at the 2018 DIA EuroMeeting in Basel. The first day of the meeting saw the signature session, which was held in cooperation with the WHO and entitled "Towards access 2030: How can strengthening of regulatory systems contribute?" After two input presentations by representatives of the WHO and the Ghanaian regulatory authority, a panel discussed issues associated with attempts to strengthen therapeutic products agencies. At the session on globalisation, reliance and work sharing on 18 April, two specific examples of work sharing – the Generic Medicines Work Sharing Trial (GMWST) and the

International Generic Drug Regulators Programme (IGDRP) – were presented. Furthermore, the Agency had an opportunity to introduce itself and its work to attendees at its “Taste the Innovation” stand.

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), the FDHA and the FDFA. The overriding aim of cooperation is to help improve and expedite access to healthcare and medicines in low-resource countries.

Activities

- *Finance agreement between Swissmedic and Bill & Melinda Gates Foundation*

Swissmedic is currently implementing a finance agreement with the Bill & Melinda Gates Foundation which originally covered the period from 2016 to the end of 2018. Under this agreement, the services that Swissmedic provides are defined by specific measures. However, since projects have been slower getting off the ground in the past three years than originally planned, the agreement has been extended by one year to the end of 2019. Swissmedic will continue to implement the agreement throughout the year.

- *Supporting the African Medicines Regulatory Harmonisation (AMRH) initiative*

The first development cooperation project in which Swissmedic is involved provides support for the African Medicines Regulatory Harmonisation (AMRH) initiative, focusing primarily on the East African Community (EAC) and the Economic Community of West African States (ECOWAS). During 2018, Swissmedic continued to support the EAC’s joint assessments in various ways, including contributing its clinical expertise in reviewing authorisation dossiers. The Agency also helped the East African Community develop harmonised guidelines and provided on-the-spot support for information management systems by attending meetings of the relevant working groups. Swissmedic was also represented at the three EAC steering meetings. The first Steering Committee meeting for the West African Medicines Regulatory Harmonization (WA-MRH) programme took place in Ouagadougou, Burkina Faso, in July 2018. Swissmedic

took part in the meeting, giving a presentation of the cooperation options to the 15 attending ECOWAS countries and the WA-MRH programme secretariat.

- *Marketing Authorisation Procedure for Global Health Products (MAGHP)*

Under the second development cooperation project, African regulatory authorities and the WHO are included in a Swissmedic evaluation process for products to treat diseases that primarily affect people in southern Africa. New applications for medicinal products containing either new or known active substances are eligible for this Marketing Authorisation Procedure for Global Health Products (MAGHP), as are extensions into new applications. The MAGHP also provides a channel for obtaining scientific advice; the procedure is in the pilot phase, and initial experience is being acquired.



Special activities and events: Stakeholder management

AMRH Partnership platform

In February 2018, the New Partnership for Africa's Development (NEPAD), the political arm of the African Union, issued a call for expression of interest to join the African Medicines Regulatory Harmonization Partnership Platform (AMRH-PP). The AMRH-PP is a coordination mechanism in efforts to effectively group, foster transparency among and supervise the various partners and interest groups that support the superordinate AMRH initiative on the African continent. The AMRH-PP is the Africa chapter of the World Health Organization Coalition of Interested Parties (WHO-CIP). Swissmedic applied to join, and its expression of interest was endorsed in August 2018. The Agency is now an official technical partner (member) of the AMRH-PP and attends Steering Committee meetings of the AMRH as an observer. Swissmedic took part in the two African Medicines Regulatory Harmonization weeks under these auspices.

18th ICDRA in Dublin, 3 to 7 September 2018

The 18th International Conference of Drug Regulatory Authorities (ICDRA) took place in Dublin in the first week of September. Its theme was "smart safety surveillance". The ICDRA takes place every two years and is organised by the WHO in conjunction with a national regulatory agency. The Dublin event was attended by some 500 participants from over 100 countries. Swissmedic was represented by a four-person delegation headed by the Deputy Executive Director and made active contributions to various sessions, for example at the pre-ICDRA plenaries entitled "Regulatory collaboration, convergence and harmonisation: transfer of regulatory information" and "Partnerships to enhance better regulatory outcome", and by giving presentations on "WHO strategic approaches to improving access to safe medical products" and "Safety of blood and blood products" at the subsequent ICDRA sessions.

Information technology and telecommunication

IT management

IT management handles the strategic and operational planning and provision of information and communication technology (ICT). Key tools in doing so are the strategic direction of IT services, IT architecture and short- to long-term project planning. IT management is responsible for cost-effective, legally compliant procurement, sustainable development and the stable, secure availability of IT resources and services.

Activities

- Activities focused on adapting business processes and the supporting ICT systems in preparation for the entry into force in 2019 of the revised Therapeutic Products Act and its implementing provisions.
- IT innovation management was expanded. This involves the IT unit working in a dialogue with the business areas to analyse the effects on Swissmedic of current technical developments such as algorithmics, big data, real-world evidence, the Internet of things and deep learning. Suitable measures are then developed.
- The dialogue between the business areas and IT on project planning was also intensified and put on a more formal footing. As a result, it is now possible to obtain a more holistic view of the business requirements that IT has to fulfil, and consequently to use synergies more effectively.
- Reviews of IT processes focused on archiving and information security.

Solution development

Implementation of the projects road map represents an important foundation in achieving 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

- Four parallel work packages created the framework for introducing the new processes associated with the revision of the Therapeutic Products Act and its implementing provisions and the revision of the Medicinal Products Licensing Ordinance in preparation for the implementation of the Medicrime Convention. The new and modified functions went live at the end of December so they would be ready for use starting in January 2019.
- A new and optimised IT application for pharmacovigilance notifications was rolled out in mid-2018.
- Additional eGovernment services that include authorisation documents, product certificates and GMP/GDP certificates came on stream.
- As the authority responsible for enforcing the revised legal provisions governing medical devices, Swissmedic has until May 2020 to make all necessary preparations for implementing the new medical devices regulations in Switzerland. Accordingly, the project set up to deliver the appropriate processes, forms, documents and systems started work at the end of 2018.
- In mid-2018, a new IT application that provides support for the authorisation of Asian medicinal products without an indication under the notification procedure was rolled out.

IT operations, user support, maintenance and continuous 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 support management has the vital task of delivering and overseeing these support capabilities.

Activities

- The public tendering process for bids to replace the central IT platform and internal first-level IT support in the medium term was successfully completed.
- Swissmedic employees are now benefiting from a simplified, clearer time recording system.
- A new IT workplace system was designed.

Corporate Governance

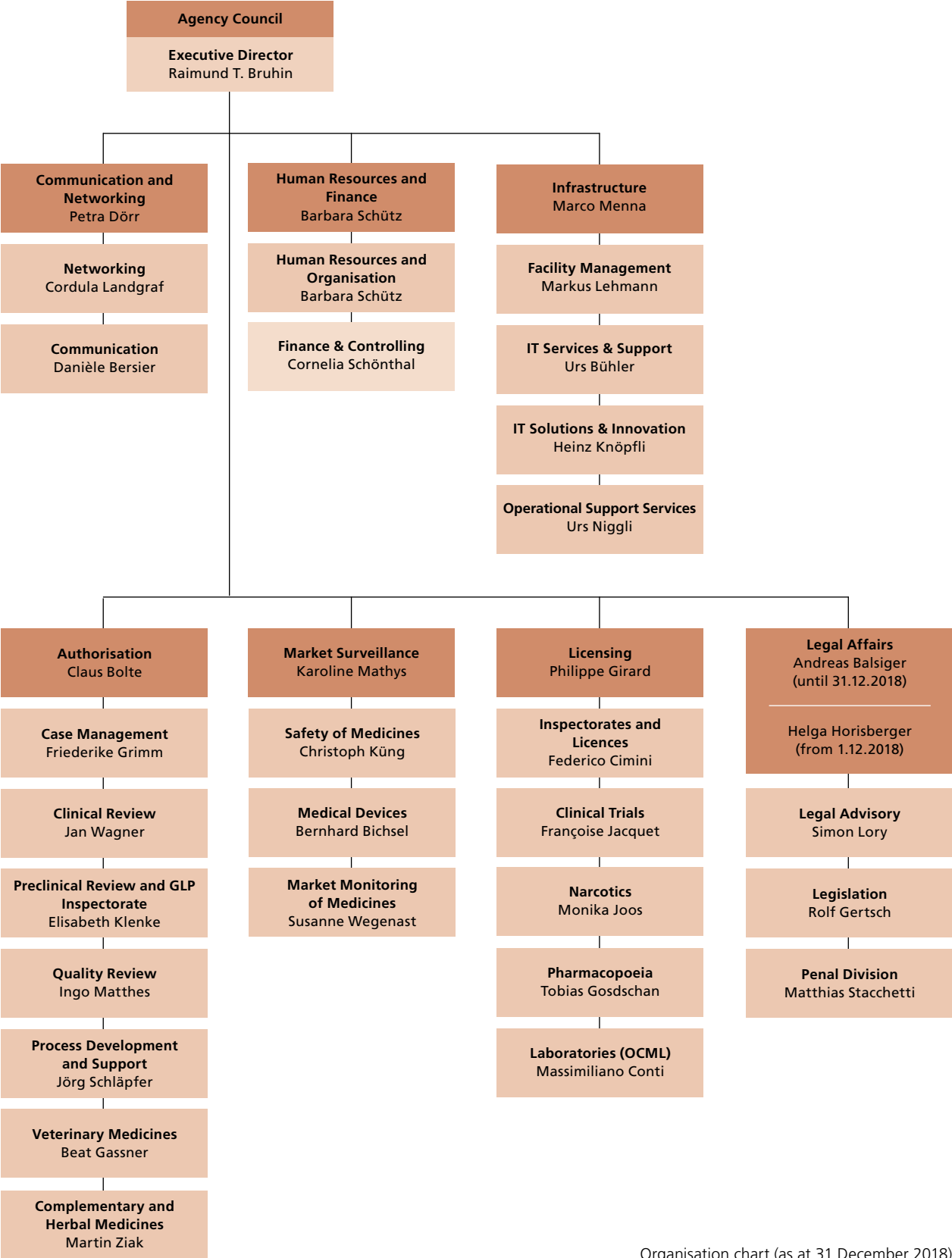
Organisation

Swissmedic is the Swiss regulatory and control authority for therapeutic products. Its activities derive from Switzerland's 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. The Swiss Agency for Therapeutic Products is a Bern-based federal public institute that is independently organised and managed, and has its own budget.

The public services it provides 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 medicinal product quality
- Drawing up standards
- Providing information
- National and international cooperation



Organisation chart (as at 31 December 2018)

Revenues

Swissmedic is financed through fees and levies, payments from the federal government for public services provided 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 2018	As a percentage of total revenues
Fees	33,183	35.93 %
Levies	44,662	48.36 %
Payments from the federal government	14,056	15.22 %
Payments received for services rendered to third parties	150	0.16 %

Agency Council

The Agency Council is Swissmedic's supervisory body. It comprises 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 is also tasked with approving the Swissmedic budget, annual accounts and Annual Report. The Agency Council's responsibilities are set out in Art. 72 of the Therapeutic Products Act (TPA; the applicable version in the reporting year).

The Agency Council comprises the following members (as at 31 December 2018):

Member	In office since
Dr. Stéphane Rossini (C)	2018
Ms. Vincenza Trivigno (VC)	2016
Dr. iur. Lukas Engelberger	2017
Prof. Olivier Guillod	2014
Prof. Reto Obrist	2010
Prof. Marie-Denise Schaller, MD	2018
Mr. Giovan Maria Zanini	2014

C = Chair; VC = Vice-Chair



Chair
Stéphane Rossini,
Dr.

Professor & Consultant,
Universities of Geneva and
Neuchâtel; R&EEC Etudes
Evaluations Conseils



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



Marie-Denise Schaller,
Prof. MD

Retired; chief physician,
department of Adult
Intensive Care Medicine,
Lausanne University Hospital



Lukas Engelberger,
Dr. iur., LL.M.

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



Giovan Maria Zanini,
Pharmacist

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



Olivier Guillod,
Prof. Dr.

Director of
the Health Law Institute
Neuchâtel, Neuchâtel

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

Management Board

The Management Board is an advisory body tasked with assisting the Executive Director. It comprises members selected by the Agency Council at the request of the Execu-

tive Director (Art. 72 para. 1 h TPA). The Management Board comprises the following members (as at 31 December 2018):



**Raimund T. Bruhin,
Dr. med.**

Executive Director



Helga Horisberger

Head of Legal Affairs –
Member of the Management
Board



**Claus Bolte,
Dr. med.**

Head of Authorisation –
Member of the Management
Board



**Karoline Mathys
Badertscher,
Dr. pharm.**

Head of Market Surveillance –
Member of the Management
Board



**Petra Dörr,
Dr.**

Head of Management Services
and Networking – Deputy
Executive Director; Member of
the Management Board



**Marco Menna,
Dr.**

Head of Infrastructure –
Member of the Management
Board



**Philippe Girard,
Dr.**

Head of Licensing – Member of
the Management Board



**Barbara
Schütz Baumgartner**

Head of Human Resources and
Finance – Member of the
Management Board

The CVs of the individual members of the Management Board can be found on the Swissmedic website.

Remuneration

Remuneration for the Agency Council in 2018 totalled CHF 189,000 (including expenses), of which CHF 41,000 was paid to the Chair.

The total remuneration paid to the Management Board (Executive Director plus 7 members of the Management Board) was CHF 1,876,642. The salaries paid to the Executive Directors (the former and then the present Executive Director as of April 2018) totalled CHF 296,634.

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 2018 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 2018 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 2018

Chairman: Rossini Stéphane, Dr.

Engelberger Lukas, Dr. iur.

Guillod Olivier, Prof. Dr.iur.

Obrist Reto, Prof. Dr. med.

Schaller Marie-Denise, Prof. MD

Vincenza Trivigno, lic. rer. pol

Zanini Giovan Maria, pharmacist

Members of the Human Medicines Expert Committee (HMEC)

Current as at December 2018

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.

Cerny Thomas, Prof. Dr. med.

Dayer Pierre, Prof. Dr. med.

Schild Laurent, Prof. Dr. med.

Vogt Markus, Prof. Dr. med.

Extraordinary members

Aicher Lothar, Dr. rer. nat.

Ballmer-Weber Barbara, Prof. Dr. med.

Beglinger Christoph, Prof. Dr. med.

Borner Markus, Prof. Dr. med.

Buser Katharina, Dr. med.

Caldelari Reto, Dr. phil. nat.

Cavin Frédy, phil. nat.

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.

Klenke Frank, PD Dr. med. and Dr. phil. nat.

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.

Özsahin Hülya, Prof. Dr. med.

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.

Wicki Andreas, PD Dr. med. and Dr. phil.

Wilks Martin F., Prof. Dr. med.

Wolf Ursula, Prof. Dr. med.

Yerly Daniel, Dr. phil. nat.

Zangemeister-Wittke Uwe, Prof. Dr. phil. nat.

Zimlich Klaus-Heinrich, Dr. rer. nat.

Advisory members

Angelillo Anne, Prof. Dr. med.

Heinrich Michael, Prof. Dr. rer. nat.

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 2018

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

Ordinary members

Brunner Katharina, Dr. med. vet.

Glaus Tony, Prof. Dr. med. vet.

Hemphill Andrew, Prof. Dr. phil. nat.

Meylan Mireille, Prof. Dr. med. vet.

Naegeli Hanspeter, Prof. Dr. med. vet.

Perreten Vincent, Prof. Dr. sc. tech.

Extraordinary members

Hoop Richard, Prof. Dr. med. vet.

Kümmerlen Dolf, Dr. med. vet.

Ruoff Kaspar, Ph.D.

Schmidt Andreas, Dr. med. vet.

Spadavecchia Claudia, Prof. Dr. med. vet.

Wahli Thomas, Prof. Dr. phil. nat.

Zinsstag Jakob, Prof. PhD DVM

Auditors

Swiss Federal Audit Office (SFAO)

Our staff – our capital

Current as at December 2018

Direktor

Bruhin Raimund T.

Executive Director

Balsiger Betts Andreas (until 31.12.18), Bolte Claus, Dörr Petra, Girard Philippe, Horisberger Helga (from 1.12.18), Mathys Badertscher Karoline, Menna Marco, Schütz Baumgartner Barbara

Our staff

Abegglen Julia, Aebischer Kathrin, Aeschbacher Monique, Aguirre Anouk, Albayrak Mehmet, Amstutz Yann, Andrejic Milan, Arnheiter Larissa, Bachmann Beat, Baeriswyl Gerda, Bailat Sylvie, Balli Sandra, Bapst Astrid, Bärtsch Martin, Bastardoz Sophie, Baumann Yvonne, Bellac Caroline, Bellwald Patricia, Berger Christoph, Bersier Danièle, Bichsel Bernhard, Bill Helena, Bitschnau Monika, Blanco Philippe, Blankenbach Kira, Blaser Beatrice, Blum Markus, Bögli Katja, Bögli-Schlüchter Franziska, Böhlen-Walther Caroline, Böhm Steffen, Bolli Richard, Bolte Claus, Borissov Petya, Borner Stefan, Boschung Andrea, Boschung Livia, Breuer Iris, Brockmann Silke, Bruhin Raimund, Brunner Stefan, Brunner Silvio, Büchi Jacqueline, Büchler Monika, Buchs Renato, Buchter Linda, Bühler Urs, Bur Kathrin, Bürge Michaela, Burgener Roger, Burgener Julia, Burkhalter Gabriele, Burri Michael, Carrel Nadja, Carulli Amico Sabina, Cavaliero Tania Cecilia, Chatelain Barbara, Chodup Piotr, Christen Tobias, Cimini Federico, Cina Susanne, Cipolli Francesca, Claussen Antonia Carlota, Cochard Nicole Sylvie, Cokoja Adisa, Colangelo Elena, Conti Massimiliano, Coso Marija, Crottet Pascal, Dalla Torre Simon, Damke Beat, De Matteis Isabella, Déverin Olivier, Dexheimer Petra, Diel Carolin, Diethelm Markus, 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, Ehmann Richard, Ehrensperger Edmund, Ehrensperger Murri Eva, Endress Eva-Maria, Endrich Michael, Engel Marie-Helene, Escandari Markus, Essen Renate, Essers Dirk, Eugster Urs, Eyal Eva, Eyquem Jeanne, Fahrni Ursula, Federer-Oetliker Martina, Feldmann Danila, Ferbitz-Scheurer Simone, Filgueira David, Fischer Lisa, Fischer Bernt, Flechtner Olivier, Fotinos Nicolas, Franscini Nicola, Fritzsche Constanze, Fuchs Sebastian, Fuhrer Therese, Furer Andreas, Gafner Verena, Gamma-Lauber Madeleine, Gassner Beat, Gaudesius Giedrius, Gautschi Matthias, Geluk Charlotte, Gertsch Rolf, Gilgen Michael, Gilgen Bernadette, Giovannangelo Céline, Girard Philippe, Glauser Daniel, Gloor Eveline, Gloor Nora, Gobet Magali, Gosdschan Tobias, Gottofrey James, Graber Angelika, Grimm Friederike, Grüter Eric, Grütter Daniela, Grützmacher Barbara, Guggisberg Stefan, Gugler Claudia, Gulkowska Anna, Gürtler Rolf, Gysin René, Häberli-Airoldi Isabelle, Haeggeli Christine, Hahn Spielmann Véronique, Haldemann Silvia, Hammel Mario, Häni Brigitte, Hatibovic Maja, Häuptli Daniel, Häuptli Thomas, Häuptli Michelle, Hausammann Georg, Häusermann Monika, Hediger Ronald, Heneka Bilkis, Hernandez Perni Maria Engracia, Herren Daniel, Herrli Stefan, Herzog Barbara Suzanne, Hess Lorenzo, Hildebrand Pius, Hofmann Linda, Hofstetter Christiane, Horisberger Helga, Horn-Lohrens Ottmar, Hottiger Thomas, Hotz Rolf, Huber Elisabeth, Huber Cornelia, Huber Jasmina, Hug-Michel Christine, Hürlimann Maria, Hürlimann Daniel, Iovino Mario, Jaggi Lukas, Jahn Katrin, Jaquet Françoise, Järman Stephan, Jentzsch Christoph, Jéquier Martine, Jermann Ronald, Johner Regula, Joos Monika, Joye Laetitia, Jungo Jacqueline, Junker Christian, Juritz Stephanie, Käser Sandra, Käser Michèle, Käsermann Donald, Keller Michel, Keller Michael, Kempná Bukovac Petra, Keusen-Weyermann Katrin, Kindler Adrian, Kläy Barbara, Klenke Elisabeth, Kleppisch Thomas, Knöpfli Heinz, Kocher-Guggisberg Beatrice, Koeninger Franziska, Köhli Michael, Kolly Philippe, Krayenbühl Jean Christian, Krebs Franziska, Krebs Michael Oliver, Kühni Martin, Kummer Robert, Kung Christoph, Kunz-Greub Marianne, Kuster André, Lack Adena, Landgraf Cordula, Langenkamp Anja, Langer Barbara, Langos-Mabboux Manuela, Lany Catharina, Lapke Conwitha, Lauer Gabriele, Lavanchy Vincent, Le Stanc Pascale, Lehmann Thomas, Lehmann Markus, Leidreiter Kirsten, Leist Roman, Leu Martin, Leuenberger Beat, Leuenberger-Bischoff Monika, Leyens Lada, Linder Ursula, Liniger-Thommen Andrea, Lippmann Hans-Georg, Lochmatter Cecchetto Priska, Löffel Werner Patrik, Löhr Kottmann Ingrid, Lory Simon, Lottaz Daniel, Lucas Christine, Ludwig Ljubica, Luginbühl-Weber Karin, Lüthi-Wyss Nicole, Lütolf Natalie, Maier Ralph, Manolio Silvana, Marazzi Céline, Marrer Edith, Marti Andreas, Mathys Badertscher Karoline, Matthes Ingo, Maurer Jessica Maria, Meincke Ricarda, Menna Marco, Meseguer Georges, Messerli

Nicole, Messi Mara, Meusburger Madeleine, Meyer Urs, Meyer Rita, Meyer Simon, Meyer Ulrike, 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, Nikolic Danijela, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Nyffeler Chiara, Op den Camp Roeland, Osswald Tschan Marco, Pagan Madrid Francisco, Paganini Lodovico, Paniga Nicoletta, Pavelic Ferretti Danijela, Pecaric Petkovic Tatjana, Pereira Claudia, Perez Eugenio, Pernusch Jenny, Petkovic Vibor, Pinsard François, Plüss Ruth, Polatti Daniela, Porporini Lucio, Prisching Andrea, Prost Francine, Puliafito Anita, Pürro Michel, Rached Eva, Ramelli Monica, Rätz Katerina, Remund Thomas, Renaudin Michael, Renftle Wolfgang, Reusser Daniel, Rickenbacher Nadja, Rieder Barbara, Riem Nicole, Riesen-Beer Sabine, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Rohr Ulrich-Peter, Roost Matthias, Roth Daniel, Roux Catherine, Ruch Claudia, Rüfenacht Francine, Rumo Anton, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sängler Michael, Santhirasegarar Luxshana, Satarasinghege Don Sandya, Schade Bettina, Schaffner Nils, Schärer Christian, Schäublin Martina, Scheidegger René, Scheidegger Michelle, Schläpfer Jörg, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Egger Dorit, Schnyder Benno, Schochat Thomas, Schöni Damian, Schönthal Cornelia, Schumacher Thérèse, Schütz Baumgartner Barbara, Schwab-Stampfli Rebekka, Schwartz Thomas, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Senessie Charles, Sergejew Thomas, Sieg Anna, Sifrig Lia, Sommer Andrea, Sorg Regula, Spohn Margot, Spörri Bernhard, Spring Andrea, Stacchetti Matthias, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stämpfli Ursula, Stauber Selina, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Steinle Patrizia, Strack Guido, Straub Andrea Katharina, Sulser Mario, Tanner Yvonne, Tanner Soland, Eveline Terkovic, Attila Leo, Teuscher Françoise, Thiess Maria, Thürig Soltermann Eva, Toma Valeriu, Tromp Jan, Tschalär Yolanda, Tschanz Lara Timea, Tschirren Markus, Tschopp Florence, Tschui Janie, Unger Matthias, Utiger Christoph, Vihertola Mari, Vilei Edy, von Mühlernen Eva, Vonlanthen Bianca, Wacker Christoph, Wagner Jan, Wälchli Sabine, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Walther Chantal, Wälti Rudolf, Wälti Markus, Waser Isabelle, Waser René, Weber Heidi, Wegenast Susanne, Wegmann Barbara, Weissmahr Richard, Weix Janine, Weller Katja, Werder Carine, Weyermann Philipp, Weyermann Andrea, Whitehead Margaret, Whitehead Frances, Wieland Christa, Wiget Jasmine, Wildner Oliver, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wittwer Regina, Wullimann Esther, Wullschleger Stefan, Wüthrich Karin, Wyss Martin, Wyss Brigitte, Wyss Kaspar, Wyss-Romanello Sabine, Zamboni Gabriella, Zaugg Kunz Sandra, Zbinden Raphael, Zemp Markus, Ziak Martin, Ziehli Salvisberg Mariette, Zurbuchen Andreas, Zurkinden Tanja

Income statement

(in KCHF)

	2018	2017
Procedural fees and income further to Art. 69 TPA	42,104	41,173
Levies on sales	44,662	44,891
Other income	383	230
Federal contribution	14,056	14,346
Other operating income	56	89
Loss of revenues from procedural fees	-8,920	-8,917
Net income	92,341	91,812
Services for third parties	-1,128	-1,220
Personnel	-57,006	-63,110
Rental, maintenance, energy, transport and insurance	-2,442	-2,702
Administration	-4,206	-4,377
IT	-9,940	-9,934
Other expenditure	-269	-283
Amortisation	-5,555	-5,742
Total operating expenditure	-80,546	-87,368
Operating income	11,795	4,444
Financial income	10	5
Financial expenditure	-149	-157
Financial result	-139	-152
Gain / Loss	11,656	4,292
Statement of comprehensive income (in KCHF)	2018	2017
Gain / Loss	11,656	4,292
Other income	-8,349	-1,589
Actuarial (losses) gains	3,307	2,703
Total comprehensive income	3,307	2,703

The full, detailed financial report containing the annual accounts for 2018 can be ordered by telephone or downloaded from our website www.swissmedic.ch (under the section "About us/Publications").

Balance sheet

(in KCHF)

	as at 31.12.2018	as at 31.12.2017
Cash and cash equivalents	2,081	863
Receivables from sales and services	19,256	20,894
Other receivables	4,886	0
Prepaid expenses	59	46
Current assets	26,282	21,803
Fixed assets	3,173	4,207
Immovable property	70,009	71,650
Intangible assets	2,798	4,473
Capital assets	75,980	80,330
Total assets	102,262	102,133
Commitments on sales and services	4,563	5,088
Other commitments	1,327	11,892
Deferred income and short-term provisions	3,780	3,812
Short-term commitments	9,680	20,792
Long-term fixed advances, long-term financial liabilities	10,000	10,000
Provisions for loyalty bonuses	2,734	2,675
Provision for pension fund commitments (net)	58,509	56,134
Long-term commitments	71,243	68,809
Gain / Loss	11,656	4,292
Reserves	12,886	3,094
Endowment capital	14,500	14,500
Accumulated actuarial losses	-17,703	-9,354
Own capital	21,339	12,532
Total liabilities	102,262	102,133

Products funded mainly by the Confederation

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result based on product accounting
Legal foundations	-6,198	0	-6,198
Information for the general public	-2,910	3	-2,907
Medical devices vigilance	-3,154	0	-3,154
Market monitoring of medical devices	-4,277	156	-4,121
Penal law	-2,114	1,018	-1,096
Total products funded mainly by the Confederation	-18,653	1,177	-17,476
Total Federal contributions			14,056
Expenditure surplus			-3,420



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

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

