swissmedic

Annual Report 2016

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

Leitbild Swissmedic

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The Agency Council currently comprises the following members (from left to right): Peter M. Suter, Olivier Guillod, Carlo Conti, Christine Beerli, Vincenza Trivigno, Reto Obrist, Giovan Maria Zanini

Foreword by Christine Beerli

Ready to meet future challenges

2016 was a year characterised by phrases such as "post-trust society", "fake news" and "alternative truth". What does this mean for a regulatory and economic oversight authority like Swissmedic, which works on the basis of scientific evidence and in whose results the population places its trust?

Moreover, how can we take account of the population's justified interest in simplification and individual responsibility while at the same time keeping the door closed to risks that would cause a public outcry if they became reality?

Parliament has marked out the path with the revision of the Therapeutic Products Act (TPA), and during 2016 Swissmedic and the Federal Office of Public Health (FOPH) worked together in exemplary fashion to deal with the major and complex challenge posed by the implementation of the legislation. The aim is to implement policy requirements as leanly and efficiently as possible.

Under the new Act, Swissmedic will from 2019 be managed on the basis of strategic objectives in place of the previous performance mandate. In conjunction with the Management Board, the Agency Council started work on the new strategic direction based on an environment analysis derived from horizon scanning activities.

We realise that there will be no black or white solutions, and that the aim must be to find the right way in a difficult environment. The trends mentioned above are examples of many emerging issues that need to be addressed proactively.

"We realise that there will be no black or white solutions, and that the aim must be to find the right way in a difficult environment."

Our focus must not only be on the future, though; we also need to keep an eye on our day-to-day business, the quality of which is the yardstick by which the organisation is measured.

In 2016 Swissmedic authorised 42 medicinal products with new active pharmaceutical ingredients – 28 more than in 2015. The FDA approved 25 medicinal products of this kind during the year under review. There is accordingly no reason to say that the Agency could detract from the attractiveness of Switzerland as a centre of innovation – on the contrary. The Agency demonstrated a remarkable level of performance, complying with processing time limits in 99% of cases (across all applications) and without exhausting its headcount budget.

Swissmedic also enjoys a substantial degree of recognition in the international arena. The meeting of the Heads of Medicines Regulatory Authorities was held in Interlaken in October 2016, and the International Council for Harmonisation (ICH) will be meeting in Geneva in 2017. Furthermore, the project funded by the SDC and the Bill and Melinda Gates Foundation to support medicinal product regulatory activities in Africa made very good progress. The project enables Swissmedic's experts to contribute their knowledge in the development aid setting too.

Christine Beerli
Chairwoman of the Swissmedic Agency Council

Foreword by Jürg H. Schnetzer

Successful in a dynamic environment

This Annual Report for 2016 uses selected criteria, figures, commentaries and brief reports to illustrate Swissmedic's business performance. The performance data that are published are determined by the government's reporting requirements on the one hand and the need for information perceived among stakeholders on the other.

We operate an internal system of key figures that are aligned with the strategic plan 2015–2018 and fed into a balanced scorecard. Ensuring that the Swiss Agency for Therapeutic Products is publicly perceived as a transparent, efficient and autonomous oversight authority with effective and extensive executive powers is the top priority within our system of objectives.

National and international cooperation and the stipulation of and compliance with quality and performance goals contribute to this public perception. Engagement with issues such as leadership culture, employment conditions and the management and documentation of business activities enables us to make efficient and even more effective use of the available resources.

At the conclusion of the 2016 financial year, Swissmedic had achieved all its annual targets and strategic interim objectives. Compliance with time limits was good in all areas, greater customer proximity enhanced transparency, and our enforcement capabilities were further strengthened by an intensified inspection programme. The demanding work on ordinances necessitated by the revision of the Therapeutic Products Act is being handled on schedule in parallel to our day-to-day business. Swissmedic is now well equipped to meet the challenges of the second half of the 2015–2018 strategy period.

The expectations of the various stakeholder groups, to the extent that they derive from our legal mandate, form a complex orientation system. And the orientation points within this system can shift as a result of new legal requirements or scientific findings. International harmonisation, new cooperation models and new best practices arrive fast, and anyone likely to benefit from a development is not slow in urging us to innovate.

As a public health authority Swissmedic must remain independent, predictable and consistent; as an expert organisation we must invest continually in developing our staff so that we can continue to fulfil our mandate competently and with dedication in the future. The entire organisation must continue to develop, learn new things and "forget" old ways in order to improve on an ongoing basis and achieve longterm success in a changing environment.

An administrative unit or authority can only be a learning organisation if its employees understand how things interrelate, learn from each other and are keen to develop personally. They rightly expect to work in a leadership environment that acknowledges and evaluates change and provides appropriate support for internal development; an atmosphere that takes the individual seriously; a working environment in which people are happy to do their best.

Jürg H. Schnetzer

Approaches such as knowledge management, peer review, communities of practice, international exchanges of experience and initial and continuing training are all targeted ways of investing in our colleagues and strengthening their exper-tise. The results of our staff surveys and the degree to which objectives are achieved show that these efforts are worthwhile: without exhausting our human resources budget we recorded an operating profit of CHF 2 million and a 99% rate of compliance with processing time limits.

At the end of this Report you will find the names of the peo-ple to whom this success is due: Swissmedic's emplo-yees.

Jürg H. Schnetzer
Executive Director

"An administrative unit or authority can only be a learning organisation if its employees understand how things interrelate, learn from each other and are keen to develop personally."

We ensure that the therapeutic products we approve are of faultless quality, effective and safe. In doing so, we make a significant contribution to safeguarding human and animal health and to maintaining Switzerland's role as a location for business and research.

Guiding principles of Swissmedic

Activities during the year

Preparations for implementation of the revised Therapeutic Products Act

The Swiss Parliament adopted the Ordinary Revision of the Therapeutic Products Act (TPA Revision, TPA2) on 18 March 2016. Preparations for entry into force of the TPA and revision of the associated enforcement legislation entail groundwork and planning for Swissmedic at different levels. Extensive operational adjustments need to be made to the Agency's processes and IT systems, and various therapeutic products ordinances (TPOs) require amendments. Work has been divided into two projects: a legislative project in collaboration with the Federal Office of Public Health (FOPH) for the revision of enforcement legislation (Legislating for TPO IV), and a project being carried out by Swissmedic to bring its processes and IT systems into line with the amendments to the Act and Ordinances (Implementation of TPO IV). Both projects started in the 2nd quarter of 2016 and were on schedule as at the end of the year. It is intended to submit the draft revisions to stakeholders for consultation during 2017. The revised act and executive legislation are expected to enter into force in 2019.

11th Summit of Heads of Medicines Regulatory Agencies and ICMRA Meeting, Interlaken

The 11th Summit of Heads of Medicines Regulatory Agencies and the Meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA) took place in Interlaken from 10 to 13 October 2016. Organised by Swissmedic, the three-day meeting (held in Switzerland for the first time) was attended by some 75 agency representatives from 23 countries on all continents. The key topic at the 2016 summit was "Effective approaches to regulation, enabling regulators to perform in the 21st century". Japan's Pharmaceuticals and Medical Devices Agency (PMDA) will be hosting the next summit in October 2017, in Kyoto.

Good practice for processing medical devices

In conjunction with the Swiss Society of Sterile Supply (SGSV/SSSH/SSSO) and the Swiss Society for Hospital Hygiene (SSHH), Swissmedic has drawn up a new edition of "Good practice for processing medical devices". With the aim of eliminating risks of infection, the updated guide is intended as a reference work to help personnel responsible for reprocessing medical devices. Published at the beginning of 2017, it is directed at hospitals and other healthcare facilities which reprocess medical devices.

Blood donation criteria for men who have sex with men: blanket exclusion to be lifted

Exactly 20 years ago, responsibility for official supervision of Switzerland's blood transfusion activities was transferred to the federal government. Tasked with this remit since 2002, Swissmedic conducts numerous inspections throughout Switzerland each year. The Agency ensures that safety risks posed by known or newly emerging pathogens or other threats are identified in good time, donor suitability criteria are continually optimised, new and more sensitive test methods are introduced, and procedures for the collection and manufacturing of labile blood products are always state of the art. Blood transfusions have never been safer. The last case of HIV infection through blood transfusion was 15 years ago.

At the end of the year, Swissmedic approved an application to relax the exclusion of MSM (men who have sex with men). The application successfully demonstrated for the first time that recipients of blood transfusions are not exposed to an increased risk of contracting a blood-borne infection. Even with leading-edge test methods in place, it is no less vital that the extensive questions on risk behaviour are answered conscientiously.

Lifestyle product or medical device...

There is hardly a beauty, cosmetic or lifestyle product that you cannot buy to make yourself more attractive, younger or slimmer – or at least appear so.

Mikrodermabrasion, performed with an ultrasound device, is claimed to smooth wrinkles in the face and promote skin renewal. Annoying spider veins are not such an appealing sight when sunbathing at the beach. They can be lasered off. Flab on the stomach and hips that is proving resistant to all attempts at dieting? No problem, there is always cryolipolysis. Resembling an electric iron, the device used freezes fat deposits off at minus temperatures without further ado.

Who hasn't once more or less seriously toyed with the idea of resorting to such a treatment, or perhaps even tried one out. But what precisely are consumers dealing with here? What kind of devices are used for these treatments, how safe are they, and who controls their quality and application? It is very difficult for the layperson to know whether something qualifies as a medical device that needs to satisfy the requirements for a therapeutic product, or whether it is simply a "lifestyle product".

Monitored by Swissmedic

In the worst-case scenario, this difference can have serious consequences. Medical devices have to meet internationally agreed standards of quality, performance and safety, and are monitored by Swissmedic. In contrast, there are no comparable regulations in place for devices intended for use in the lifestyle and cosmetics sectors.

A medical device is a product with a medical intended purpose. It is essentially the manufacturer who decides if a product is intended for medical use. Medical devices are therapeutic products used, among other purposes, to prevent, identify, treat and monitor diseases. They are not limited to complex diagnostic devices or artificial heart valves, stents and hip implants. Plasters, injection cannulas, crutches and condoms also count as medical devices. There are currently around 500 000 different medical devices on the market in Europe. The precise figures for Switzerland are not known.

These devices are divided into different risk categories and groups, with safety, health protection and performance requirements varying depending on classification. Medical devices may only be placed on the market if conformity is guaranteed.

Regulation and surveillance

Part of Swissmedic's remit is responsibility for market surveillance in Switzerland, which includes the safety of medical devices. Unlike medicinal products, medical devices in the EU and Switzerland are not subject to pre-market authorisation by a state authority. Higher-risk products are assessed by one of the 60 or so European Notified Bodies before being granted a CE mark. The CE mark attests to conformity with the requirements. For their part, agencies such as Swissmedic or the authorities of the EU Member States regularly monitor the Notified Bodies and will take action in the event of market surveillance problems.

Under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (Mutual Recognition Agreement, MRA), Switzerland is integrated into the European market for these products. Working closely with its European partner authorities, Swissmedic monitors the products on the basis of random checks, inspections, and reports from the market. Swissmedic also keeps the public informed of new safety findings. Manufacturers can and must, for instance, organise product recalls on their own responsibility. Swissmedic will only intervene when safety concerns arise.

Not easy for laypersons to distinguish

What does this mean for a laser device that removes spider veins? Is it a medical device or isn't it? Depending on whether the intended use foreseen by the manufacturer is medical or not, the same product may conceivably come onto the market once as a medical device and another time as a product for cosmetic application.

Who is actually permitted to carry out medical or cosmetic treatments with high-energy laser devices? In the case of laser devices with a medical intended use, this is clearly regulated by the Medical Devices Ordinance: Class 4 laser devices may only be used by a physician, or by a trained professional under the supervision of a physician. Incidents involving such devices must be reported to Swissmedic.

The provision of cosmetic laser treatments, such as hair removal, is not subject to any special requirements or controls. A lack of professional knowledge on the part of the persons using the devices can lead to severe complications, including burns or scars. Legislation in this area is to be made stricter. The National Council and the Council of States have already approved a tightening up of the regulations. A commission appointed by the Federal Office of Public Health is currently drafting the details. Certain laser treatments will in future have to be performed by physicians, and the training of non-medical personnel is to be improved.

EU update

In the wake of scandals surrounding silicone implants and hip implants, regulations governing medical devices and, in particular, their implementation have been tightened. Comprehensive revised and extended rules are expected to be adopted by the EU Parliament in the spring of 2017. The objective is to provide greater safety for consumers. New and much tougher requirements (e.g. for clinical data) will make it harder to get market access for new products.

Fresh cell therapies – risk as a high price for hope

Coordinated campaign by the Swiss authorities to combat illegal treatments is proving effective

Health risk rather than fountain of youth: A coordinated campaign initiated in 2014 by Swissmedic, the Federal Office of Public Health (FOPH) and the Cantonal authorities against illegal fresh cell therapies in Switzerland is having a lasting impact. The public in Switzerland and abroad has been made aware, and non-authorised treatments and preparations have to be withdrawn. Charges were brought against a number of providers. The campaign came to a successful conclusion in 2016.

So-called fresh cell therapies are potentially dangerous: There is no scientific evidence that treatments using fresh cells actually provide any benefits. It has, however, been proven that non-authorised products can pose a risk to health. Nevertheless numerous Swiss hospitals and private clinics have been offering fresh cell therapies in recent years. These treatments were particularly popular among tourists from China, Russia and the Middle East.

In 2014, Swissmedic and the FOPH, in partnership with the Cantons, agreed to take coordinated steps against such treatments. An action plan was drawn up to put a stop to the illegal manufacture and use of preparations for fresh cell therapy in Switzerland.

Numerous reports in several cantons

In an initial step, Swissmedic and the FOPH, in close collaboration with the Cantonal authorities, sought to get a general picture of the therapies on offer and the preparations being used. Reports pointed to activities involving fresh cell preparations at a total of 37 clinics and practices in several cantons. They were called on either to cease these activities or immediately apply for a licence and authorisation. Investigations revealed that none of the institutions had produced, imported or injected into patients preparations derived from living animal cells or tissues.

In four cases where extracts had been produced from animal cells or tissues and administered to patients, Swissmedic issued rulings against manufacturers and suppliers, prohibiting them from producing or using the preparations without authorisation or a licence. A number of appeals against these decisions were lodged with the Federal Administrative Court. The judgements are still outstanding. Swissmedic raised objections against 14 institutions for publishing misleading claims on their websites. The suppliers were asked to correct the information and remove references to fresh cell treatments. In at least five cases, healthcare professionals were suspected of using properly authorised medicinal products for indications other than those authorised by Swissmedic (off-label use) and offering them as a form of fresh cell therapy.

Preventive impact

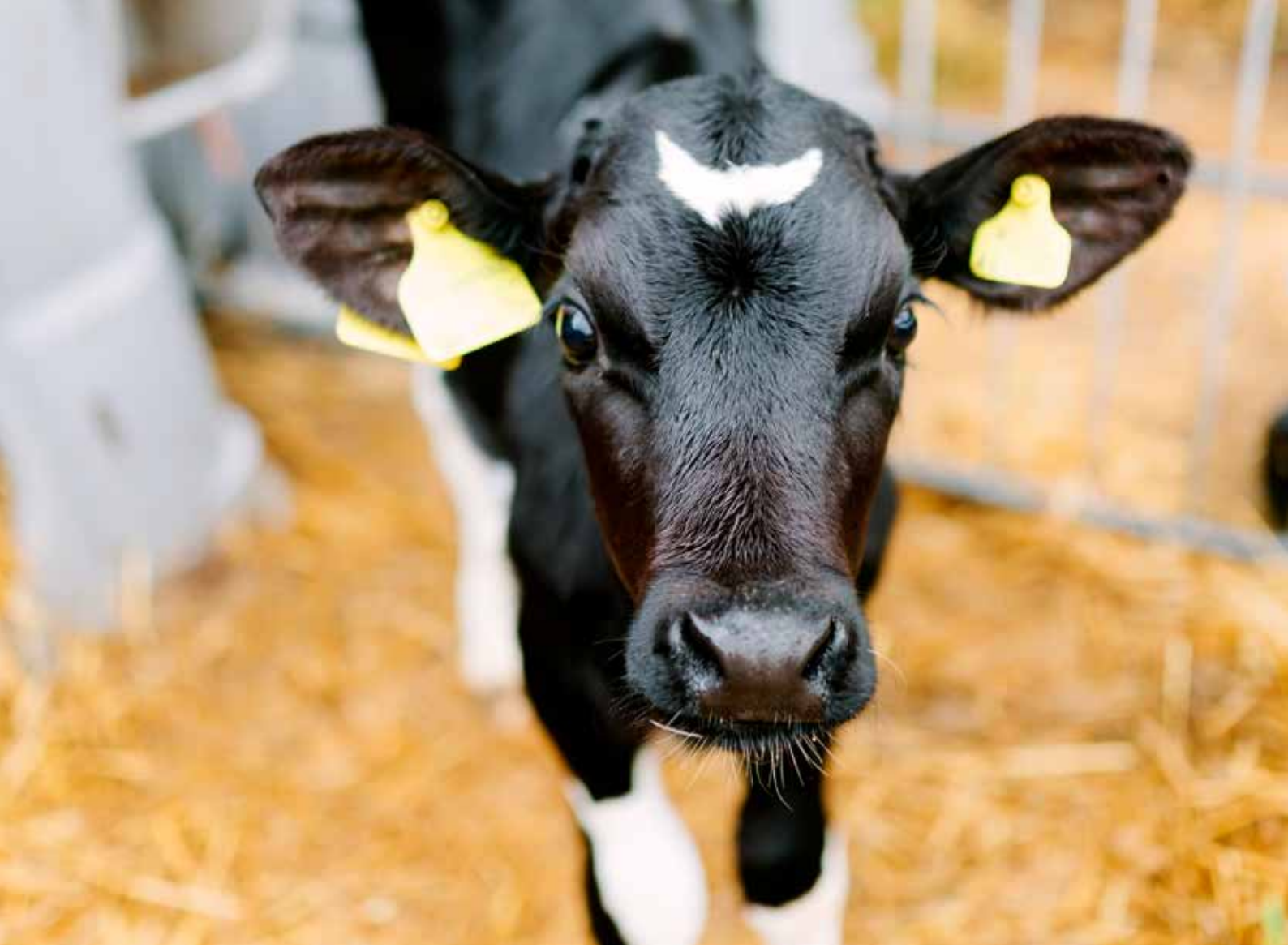
The campaign raised awareness within the sector and professional associations as well as among the general public as potential clients. The efforts of Switzerland's authorities also earned positive reactions from abroad. In addition to numerous Swiss media outlets, the leading Chinese TV stations and news agencies carried extensive coverage of the campaign. Visa applications from China for medical treatments in Switzerland were down by half over the past two years. Whether the decline is solely related to the campaign against fresh cell therapies is, however, a matter of conjecture.

Fresh cell treatments are now subject to continuous monitoring by the federal and Cantonal authorities. Cantonal-level monitoring of the lawful use of medicinal products by healthcare professionals will specifically play an important role. Switzerland aims to provide nothing less than high-quality health services.

What is so-called fresh cell therapy

Fresh cell therapy refers to a treatment originally developed by Swiss doctor Paul Niehans around 1930. Living animal cells – usually harvested from sheep foetuses or placenta – are mixed with an isotonic salt solution and injected into the patient's muscles. It is becoming increasingly common today to use frozen or dried cells, cell fragments or cell extracts instead of preparations containing living cells. The aim of such a therapy is to revitalise and rejuvenate (anti-ageing) the person being treated. Fresh cells and fresh cell preparations have in some cases been advertised as treatments for migraine or chronic illnesses or as an alternative cancer therapy. There is no scientific basis to claims that fresh cell therapies work. The risks include allergies, abscesses at the injection site, blood poisoning or the transmission of pathogens.

Legislation varies depending on the form of treatment: A fresh cell therapy with living cells is a xenotransplantation and as such falls under the Transplantation Act in Switzerland. It needs to be authorised by the FOPH. Authorisation is subject to strict conditions designed to prevent pathogens being transferred from animals to humans. On the other hand, preparations not containing living cells are medicinal products covered by the Therapeutic Products Act (TPA). Up until 2010, the Cantonal authorities could classify such a preparation as a magistral formula, i.e. a medicinal product prepared for a specific individual. This is no longer permissible since the TPA was amended in October 2010, and preparations are now subject to authorisation as medicinal products by Swissmedic. Authorisation is only granted if the quality, safety and efficacy requirements are satisfied. As at the end of 2016, neither the FOPH nor Swissmedic had issued any licences or authorisations for such preparations.



Veterinary medicinal products regulations at Swissmedic

Antibiotic resistance and the challenges facing veterinary medicinal products regulators

Nobody in Switzerland wants to stand idly by and watch as calves die in fattening stations although modern and effective antibiotics are available to treat them. No patient has any desire to lie in hospital with a life-threatening infectious disease because pathogenic bacteria have developed a resistance to antibiotics. And industry still needs a financial incentive to develop and market new and innovative veterinary medicinal products. Swissmedic has to factor in these different considerations when fulfilling its mandate in the area of veterinary medicinal products.

Alexander Fleming, the discoverer of the first antibiotic, penicillin, evidently foresaw the problem: "The time may come when penicillin can be bought by anyone in the shops," he remarked in his Nobel acceptance lecture in 1945. "Then there is the danger that the ignorant man may easily underdose himself and by exposing his microbes to non-lethal quantities of the drug make them resistant." Fleming illustrated this point using the example of an untreatable pneumonia infection with a fatal outcome.

Antibiotic resistance increasing

In response to the problem of resistance increasingly jeopardising the successful fight against infectious diseases in humans and animals, the Federal Council initiated the "Strategy on Antibiotic Resistance" (StAR) in 2013. Since the health of people and animals and their surroundings are closely interlinked, antibiotic resistance affects human medicine, veterinary medicine, agriculture and the environment alike. Only a comprehensive, interconnected approach offers any prospect of success. For that reason, StAR consistently follows a one health strategy that acknowledges the systemic relationships between humans, animals, environment and health.

Sales of antibiotics used in veterinary medicine have dropped by more than 40 percent over the past few years. While this represents a partial success, the problem of resistance has grown more acute. One explanation for this is the all too frequent use of so-called critical antibiotics in veterinary medicine.

In light of the resistance situation, the use of newer and innovative veterinary medicinal products containing active substances from the third- and fourth-generation fluoroquinolone, macrolide and cephalosporin groups needs to be critically evaluated today since the same active substances are also crucial for the treatment of infectious diseases in humans. Use of these antibiotics in animals can lead to a selection of resistant germs which are treatable in humans only to a limited degree or with great effort.

Numerous new, innovative antibiotics have come onto the market as veterinary medicinal products over the past 20 years. Fortunately, old and established preparations are still being used to treat animals. These include active substances from the penicillin, tetracycline and sulfonamide groups.

Coordinating with national and international partner authorities

Growing resistance is a global problem that is confronting all regulatory agencies. Swissmedic coordinates with national and international partners to determine what is required or necessary. Swissmedic therefore considers on a case-by-case basis which criteria an old and established preparation that is to be used again in future as a first-line treatment must satisfy. Doing so ensures that these preparations remain on the market and there are no shortfalls in supplies of first-line antiobiotics. This prevents veterinary practices from having to bridge bottlenecks with second-line treatments in the form of reserve antibiotics.

It is neither reasonable nor feasible for Switzerland to attempt to resolve this conflict of objectives on its own, and it has been recognised that there is only one way to achieve the goal. Coordination with national and international partner authorities is essential. Swissmedic will therefore aim to network more actively in the veterinary medicinal products field and intensify consultation among the various stakeholders. In the specific case under discussion, international networking is essential. For instance, requirements to update the authorisation documentation of old preparations will be closely coordinated with those of the European partner authorities. The dialogue with associations in the veterinary medicinal products sector is also to be stepped up. A mutual understanding of requirements and possibilities will be crucial.

Cooperation with national and international bodies in the veterinary medicinal products field will be coordinated with the relevant federal units. This will ensure that information is shared and avoid duplications.

Responsibilities of Swissmedic in the area of veterinary medicinal products

The Veterinary Medicines department is part of Swissmedic's Authorisations division. The ten-strong team is not only responsible for the authorisation of medicinal products for animals, it is also the central liaison point for matters relating to the safety of veterinary medicinal products. The department draws up scientific evaluations and is responsible for questions on delimitation in connection with veterinary medicinal products. By working closely with the Swissmedic Veterinary Medicines Expert Committee (VMEC), it can draw on the academic and veterinary know-how of the Vetsuisse Faculty and practising veterinarians.

Outlook

Revision of EU medical devices legislation

The EU began revising its medical devices legislation in 2012 and published the latest versions of the new Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR) in June 2016. These will no longer be directives but regulations which are directly applicable in the EU Member States. They are expected to enter into force in the first half of 2017. These provisions become legally binding 20 days after publication and will subsequently enter into force in stages after 6 months to 5 years in all EU Member States. Switzerland has to integrate the new regulations into Swiss law in good time if it wishes to continue participating in the European internal market for medical devices and avoid technical trade barriers. At the same time, access to the EU's current and new databases and expert groups is indispensable for ensuring effective and efficient market surveillance in Switzerland.

Maintaining equivalence of the provisions calls for far-reaching adjustments to Swiss law and ordinances and to the MRA. After an initial approximate analysis of the ramifications, a project group led by the FOPH and made up of FOPH, Swissmedic and SECO personnel was set up in June 2016. Project planning envisages a multi-stage approach to ensure timely implementation in Swiss law. Swissmedic is largely providing specialist input. Responsibility for adapting legal texts within the given schedule rests with the FOPH, while SECO is taking the lead in effecting the necessary adjustments to the MRA.

Narrower application of mandatory prior control of public advertising

With effect from 1 January 2017, mandatory prior control of advertising directed at the general public – regardless of the medium used – will be limited to preparations in the so-called sensitive groups (analgesics, sleeping aids and sedatives, laxatives and anorectics) if potential for dependence or abuse is mentioned in the medicinal product information. Greater responsibility is to be placed with the originators of public advertising (authorisation holder or third parties).

Switzerland to host its first ICH Conference

In the past, ICH meetings rotated between the three "classic" ICH regions of the European Union (EU), the USA and Japan. Thanks to organisational changes at ICH, which include allowing future meetings to be held in other regions, the ICH Conference in autumn 2017 will be taking place in Switzerland for the first time. As a member of both the Management Committee and the Assembly, Swissmedic will be organising the meeting in close cooperation with the ICH Secretariat and looks forward to welcoming international ICH experts to Geneva.

Portal expansion

Under the eGov expansion project, Swissmedic has created an eSubmissions platform that enables it to electronically exchange information and documents with pharmaceutical companies. The 17 companies participating in a pilot run since October 2016 can submit their authorisation applications to Swissmedic in eDok or eCTD format. The newly developed platform also handles Swissmedic correspondence during the application processing procedure. If the companies so require, Swissmedic attaches a legally valid electronic signature to official decisions. The first such decision was issued in December 2016. Following the launch in May 2017, the eGov expansion project will allow the fully paperless processing of applications.

During pilot operation, approximately one quarter of all authorisation applications were filed with Swissmedic via the eSubmissions platform. With the help of the new platform, Swissmedic was able to process all these submissions without any major problems.

The companies taking part in the pilot were invited to report on their experiences and submit proposals for improvement. These ideas are being taken on board in the course of portal fine-tuning to ensure that all companies can be offered a fully developed solution at the time of the launch. The pilot companies' positive assessment of collaboration with Swissmedic translated into a very high level of acceptance of the solution and will bring the Agency closer to its goal of receiving as many submissions as possible electronically. The Swissmedic Portal is scheduled to be opened to all authorisation holders in Switzerland in May. Future plans for the Portal include the addition of more features and the involvement of other business areas within Swissmedic.

Facts and figures

Business statistics as at end 2016

Firms with a Swissmedic licence
The licences below were attributed to a total of 1,098 firms.

Manufacturing of medicinal products	
Manufacturing of medicinal products (with a licence for wholesale distribution)	243
Manufacturing of medicinal products (without a licence for wholesale distribution)	94

Wholesale distribution of medicinal products	
Import of medicinal products	563
Wholesale trade of medicinal products	833
Export of medicinal products	442
Foreign trade with medicinal products	377
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)	122
Institutions with a Swissmedic licence for handling blood or labile blood products (blood transfusion activities)	26

Controlled substances	
Establishment licences for handling controlled substances	361

Number of authorisations by type of product as at end 2016

Therapeutic products code	Number of authorised medicinal products
Synthetics human	5,019
Biotechnologicals	327
Vaccines	62
Blood products	114
Radiopharmaceuticals	51
Generators	7
Bacterial and yeast products	26
Allergens	346
Transplant/tissue products	3
Phytopharmaceuticals	641
Homeopathics	660
Ayurvedic medicinal products	1
Anthroposophics	420
Tibetan medicinal products	6
Veterinary medicines	734
Total	**8,417**

Number of authorisations by dispensing category as at end 2016

Dispensing category/Authorised medicinal products		Number of authorised medicinal products
A	Dispensed once only on medical or veterinary prescription	1,770
B	Dispensed on medical or veterinary prescription	3,855
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	46
C	Dispensed after expert advice from medical personnel	597
C/D	Dispensed after expert advice from medical personnel/after expert advice	23
D	Dispensed after expert advice	1,926
E	Dispensed without expert advice	167
Total		**8,417**

Homeopathic and anthroposophic medicinal products without indication authorised by the notification procedure as at end 2016

Single products	11,067
Combined products	1,084

Swissmedic as an agency

Staff headcount at year end	420
Full-time positions at year end	348
Percentage of women	56.4 %
Percentage of men	43.6 %
Staff working part time (part time is defined as working up to 89 % of a full-time post)	47.1 %
Average age of staff	47.4
Women	45.8
Men	49.4
Fluctuation rate	4.5 %

Language distribution	
German	84.8 %
French	11.7 %
Italian	3.5 %
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. By doing so, the sector ensures that all medicinal products available to the Swiss population are of high quality, safe and effective. This also includes constantly evaluating new information on the characteristics of a product throughout its entire life cycle.

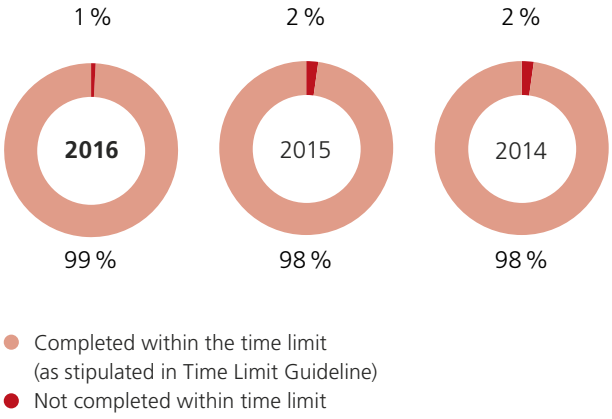
Activities

- A total of 12,678 applications were submitted in 2016, while 12,933 applications were finalised. The results for the last 12 months show that 99 % of all applications were finalised on schedule.
- Of the 30 scientific advice meetings, 18 pre-submission meetings and 17 clarification meetings requested in 2016, 44 were answered in writing, while face-to-face meetings took place in 21 cases.
- In the course of cooperation with the Clinical Trials department (Licensing division), the Preclinical Review department undertook 11 assessments for the notification of clinical trials, while the Quality Review department undertook 30.

Time limits

In 2016, 99 % of all applications were completed within the prescribed time limits. 98 % of applications for the first marketing authorisation of innovative medicinal products (ZL1A) and 86 % of applications for non-innovative medicinal products were completed on schedule (if the delayed CHM applications – ZL1B – submitted prior to 2015 are excluded, the figure for this category rises to 100 %). 100 % of applications under the fast-track authorisation procedure and for the authorisation of new active substances (NAS) were completed on time. The percentage for the different types of variation reached 99 %.

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



Authorisation of human medicinal products

First authorisations

A first marketing authorisation of a medicinal product is granted after comprehensive checking of the documentation submitted by the applicant on safety, efficacy and quality. The authorisation procedure distinguishes between innovative medicinal products (medicinal products with new active pharmaceutical ingredients or major variations thereto) and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients and co-marketing medicinal products). Major variations, such as a new indication, paediatric use or a new pharmaceutical form of a medicinal product, require a new authorisation procedure.

Activities

- In 2016, Swissmedic received 249 applications for first authorisations of innovative medicinal products and major variations thereto, and 252 applications were completed.
- Of the 42 medicinal products with new active pharmaceutical ingredients that were authorised for the first time, seven were completed by means of the fast-track procedure.
- Of the 229 applications completed for non-innovative first authorisations, 39 concerned co-marketing products.
- No requests for the parallel importation of a medicinal product were submitted in 2016.

Human medicinal products with a new active pharmaceutical ingredient authorised in 2016

Therapeutic area (ATC)	Active pharmaceutical ingredients	Product name	Application
Alimentary tract and metabolism	Asfotasum alfa	Strensiq®, solution for injection	Treatment of hypophosphatasia (inherited metabolic disorder)
	Elosulfasum alfa	Vimizim®, concentrate for solution for infusion	Treatment of mucopolysaccharidosis, type IVA (inherited metabolic disorder)
	Migalastatum	Galafold®, capsules	Fabry disease (inherited metabolic disorder)
	Sebelipasum alfa	Kanuma®, concentrate for solution for infusion	Long-term enzyme replacement therapy for patients of any age with LAL deficiency (inherited metabolic disorder)
	Teduglutidum	Revestive®, powder and solvent for solution for injection	For the treatment of adults with short bowel syndrome who are dependent on parenteral nutrition
Anti-infectives for systemic use	Ceftolozanum	Zerbaxa®, powder for concentrate for solution for infusion	Complicated intra-abdominal infections in combination with metronidazole; complicated urinary tract infections
	Cobicistatum	Genvoya®, film-coated tablets	HIV infection
	Elbasvirum	Zepatier®, film-coated tablets	Chronic hepatitis C of genotypes 1 and 4 in adults

Therapeutic area (ATC)	Active pharmaceutical ingredients	Product name	Application
	Proteinum L1 papillomaviri humani typus 11	Gardasil 9®, suspension for injection in pre-filled syringe	Human Papillomavirus vaccine (types 6, 11, 16, 18, 31, 33, 45, 52, 58)
	Sofosbuvirum	Epclusa®, film-coated tablets	Chronic hepatitis C of genotypes 1-6 in adults
	Tedizolidi phosphas	Sivextro®, film-coated tablets	Acute bacterial skin and soft tissue infections
Antineoplastic and immunomodulating agents	Blinatumomabum	Blincyto®, powder for concentrate for solution for infusion	Recurrent or refractory acute lymphoblastic leukaemia
	Daratumumabum	Darzalex®, concentrate for solution for infusion	Multiple myeloma
	Elotuzumabum	Empliciti®, powder for solution for infusion	Multiple myeloma
	Ixekizumabum	Taltz®, solution for injection in pre-filled syringe	Psoriasis
	Olaparibum	Lynparza®, capsules	Maintenance treatment of advanced ovarian cancer
	Osimertinibum	Tagrisso®, film-coated tablets	EGFR-T790M mutation-positive non-small-cell lung cancer
	Talimogenum laherparepvecum	Imlygic®, solution for injection	Treatment of adults with melanoma with regional and distant metastases
	Trametinibum	Mekinist®, film-coated tablets	Unresectable or metastatic melanoma with a BRAF-V600 mutation
Blood and blood-forming organs	Albutrepenonacogum alpha	Idelvion®, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in patients with haemophilia B (factor IX deficiency)
	Efmoroctocogum alfa	Elocta®, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in previously treated patients with haemophilia A
	Eftrenonacogum alpha	Alprolix®, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in previously treated patients with haemophilia B
	Rurioctocogum alfa pegolum	Adynovi®, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in previously treated patients (aged 12 and over) with haemophilia A
	Selexipagum	Uptravi®, film-coated tablets	Pulmonary arterial hypertension
	Simoctocogum alfa	Nuwiq®, powder and solvent for solution for injection	Treatment and prophylaxis of bleeding in patients with previously treated haemophilia A
	Susoctocogum alfa	Obizur®, powder and solvent for solution for injection	Treatment of bleeding episodes in adults with acquired haemophilia

Therapeutic area (ATC)	Active pharmaceutical ingredients	Product name	Application
	Vorapaxarum	Zontivity®, film-coated tablets	Reduction of atherothrombotic events after a heart attack or in patients with a history of peripheral arterial occlusive disease
Dermatologicals	Ivermectinum	Soolantra®, cream	Topical treatment of inflammatory lesions of rosacea in adults
Cardiovascular system	Alirocumabum	Praluent®, solution for injection in pre-filled syringe	Severe forms of hypercholesterolaemia in addition to statins
	Evolocumabum	Repatha®, pre-filled pen	Severe forms of hypercholesterolaemia in addition to statins
Nervous system	Brivaracetamum	Briviact®, solution for injection	Antiepileptic
	Ioxapinum	Adasuve®, single-dose powder for inhalation	Neuroleptic
	Vortioxetinum	Brintellix®, film-coated tablets	Antidepressant
Musculoskeletal system	Febuxostatum	Adenuric®, film-coated tablets	Uricostatic (for lowering uric acid levels)
Respiratory tract	Ivacaftorum	Orkambi®, film-coated tablets	Cystic fibrosis
	Mepolizumabum	Nucala®, powder for solution for injection	Add-on treatment for severe eosinophilic asthma in adults
Genitourinary system and sex hormones	Avanafilum	Spedra®, tablets	Erectile dysfunction
	Silodosinum	Urorec®, hard capsules	Symptomatic treatment of functional problems associated with benign prostatic hyperplasia (BPH)
	Tolvaptanum	Jinarc®, tablets	Slowing the progression of cyst development and renal insufficiency in autosomal dominant polycystic kidney disease
Miscellaneous	Acari allergeni extractum	Acarizax®, powder for oral administration	Desensitisation
	Fluorodopum (18-F)	Dopaview®, solution for injection	Radiodiagnostic agent for use in Positron Emission Tomography (PET) in neurology and oncology
	Idarucizumabum	Praxbind®, solution for injection/infusion	For use in patients treated with Pradaxa who experience episodes of severe, uncontrolled bleeding (Pradaxa antidote)

Human Medicines Expert Committee (HMEC)

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

Activities

- The HMEC advisory panel met 12 times during 2016 and issued 83 recommendations regarding marketing authorisation applications. The majority of them concerned new authorisations or additional indications for medicinal products.
- Furthermore, 36 expert reports for the purpose of full assessments and 31 reports on individual aspects were provided by the HMEC experts.

Number of HMEC recommendations relating to marketing authorisation applications

2016	2015	2014
83	75	79

Extensions and discontinuations

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

Activities

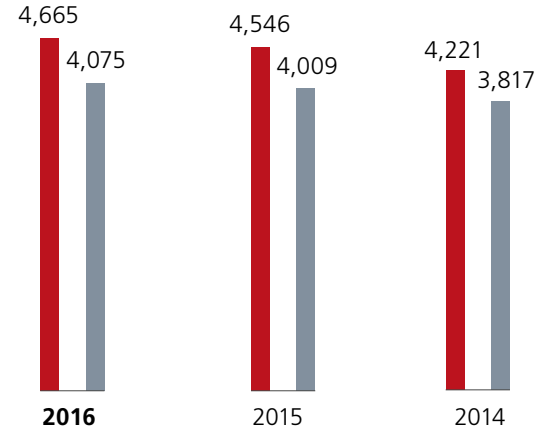
- In 2016, a total of 1,200 applications to extend the marketing authorisation were submitted, and 1,173 applications were completed.
- 187 applications for the discontinuation of a product and 23 applications for the discontinuation of a dosage strength of a product were submitted.
- 188 applications for the discontinuation of a product and 21 applications for the discontinuation of a dosage strength of a product were completed. At the same time, authorisation was not extended for 77 products.

Variations requiring approval and variations requiring notification

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

Activities

- A total of 4,660 variations requiring notification were submitted in the year under review; 4,665 notifications were completed.
- As regards variations requiring approval with scientific assessment, 3,872 applications were submitted and 4,075 were completed.
- Collective applications and multiple applications are counted here as one application.



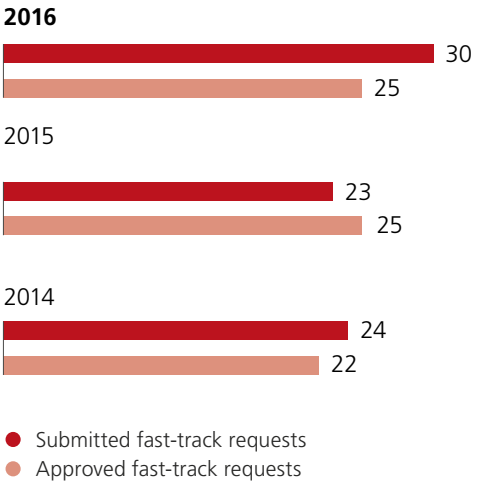
The fast-track authorisation procedure

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

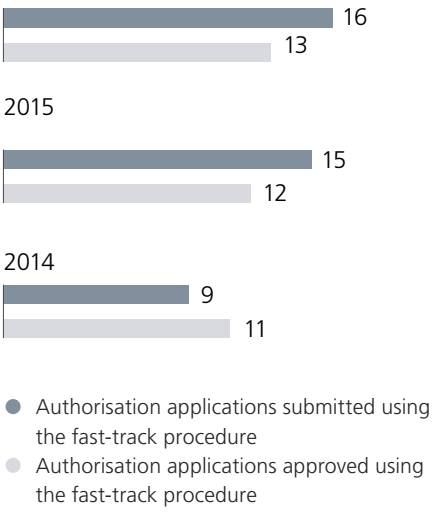
After a positive assessment of these conditions on the part of Swissmedic, the request for the fast-track procedure is approved and a corresponding application may subsequently be submitted. For Swissmedic, the time limit for processing the authorisation application is reduced from 330 to 140 days. For applicants, the fee is subject to a 50 % surcharge.

Activities
- In 2016, 30 requests for the fast-track procedure to be applied were submitted, and 25 fast-track requests were approved.
- 16 authorisation applications using the fast-track procedure were submitted and 13 were completed.
- All of the applications submitted using the fast-track procedure were completed on time.

Fast-track requests



Fast-track authorisation applications



The Procedure with Prior Notification (PPN)

Since 1 January 2013, Swissmedic has offered applicants the option of having the assessment carried out 20 % more rapidly, provided that they give prior notification of the submission date of their application (notification 5 – 8 months or, from 1 January 2016, 3 – 6 months before the planned submission date). For this to be accepted by Swissmedic, the following conditions must all be fulfilled:

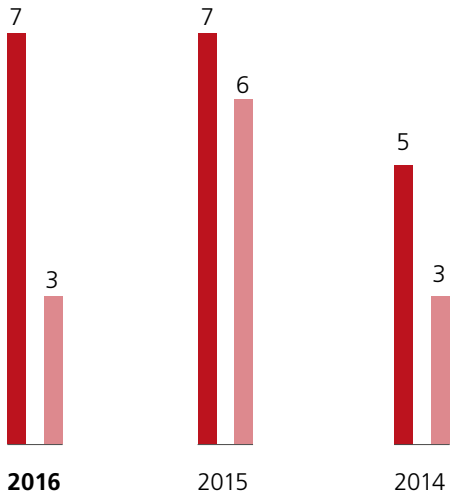
– The authorisation application must concern the first authorisation of a human medicinal product with a new active substance (NAS) or an additional indication.
– The clinical and preclinical studies should have been fully completed by the time the application is submitted. Intermediate analysis must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

If these conditions are fulfilled, the PPN request is approved and the application can then be submitted using the procedure with prior notification. For Swissmedic, the time limit for processing the authorisation application is reduced from 330 to 264 days. For applicants, the fee is subject to a 100 % surcharge.

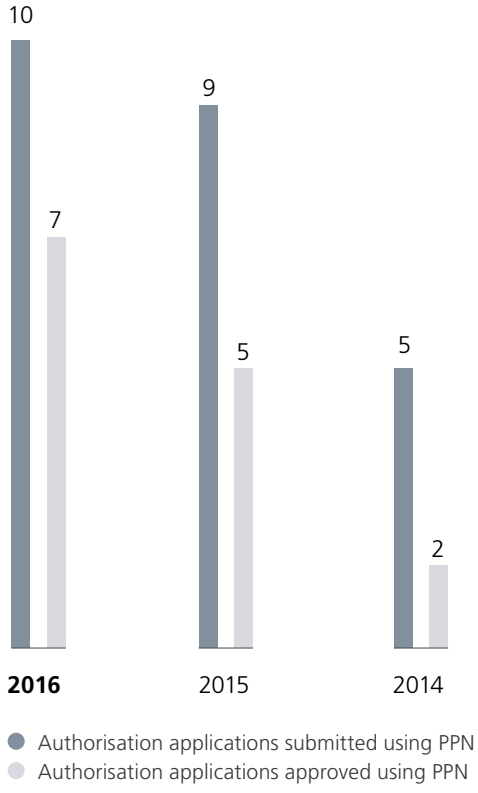
Activities

- Of the seven PPN requests submitted in 2016, three were approved. Four requests are currently still being processed.
- In 2016, ten authorisation applications using PPN were submitted and seven were completed; one further submission is already planned.

Requests for PPN



Applications using PPN



Applications under Article 13 TPA

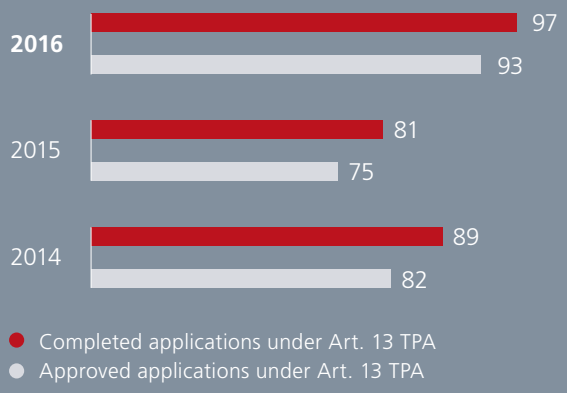
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose if the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

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

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

Activities

- In 2016 the total number of applications reviewed and approved under Art. 13 TPA increased from 75 to 105, an increase of 40 % on the previous year.
- Of the 97 authorisation applications under Art. 13 TPA that were completed in 2016, 93 were approved (96 %), three were withdrawn and one was rejected.
- Of the 97 completed applications, four involved the new notification of a new active substance, 14 "known active pharmaceutical ingredients with innovation", 27 "known active pharmaceutical ingredients without innovation", eight "known active pharmaceutical ingredients of complementary and herbal medicines", eight "major variations" including five additional indications, and 27 variations requiring approval.



Human medicinal products	2014		2015		**2016**	
	Appr.	Rej.	Appr.	Rej.	Appr.	Rej.
New notification of a new active substance	0	1	0	0	4	0
Known active pharmaceutical ingredients with innovation	8	2	7	2	12	2
Known active pharmaceutical ingredients without innovation	32	0	24	3	26	1
Known active pharmaceutical ingredients of complementary and herbal medicines	1	0	6	0	8	0
Variations requiring approval	33	0	34	0	27	0
Additional indications	1	0	1	0	4	1
Other major variations	5	2	3	1	3	0
Other applications	2	2	0	0	9	0
Total	**82**	**7**	**75**	**6**	**93**	**4**

Approval Rejection/withdrawal of the application

Special categories of human medicinal products

Orphan drugs

Swissmedic recognises the status as a medicinal product for a rare disease (orphan drug) on application. The applicant must prove that the medicinal product is used for the diagnosis, prevention or treatment of a rare, life-threatening or chronically debilitating disease that affects at most 5 out of 10,000 people. 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

- In 2016, 38 applications for recognition of orphan drug status were submitted.
- The status was granted to 33 products.
- Sixteen products were newly authorised as orphan drugs. Further orphan indications were approved for nine previously authorised orphan drugs.
- The status was discontinued for three 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 foresees a reduction of 90 % in fees for the authorisation of medicinal products with exclusively paediatric indications and for corresponding major variations. This measure is intended to encourage developments in the area of paediatric medicines. Inspections relating to paediatric clinical trials are considered important: Annual planning will continue to take account of inspections to assess compliance with GCP.

Activities

- The submission of PIPs proved helpful with regard to the notification of paediatric clinical trials. A total of 17 paediatric trials were authorised in 2016.

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

- As before, three processes for pathogen inactivation in labile blood products have been authorised in Switzerland by Swissmedic. With the exception of one application involving a variation of the quality documents for an approved procedure, there were no new applications for authorisation of special manufacturing procedures for transplant products or labile blood products in 2016.

Transplant products

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

Activities

- In 2016, one product based on gene therapy (oncolytic immunotherapy) was authorised for the treatment of melanoma.
- Approval was granted for one fast-track procedure for a product based on oligonucleotides. This was a product for spinal muscular atrophy for which no effective treatment is currently available.
- Four scientific advice meetings were held, during which the specific requirements for transplant products, gene therapy products and genetically modified organisms (TpP/GT/GMO) were established.
- Orphan drug status was granted for three products (oligonucleotides for spinal muscular atrophy, allogenic adipose-derived stem cells for complex perianal fistula and autologous tissue-engineered dermo-epidermal substitute for treatment of partial deep dermal and full-thickness burns).
- Four quality variation requests for TpT/GT were approved.
- At the start of May 2016, in an early part of a revision of the Transplantation Act, the FOPH approximated the definition of transplant products to the working definition used to date by Swissmedic and the FOPH, thus creating a better legal basis for established practice.

Complementary and herbal medicines

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

Activities

- 96 % of the delayed complementary and herbal medicine applications (first authorisations and variation requests) submitted between 2014 and 2015 were processed.
- Compliance with the processing time limits was 95 % for applications completed in 2016.

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

- In 2016, 154 products without an indication were given a first authorisation using the notification procedure. 74 of these were single products, 80 were combined products.
- 24 applications for simplified authorisation with a reduced dossier were completed. 22 of these products were authorised and 2 applications were rejected or withdrawn.
- The programming and test activities for an update of the "HOMANT" program used to notify homeopathic and anthroposophic medicines without an indication were completed. Preparations for the submission of notifications via the portal were initiated.

Herbal medicinal products

Herbal medicinal products or preparations contain only herbal substances or preparations. Within the framework of the simplified authorisation procedure it is possible, in many cases, to waive the need for separate clinical investigations. For herbal medicinal products that have been used for medicinal purposes for at least 30 years, and of that at least 15 years in western European cultures, traditional authorisation is possible. For cough and throat drops or pastilles, a notification process exists for dispensing in category E.

Activities

- 27 applications for non-innovative first authorisation of herbal medicinal products were completed. 6 of them concerned co-marketing products.
- Swissmedic employees talked about herbal medicinal products at international congresses including the Herbal Medicinal Products Symposium in Bonn and the Phytotherapy Congress in Bonn.

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

- Assessment of two sets of specimen quality documentation for Asian medicinal products was completed. The companies concerned will receive a decision by the end of the first quarter of 2017.
- Work also started on the revision of the TAS list. As soon as these two projects have been completed, product notifications for Asian medicinal products without an indication can be submitted.

Veterinary medicinal products

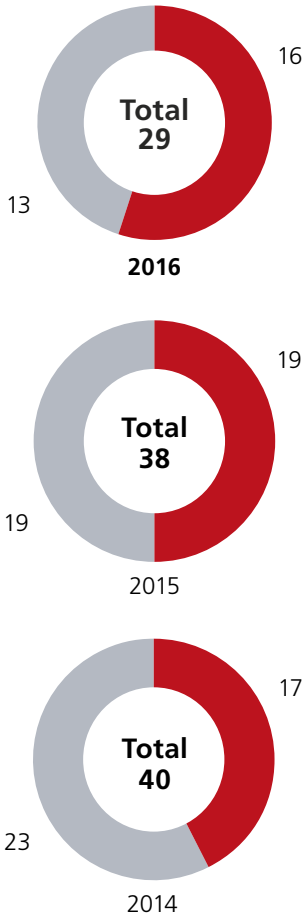
Authorisation of veterinary medicinal products

The first marketing authorisation of a veterinary medicinal product is granted following the examination of the documentation submitted by the applicant on safety, efficacy and quality. The authorisation procedure distinguishes between innovative medicinal products (medicinal products with new active pharmaceutical ingredients or major variations thereto) and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients and co-marketing medicinal products). Major variations to a medicinal product require a new authorisation procedure. An important aspect of the safety assessment of products that are used on livestock concerns their effect on the safety of foodstuffs. Within the authorisation procedure, the currently valid standards specified in legislation on foodstuffs are used to specify the 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.

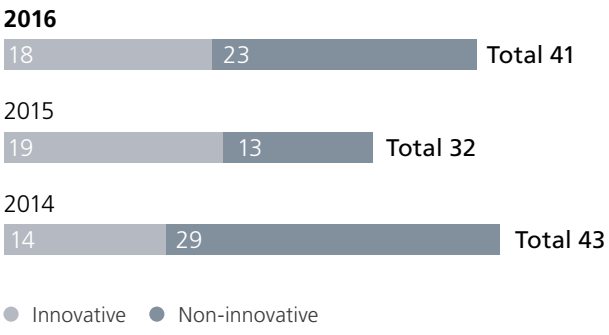
Activities

- 16 applications for innovative first authorisation and major variations were submitted, and 18 applications were completed.
- 23 applications for non-innovative first authorisation were completed, one concerning a co-marketing product and nine the first authorisation of a medicinal product containing a known active ingredient, including one application for temporary authorisation.
- All applications were approved with the exception of one application for authorisation of a known active ingredient.
- All of these applications were processed within the prescribed time limits.

Number of applications for first authorisation submitted:



Number of applications for first authorisation completed:



Veterinary 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 five meetings in 2016, the VMEC assessed 15 applications for authorisation or a variation of the authorisation. The Expert Committee also discussed two regulatory guidelines for the authorisation of veterinary medicines.

Extensions and discontinuations

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

Activities

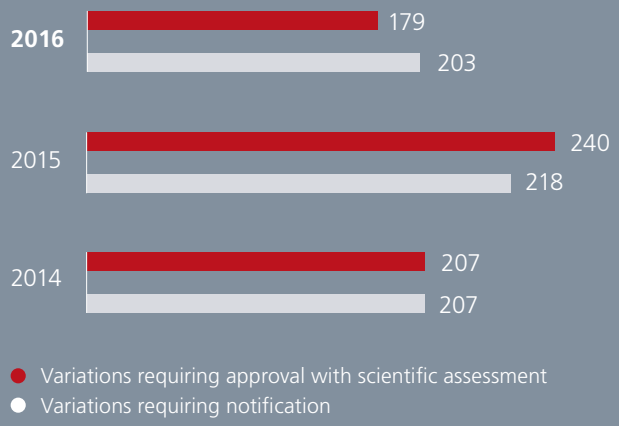
- In 2016, the authorisation was extended for 131 products.
- At the same time, the authorisation holders discontinued the marketing of 24 products.
- Applications to discontinue 5 products were completed, and the authorisations of 19 products were not extended.

Variations requiring approval and variations requiring notification

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

Activities

- In 2016, 179 variations requiring approval with scientific assessment and 203 variations requiring notification were completed.



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 medicinal product was granted MUMS status in 2016.
- Two applications for authorisation of products with known active ingredients were approved.

Applications under Article 13 TPA for veterinary medicinal products

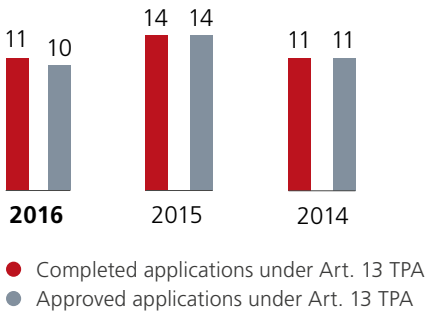
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose if the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

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

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

Activities

- 10 of the 11 authorisation applications for veterinary medicinal products under Art. 13 TPA that were completed in 2016 were approved.
- The authorisation of one product was rejected after its authorisation had been stopped in the European Union because of safety concerns.
- Of the 11 completed applications, two involved "known active pharmaceutical ingredients with innovation", five "known active pharmaceutical ingredients without innovation", three "major variations" (including one additional indication) and one variation requiring approval.



Veterinary medicines	2014		2015		**2016**	
	App.	Rej.	App.	Rej.	App.	Rej.
Known active pharmaceutical ingredients with innovation	2	0	3	0	1	1
Known active pharmaceutical ingredients without innovation	5	0	3	0	5	0
Variations requiring approval	4	0	4	0	2	0
Additional indications	0	0	2	0	1	0
Other major variations	0	0	2	0	2	0
Total	**11**	**0**	**14**	**0**	**11**	**1**

● Approval ● Rejection/withdrawal of the application

Appeals procedure regarding the authorisation of human and veterinary medicinal products

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

Activities

- In 2016, three appeals were lodged with the Federal Administrative Court against official decisions taken by the Agency in connection with product authorisations. The cases are still pending. One decision by the Federal Administrative Court was contested before the Federal Supreme Court. This case is also still pending.
- Of the appeals already pending before the Federal Administrative Court, three were dismissed. One appeal was rejected. The Federal Administrative Court issued judgements rejecting 14 pending cases.

Table of performance indicators for human and veterinary medicinal products

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

Performance indicator	Target	Result
Application category	**2016**	**Total 2016**
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 %	98 %
First marketing authorisations of non-innovative medicinal products (ZL1B); proportion of procedures completed within the prescribed time limits	95 %	86 %
Extensions / discontinuations of marketing authorisations (ZL2); proportion of procedures completed within the prescribed time limits	95 %	99 %
Scientific variations (ZL3A); proportion completed within the prescribed time limits	95 %	98 %
Administrative variations (ZL3B); proportion completed within the prescribed time limits	95 %	99 %

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

New record for compliance with time limits

Rapid market access for innovative medicinal products, particularly oncological products, is still an issue. In addition to a 99 % rate of compliance with the time limits across all application types, as in previous years, time-limit compliance was achieved in 100 % of fast-track applications. This makes the fast-track procedure one of the fastest review procedures in the world.

Evaluation reports accessible to applicants

Applicants can request to see the evaluation reports for applications for medicinal products with new active pharmaceutical ingredients, medicinal products with known active pharmaceutical ingredients and biologically similar medicinal products (biosimilars) and for major variation applications submitted to Swissmedic after 1 July 2015. In 2016, the first 24 of these open evaluation reports were sent to the applicants with the official decision.

Comparison of authorisation decisions issued by Swissmedic / EMA / FDA

A comparative study of authorisation decisions issued by Swissmedic in the period 2005 – 2014 shows that the regulatory authorities Swissmedic, EMA and FDA (in the USA) assess innovative medicinal products uniformly in 80 % of cases and differently in 20 % of cases. The highest degree of concordance exists between authorisation decisions taken by Swissmedic and the EMA at 90 %; 84 % of the decisions taken by Swissmedic and the FDA were the same. The decisions taken by Swissmedic were taken independently of the chronological order in which the decisions were taken by the comparator authorities. Where the official decisions differed, the main reasons for rejection by Swissmedic were safety concerns and efficacy concerns in roughly equal proportions. Although these benefit-risk assessments differed in some cases, market withdrawals were a rare event overall, accounting for 4-5 % of decisions. However, in cases in which the regulatory authorities issued differing decisions, market withdrawals were three times more common than when the decisions were uniformly positive. If only one of the three authorities granted authorisation, market withdrawals were five times more common.

Licensing

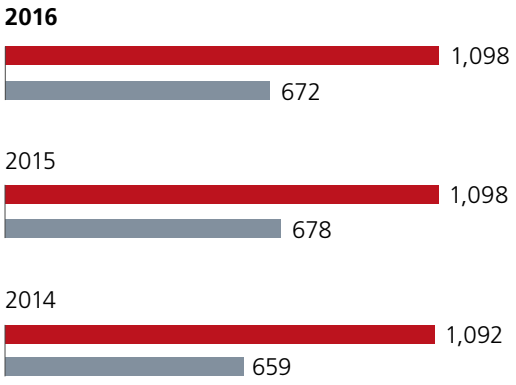
Licensing of medicinal and transplant products

Establishment licences for medicinal and transplant products

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

Activities

- At the end of 2016, 1,098 companies held an establishment licence for the manufacture, wholesale, import, export and trade in foreign countries of medicinal and transplant products. Some of these companies carry out several of the activities mentioned.
- In 2016, the number of licences issued for the first time, extended or amended was 672, which is slightly lower than for the previous year.



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

Performance indicator

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

● Target ● Result

Special licences for medicinal and transplant products

On application and within two working days, Swissmedic issues medical professionals with a special licence 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

- In 2016 the number of special licences granted continued to fall thanks to the simplified procedure for radiopharmaceuticals introduced in the previous year.

Total special licences issued

2016	2015	2014
1,455	1,744	2,567

Performance indicator

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

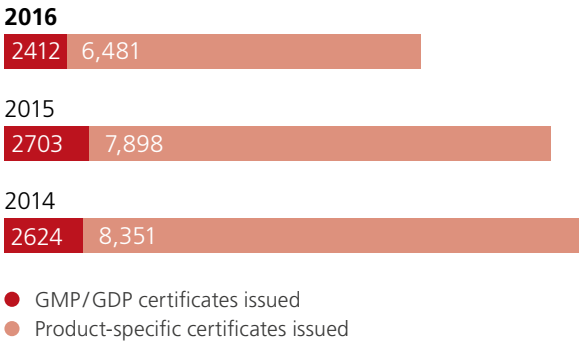
● Target ● Result

Certificates for medicinal and transplant products

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

Activities

- The structured order form for product certificates introduced in 2015 has proved successful. The time limit for issuing these certificates was respected in all cases in 2016.
- The number of product-specific certificates has continued to fall.
- The number of GMP/GDP certificates is also declining.



Performance indicator

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

Product 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. The Agency must be notified of domestic deliveries of narcotics from Lists A, B and D in accordance with Annex 1 of the Ordinance of the Federal Department of Home Affairs on the Directories of Narcotics, Psychotropic Substances, Precursors and Auxiliary Chemicals (BetmVV-EDI). Accounts must be kept by the licence holder of all transactions involving controlled substances. Corresponding annual accounts should be prepared and submitted to Swissmedic. Swissmedic examines these annual accounts and forwards a consolidated report to the "International Narcotics Control Board" (INCB, UNO, Vienna) in accordance with international agreements.

Activities

- In 2016, 361 companies were in possession of an establishment licence for handling controlled substances. At 196, the number of processed applications for modifications, renewals or the start of operations was higher than the previous year.
- 7,380 import and export permits were issued for international trade, 98 % of which were issued electronically.
- For the purpose of reporting to the International Narcotics Control Board (INCB) in accordance with international agreements, Swissmedic examined the annual accounts submitted by 464 company sites.
- Swissmedic analysed 35 substances and applied to the Federal Office of Home Affairs for their inclusion in the relevant Ordinance (BetmVV-EDI).

Performance indicator

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

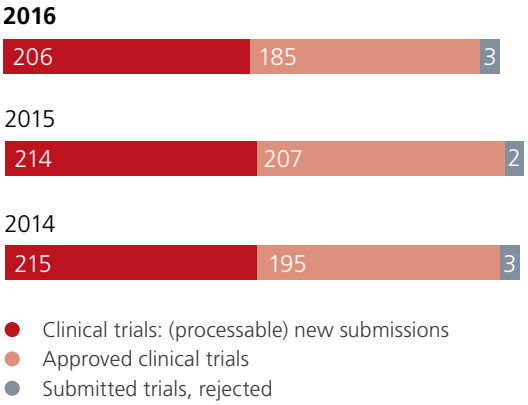
Target Result

Clinical trials with medicinal products and transplant products

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

Activities

- Swissmedic received 206 applications for clinical trials with medicinal products in 2016. Only 199 of these applications could be processed, as the rest were either incomplete or fell outside the remit of the Clinical Trials division. In total, 185 clinical trials were approved, including 45 in category B and 140 in category C. Five of the applications in the latter category concerned a first-in-human trial. Three clinical trials were rejected and four were withdrawn by the sponsor during evaluation. The other applications are currently being processed. A general trend towards more complex products and, as a result, more complex dossiers has been observed.
- On the other hand, 2,990 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 89 reports of suspected unexpected serious adverse reactions (SUSAR).
- Swissmedic continued to work with the FOPH and swissethics, the Association of Swiss Ethics Committees, on research involving humans, with the aim of coordinating and harmonising the three bodies, interpretation of certain provisions of the law. In connection with these efforts, Swissmedic took part in four meetings organised by the FOPH agency responsible for coordinating research involving humans.
- The performance indicator was missed as resources were not sufficient to handle additional tasks (analysis of clinical trials for integration into SAP, development of submission forms).



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

- As regards TpP/GT/GMO products, nine applications for authorisation were submitted to Swissmedic, five of which concerned in vivo or ex vivo gene therapy-based products. Increasing complexity was noted not only in the products, but also in the severity of the intended indications, which included cancer and multiple sclerosis. The procedures for four of these applications were completed in 2016.
- Moreover, 57 amendments to an authorised clinical trial with TpP/GT/GMO products were submitted, 52 of which were completed. Most of these were substantial amendments requiring scientific assessment.
- Twelve scientific advice meetings were conducted with stakeholders in relation to TpP/GT/GMO clinical trials.
- There was a significant increase in the reporting of adverse reactions to TpP/GT/GMO products following an active information campaign aimed at the relevant stakeholders.

Performance indicator

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

Target Result

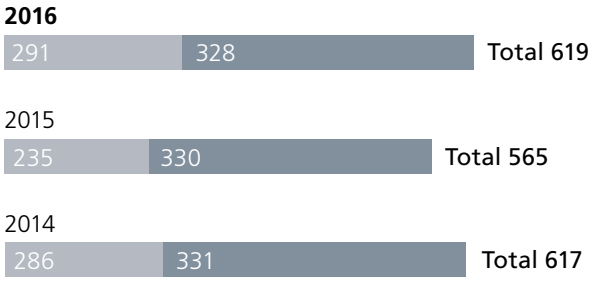
Inspections

GMP and GDP inspections

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

Activities

- In 2016, the Swissmedic inspectorate carried out 65, the regional inspectorates 554 GMP/GDP inspections of manufacturers and wholesale companies, giving a total of 619 inspections.
- The inspections carried out by the Swissmedic inspectorate concerned the following areas: transplant products 23 %, blood transfusion services 16 %, pre-approval inspections 9 %, "for cause" inspections 14 %, pharmaceutical sector inspections 29 %.
- Various technical interpretations were revised with a view to harmonising the Swiss inspectorate system. The new EU GDP guidelines were implemented in Switzerland without any major problems.
- Both the Swissmedic inspectorate and a number of regional inspectorates passed the reaccreditation audits conducted in 2016 in accordance with the requirements of the new international standard ISO/IEC 17020:2012. The reaccreditations have been confirmed by SAS for a further five years. After a restructuring process, the Regional Medicines Inspectorate of Western Switzerland (ISOPTh) is now able to conduct those inspections that fall within its jurisdiction independently.
- Four active pharmaceutical ingredient manufacturers – two in India, two in China – were inspected in collaboration with the European Directorate for the Quality of Medicines & HealthCare (EDQM), while two manufacturers in China were inspected with the WHO. Swissmedic also took part in ongoing assessments of partner authorities within the framework of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).



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

Clinical trials carried out in Switzerland by sponsors and research institutes, as well as trial locations, facilities and laboratories, are inspected by Swissmedic on a random basis according to defined risk criteria with regard to compliance with the rules of Good Clinical Practice (GCP). In doing so, Swissmedic also verifies whether the safety and personal rights of the study participants are guaranteed. Checks are also carried out to establish whether the implementation of the trials satisfies the scientific criteria for quality and integrity. Pharmacovigilance inspections (Good Vigilance Practice, GVP) are above all designed to examine compliance with the legally prescribed mandatory reporting of adverse drug reactions in clinical trials as well as spontaneous reports.

Activities

- During 2016, Swissmedic conducted 24 GCP inspections in connection with clinical trials of medicinal products in Switzerland.
- It also carried out 8 GVP inspections in Switzerland.
- Within the framework of PIC/S, Swissmedic participated in one programme of GCP inspections and two programmes of GVP inspections. In this context, Swissmedic accompanied three GVP inspections carried out by foreign authorities in Italy, Sweden and Great Britain. One of the 24 GCP inspections conducted in Switzerland was also part of the PIC/S programme.
- In 2016, Swissmedic's GCP/GVP inspectors again participated in the EM's Inspectors Working Groups.
- One GCP/GVP inspector also acted as the Swiss expert contributing to the working group tasked with the revision of the ICH E6 GCP Guideline. The revised version ICH E6(R2) was adopted by the ICH Assembly in November 2016.
- Four inspections relating to clinical trials with standardised transplants or gene therapy were conducted in 2016. The inspectors reported a good GCP standard at the inspected establishments.

Performance indicator

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

● Target ● Result

GLP inspections

With the exception of pharmacodynamics for notification or authorisation procedures, non-clinical assessments for authorisation in Switzerland are to be carried out in accordance with Good Laboratory Practice (GLP). Swissmedic's GLP unit carries out monitoring activities (inspections or study audits) with the relevant divisions of the Federal Office for the Environment (FOEN) and the Federal Office of Public Health (FOPH) within the framework of the GLP monitoring programme. Additional requirements imposed by 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

- A total of 9 routine inspections and one first inspection were carried out in 2016. An inspector from China accompanied one of these routine inspections so that he could familiarise himself with the Swiss GLP monitoring programme.
- Three test facilities withdrew from the monitoring programme during the year, and one former test facility now operates as a service provider. A further service provider was added to the GLP Register.
- The service providers offer defined services (e.g. archiving or IT support) for test facilities and are now listed on the GLP website.
- At the request of the OECD Working Group on GLP, in January 2016 the Israeli GLP monitoring programme was reviewed by the Swissmedic GLP unit in collaboration with an inspector from Finland (Fimea).

Performance indicator

GLP inspections; degree to which the annual plan was fulfilled

● Target ● Result

Inspections for third parties

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

Activities

- In 2016, Swissmedic carried out 24 inspections for the FOPH and three for the Principality of Liechtenstein.

Inspections by foreign authorities in Switzerland

Swissmedic and the regional inspectorates operated by the Cantons will, if required, accompany inspections of companies in Switzerland by foreign authorities. In so doing, the Swiss inspectors assume the role of representatives of the Swiss inspections system.

Activities

- In 2016, foreign authorities carried out 81 GMP inspections at pharmaceutical companies in Switzerland. The inspecting authorities were the USA with 37 inspections, Brazil with 14, Belarus with eight, Russia with seven, Korea with four, Turkey with three, Mexico and Taiwan with two each, and China, Kazakhstan, Ukraine and Jordan with one inspection each.
- Swissmedic also accompanied one GCP inspection carried out by the UK authority (MHRA) in Switzerland.

Inspections by foreign authorities in Switzerland

2016	2015	2014
82	60	76

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

- In mid-2016 Swiss Transfusion SRC publicly announced its wish to replace the existing unlimited ban on "men who have sex with men" (MSM) with a 12-month deferral period after the last MSM contact, and its intention to submit a corresponding application to Swissmedic. This was approved at the end of 2016.
- The Zika virus (ZKV) has spread rapidly across the Latin American continent and the Caribbean islands over the past 1-2 years. Since there is evidence to suggest that ZKV can be transmitted via blood transfusions, measures have also been taken in Switzerland. Donors must refrain from giving blood for at least one month after visiting a ZKV risk area. Donors with a confirmed or suspected ZKV infection may not give blood until one month after they have made a complete recovery. Swiss Transfusion SRC has also drawn up a Zika preparedness plan in consultation with the authorities.
- Since cases of the hepatitis E virus being transmitted via blood transfusions have increased in other countries, Swissmedic, Swisstransplant and Swiss Transfusion SRC have jointly issued a recommendation that immunosuppressed transplant recipients (organs and stem cells) be tested for the hepatitis E virus if their liver enzyme levels are elevated, since transmission via a transplant or blood units has been observed in isolated cases.
- Other risks arising from the spread of transmissible diseases such as dengue fever or Chagas disease, not to mention the occurrence of West Nile Virus (WNV) cases in nearby countries, have been addressed by regularly adapting donor suitability criteria to the epidemiological situation. Swissmedic has also asked Swiss Transfusion SRC to carry out risk assessments of a number of topical issues. Apart from the Zika virus and classical blood-borne infections, the assessment will also focus on the possible implications of an increase in the number of individuals from countries with a high risk of infection (refugees).
- Together with the Cantons, a Guide for Quality Assurance in Transfusion Practice has also been produced for the first time. The document is due to be approved shortly and is aimed at hospitals that carry out blood transfusions.

Licensing of microbiological laboratories

Establishment licences for microbiological laboratories

A new task has been assigned to Swissmedic with the introduction of the revised Federal Act on Combating Communicable Human Diseases (Epidemics Act, EpidA; SR 818.101). 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

- Swissmedic provided information about the new legal requirements for microbiological laboratories in various publications and at events held by professional associations. Swissmedic also added a dedicated page to its website with important information on these establishment licences.
- At the end of 2016, 45 laboratories possessed a microbiological laboratory licence issued by Swissmedic according to the new legislation. Existing certificates of recognition issued by the FOPH and licences issued by Swissmedic were transferred to a new licence, thereby combining all the activities and sites of a laboratory in the new licence. 63 % of the licensed activities concerned patient diagnosis, 27 % screening and 10 % environmental analytics.
- In accordance with the transitional provisions, around 80 laboratories still possess a valid FOPH certificate of recognition as a microbiological laboratory or a Swissmedic licence issued according to the old legislation.
- Important topics in the first year of implementation included the applicability of the new Ordinance to specific laboratory situations, for example concerning the management requirements pertaining to type B special laboratories and the rapidly growing use of decentralised near-patient diagnosis in hospitals (point-of-care testing).

Inspections of microbiological laboratories

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

Activities

- Compared to previous years, Swissmedic has intensified its inspection activities in microbiological laboratories, conducting 41 inspections in 2016. Differences were noticed between the inspection results of accredited and non-accredited laboratories. These findings will be incorporated into inspection planning so as to make best use of the option provided by the new Ordinance of taking account of accreditation when monitoring laboratories.

Inspections of microbiological laboratories (since 2016)

41

2016

Official Medicines Control Laboratory (OMCL)

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

Activities

- In the area of batch release, various measures were implemented to increase efficiency and improve the documentation of results. The reproducibility of test results was once again increased and the risk of error further minimised by transferring tests to a pipetting robot. In another project, the previous practice of documenting analyses on paper was superseded by recording in the Laboratory Information System (LIMS). As a result, the whole process of batch release can be tracked in LIMS.
- Newly established analytical methods:
  – Thanks to the recent addition and accreditation of nephelometry (an optical analytical technique), it is now possible to quantify the subgroup distribution of IgG antibodies and the maximum permitted content of type IgA antibodies in human immunoglobulins.
  – X-ray fluorescence spectroscopy (XRF) has also been newly established and accredited for use in investigating the elemental composition of pharmaceutical preparations.
  – Furthermore, a mass spectrometry technology known as scheduled multiple reaction monitoring (MRM) was introduced, whose applications include the extremely selective and sensitive quantification of genotoxic impurities.
- Using the newly learned method of value stream mapping, the OMCL is able systematically to evaluate and optimise established process specifications. By implementing this process of continuous improvement, the OMCL safeguards up-to-date and efficient procedures.

Analysis conclusions for new marketing authorisations and market monitoring

	2014	2015	2016
Authorisation procedure: number of medicinal products examined	54	37	39
Market monitoring: number of medicinal products examined	1,980	1,333	1,187
Other (pharmacopoeia, round robin tests)	375	526	479
Total	**2,409**	**1,896**	**1,705**

Batch assessments and plasma pool analysis

	2014		2015		2016	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU)	701	74	748	65	712	64
Notifications	312	169	321	135	357	157
Plasma pool analyses	2,337	–	2,375	–	2,467	–
Product analyses as WHO reference laboratory	–	16	–	13	–	9

Performance indicator

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

● Target ● Result

Appeals procedures regarding licences

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

Activities

- Two appeals were lodged before the Federal Administrative Court against official decisions by the Agency in connection with licences in 2016. One appeal was not admitted, the other is still pending.
- Of the appeals already pending before the Federal Administrative Court, one was dismissed.

Special activities and events: Authorisation

Swissmedic is assigned new tasks under revised Epidemics Act

The Federal Act on Combating Communicable Human Diseases (Epidemics Act, EpidA; 818.101) has been revised and was enacted, together with the implementing provisions, by the Federal Council with effect from 1 January 2016. As a result, laboratories that conduct, or want to start conducting, microbiological tests for the identification of communicable diseases will be subject to exclusive monitoring by Swissmedic.

Stem cell therapies

Comprehensive proceedings were initiated against two companies that had manufactured stem cell preparations and offered associated treatments without a licence. As a temporary measure, a ban on the handling of transplant products without a licence has been ordered, and the suspensive effect of any appeals was revoked. One case is still pending before the Federal Administrative Court.

Market surveillance

The quality, safety and efficacy of medicinal products and medical devices continue to be monitored by Swissmedic even after they have obtained marketing authorisation.

Medicinal products

Medicinal product vigilance

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

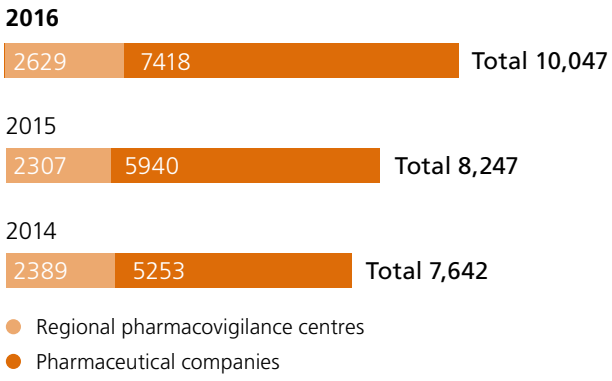
Pharmacovigilance

Within the framework of the pharmacovigilance network, the direct reports from healthcare 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

- Swissmedic received 10,047 first reports of suspected adverse drug reactions (ADR) in 2016. 2,615 of them were sent by the six regional pharmacovigilance centres (RPVC), 7,432 by the industry. As in previous years, there was again a sharp rise in the number of reports received (+21.8 %), due to an increase in the volume reported by firms. In addition, the number of follow-up reports increased by 41.7 % compared with the previous year to 3,056. This puts Switzerland in 6th place worldwide in terms of reporting rate.
- The percentage of industry reports notified electronically to Swissmedic rose to more than 90 %, most of them arriving via the pharmacovigilance gateway. A further six firms were given gateway access in 2016, bringing the total number using this reporting route to 24 in February 2017.
- The second electronic reporting route, the online reporting portal ElViS (Electronic Vigilance System), was launched in October 2014, enabling healthcare professionals to report ADR online to one of the regional pharmacovigilance centres. In 2016 Swissmedic received 204 reports from healthcare professionals via the portal. By the end of 2016, most of the pharmaceutical firms without access to the gateway were also reporting via ElViS. At the end of the year, 108 companies had access to this reporting route, twice the number in 2015.

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



Performance indicator

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

Target Result

Haemovigilance

The primary function of haemovigilance is to systematically monitor the adverse events associated with the collection, production and administration of blood transfusions with the aim of identifying new risks and quality defects at an early stage. In addition to a general assessment of risk, the system is also used to trigger and evaluate preventive measures both at individual blood transfusion services and hospitals and on a national level. Periodic evaluation and publication of the haemovigilance data provides information on the nature and magnitude of transfusion risks in Switzerland. The presentation of transfusion risks provides the treating doctor with a basis for the benefit-risk analysis when considering a transfusion and for providing advice to the patient about possible adverse effects.

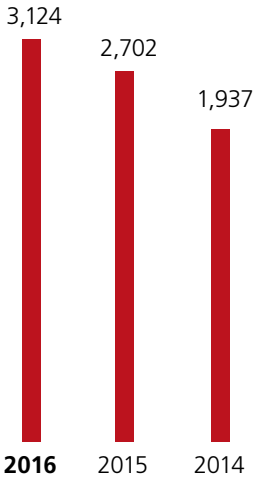
Quality assurance in the use of labile blood products plays an elementary role in the Swiss haemovigilance system.

Activities

- Guidelines on quality assurance in the transfusion chain have been drawn up by professionals working in Cantonal administrations and hospitals in order to improve transfusion safety; they will be published in 2017.
- The overall reporting rate is calculated from the total number of haemovigilance reports. It includes all report types. The reporting rate increased again in 2016 (+16 %). This increase can be interpreted as a sign of greater reporting and quality awareness: www.swissmedic.ch/haemovigilance-report.
- Two safety-relevant publications on transfusion-related infectious diseases appeared:

– Hepatitis E in transplant recipients (HPC)
– "A Case of Possible Chagas Transmission by Blood Transfusion in Switzerland". Transfus Med Hemother 2016; 43: 415-417.

Adverse events involving blood products: Number of reports



Performance indicator

Report on new findings

Training courses for haemovigilance officers

Target Result

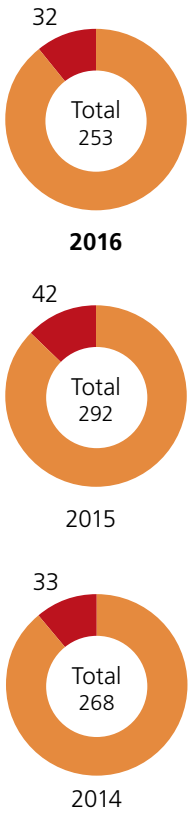
Vigilance for veterinary medicinal products

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

Activities

- A report on the evaluation of adverse drug reaction (ADR) reports relating to veterinary medicinal products in 2015 was published in the journal Swiss Archive of Veterinary Medicine (Müntener et al., Schweiz. Arch. Tierheilk., 158: 743-747, 2016).
- In 2016 the number of adverse reactions to veterinary medicinal products submitted to Swissmedic was 253, which constitutes a decrease of 13 % compared to the previous year. Thirty-two of these reports were passed on to Swissmedic by Tox Info Suisse.
- Once again, ADR reports in 2016 primarily involved dogs (179) and cats (32), followed in third place by cattle (17). The medicinal product categories most frequently involved were antiparasitic drugs (144 reports) or products containing hormonally active substances (26), followed in third place in 2016 by anti-infectives (19). This distribution is largely comparable to that recorded in 2015.
- Five signals were generated from the 253 reports and from the analysis of the periodic safety update reports (PSUR). Two of them involved products for use in farm animals.

Adverse drug reactions, veterinary medicinal products



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

Performance indicator

Report on new findings

- Target
- Result

Risk management

As part of the procedure for authorisation of new medicinal products, firms must provide, for assessment, a pharmacovigilance plan in accordance with the guidelines of the International Conference on Harmonisation (ICH). This plan must be kept up to date by the firms and submitted, for example, as an update within the framework of regular post-authorisation reporting. In the plan, the authorisation holder must take a stance regarding both the known and the potential risks associated with the new medicinal product and demonstrate how they will be prevented, followed up, and what measures will be taken to address any missing findings.

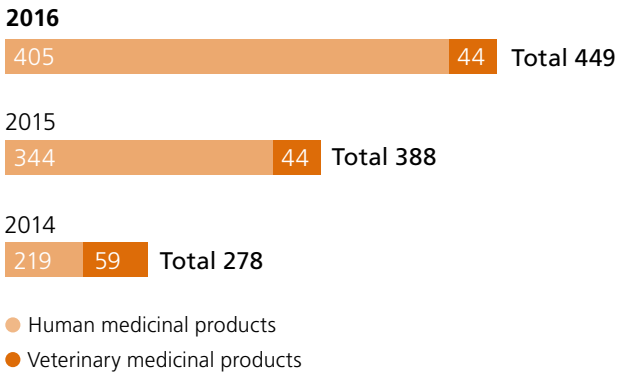
Swissmedic also assesses the regular reports that must be submitted by the firms – Periodic Safety Update Reports (PSUR) and Periodic Benefit Risk Evaluation Reports (PBRER). Swissmedic's tasks also include the assessment of international data on the safety of medicines. A central element is the identification, assessment and follow-up of safety signals from national and international sources.

Activities

- Assessment of pharmacovigilance plans increased again last year. Such plans were evaluated as part of 105 applications for first authorisation and major variations. The resulting measures are published on the Swissmedic website in the form of a brief summary, the Risk Management Plan (RMP) summary. The purpose of publication is to provide healthcare professionals with more information about product risks and their post-authorisation monitoring.
- In 2016 Swissmedic concluded a pilot project started in 2015 to publish RMP summaries. During this pilot phase, Swissmedic defined the processes and the content to be published and set out this information in an information sheet. By the end of 2016, 19 RMP summaries had been linked on the Swissmedic website and on the AIPS medicinal products information platform.
- Swissmedic processed 193 signals in 2016, 34 originating from reports from Switzerland and 159 from international observations.

Pharmacovigilance plans: Number of assessments

PSUR/PBRER: Number of assessments



Performance indicator

Number of signals identified from national reports or international sources

Risk mitigation measures

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

Activities

- Boxed warnings drawing attention to the risk of an overdose were added to the texts of the package leaflets and packaging supplied with medicinal products containing methotrexate. Other risk-mitigation measures were also taken, among them a reduction of the pack sizes.
- In addition to updating the medicinal product information about use of valproate-containing products during pregnancy and breast-feeding, a circular (DHPC) approved by Swissmedic was sent to the firms and a downloadable patient card was published on the Swissmedic website.
- Swissmedic also drew attention to the risk of multiple spinal fractures following discontinuation of denosumab (Prolia®). This usually arises in association with the loss of bone minerals that can occur after treatment with Prolia® is stopped, mainly in patients with a prior history of spinal fracture.
- Swissmedic follows the safety-relevant activities and measures imposed by foreign authorities such as the FDA and EMA and reviews the necessity of implementing measures in Switzerland too.

Performance indicator

Number of completed procedures (including reviews)

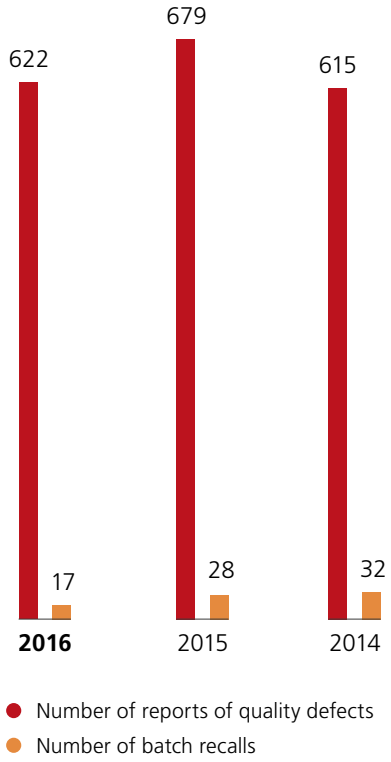
● Target ● Result

Quality defects and batch recalls

Swissmedic records quality defects in medicinal products and takes the necessary measures. A reported quality defect is assessed, prioritised and processed. Depending on the potential risk of the defect in question, a batch recall or a circular for healthcare professionals is necessary. The assessment also takes possible supply shortages into consideration. A further important aspect of market monitoring is the international exchange of information and the examination of foreign reports with regard to their significance for the Swiss market.

Activities

- Following an increase in recent years, the number of reported quality defects has stabilised at around 650 per year. 72 % of them affected Switzerland, and 80 cases involved a Class 1 or 2 serious defect.
- Official decisions to carry out 17 batch recalls were taken.
- One emergency medicinal product was recalled down to patient level as there was the possibility of the needle becoming detached from the syringe. This meant that the medicinal product could not be administered in an emergency situation, which could have potentially led to life-threatening situations.
- A larger number of reports concerning non-compliant manufacturers (GMP non-compliance) were submitted in 2016. The reports covered facilities in China, India, Italy, Hungary and elsewhere, most of them operated by manufacturers of active pharmaceutical ingredients. The authorisation holders of the products concerned were requested to switch to alternative suppliers of active pharmaceutical ingredients or to intensify their monitoring activities.
- In 2016, 32 applications to temporarily distribute a medicinal product produced for other countries in order to overcome supply shortages were submitted, 20 of which were approved.

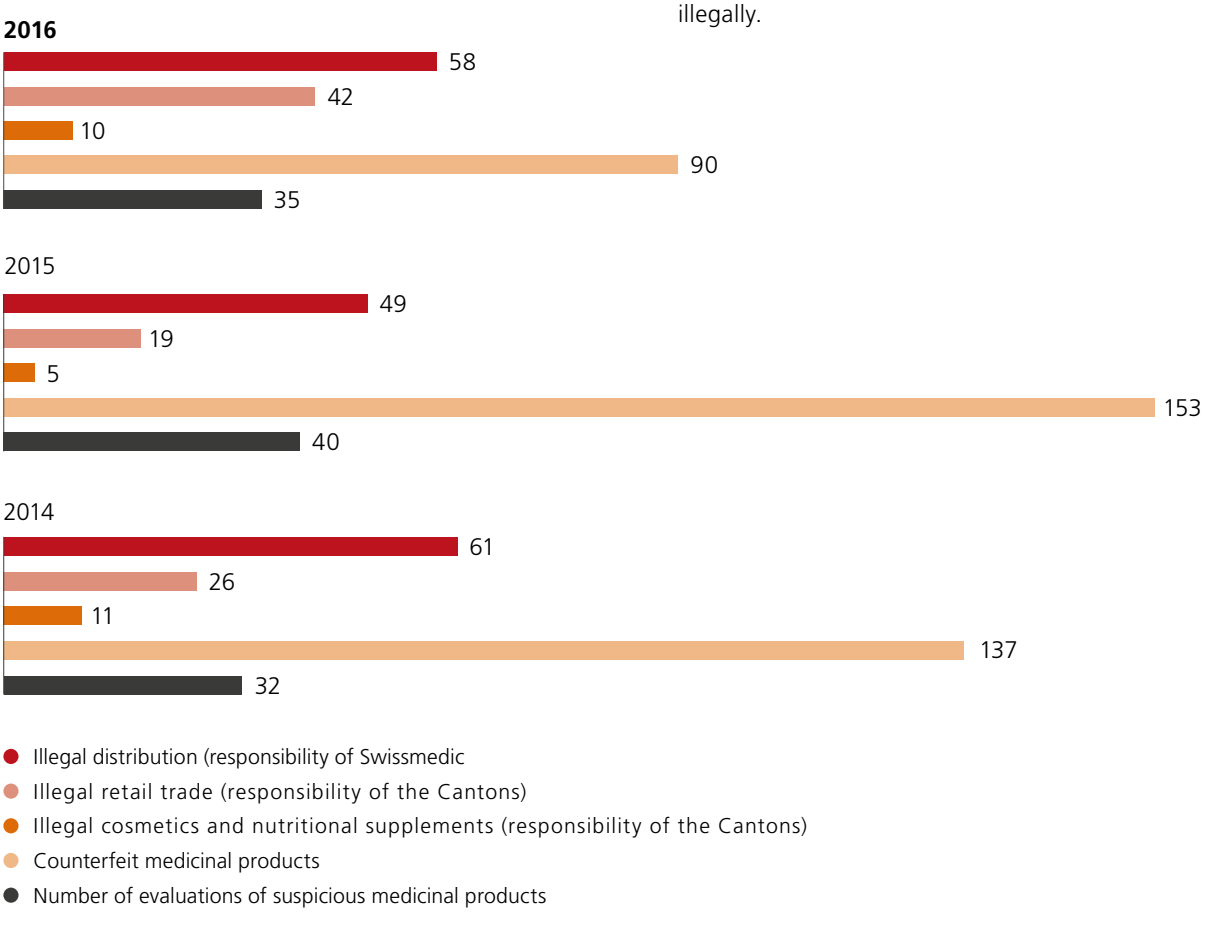


Measures against illegal medicinal products

Swissmedic is tasked with warning the public about the possible dangers of illegal medicinal products. It does so, for instance, by publishing information on the Swissmedic website or by issuing press releases. In order to reduce risks, it is particularly important to inform healthcare professionals and the public about new findings without delay, to foster a regular exchange with product users, and to maintain good national and international networking. Swissmedic receives reports on illegal products, activities and distribution, examines them and, if necessary, initiates measures. Swissmedic also controls illegally imported medicines in close collaboration with the customs authorities, and if necessary orders their return or destruction.

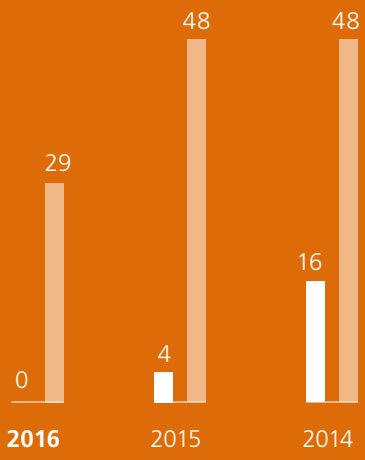
Activities

- In 2016, Swissmedic received 287 reports of suspected illegal activities related to medicinal products. Fifty-eight reports contained information pointing to distribution of the products in Switzerland.
- Fifty-two cases were transmitted to the Cantons for further follow-up, since they concerned the retail trade or illegal products that do not come under the legislation on therapeutic products.
- Ninety reports on counterfeiting were received in 2016, most of which (75) did not involve Switzerland.
- The 15 cases of counterfeiting that did affect Switzerland mostly concerned offers on action platforms that could be eliminated rapidly. Some cases, however, involved foreign counterfeit products being traded through Swiss firms. One such case was discovered in the spring. The product was a hepatitis C treatment imported from India by a Swiss trading firm and distributed in Israel.
- The Swiss customs authority reported 1,028 illegal imports of medicinal products to Swissmedic. Theses resulted in the initiation of 939 administrative proceedings and the destruction of the goods in 95 % of the cases.
- A total of 103 countries took part in Operation PANGEA, an international week of action targeting illegal Internet sales of medicinal products that was held for the ninth time in 2016. The Swiss customs authority, Swissmedic and Antidoping checked more than 2,000 shipments, 765 of which contained medicinal products or doping agents; 82 were confiscated. The analysis showed that most illegally imported medicinal products originate from India, followed by Germany (generally only a staging point for Asian medicinal products), while Cambodia ranked third for the first time. This year's operation confirmed the projected figures from 2013; some 40,000 shipments of medicinal products are imported annually, half of them illegally.



Control of advertising

Swissmedic controls and monitors the advertising of medicinal products. One aspect of the work is to examine and assess advertising material for which prior control is mandatory in order to ensure that it complies with the relevant provisions of the legislation on therapeutic products. Swissmedic also follows up information regarding infringements of advertising legislation and decides whether administrative proceedings need to be initiated, or in which cases legal compliance can be re-established by means of an official objection. To promote the transfer of knowledge, Swissmedic informs interested stakeholders of the currently valid legal basis for the advertising of medicinal products.



- Number of applications for advertising in the printed media (including the Internet)
- Number of applications for advertising in electronic media

Activities

- A partial revision of the Therapeutic Products Advertising Ordinance entered into force on 1 April 2016. The mandatory information must now point out that the medicinal product has been authorised by Swissmedic. A three-year transition phase has been established to give affected firms the opportunity to implement the changeover flexibly. This means that advertising to the public of medicinal products in dispensing categories C and D that do not meet the conditions of the revised Therapeutic Products Advertising Ordinance – i.e. the mandatory information does not mention the authorisation status – may no longer be disseminated from 1 April 2019.
- The 29 applications submitted in 2016 involved only TV spots. No printed media were submitted during the year.
- Swissmedic received a total of 38 advertisements targeting the public or healthcare professionals. In three cases administrative proceedings were initiated and in three cases an official objection was issued.

Performance indicator

Prior control of advertising: proportion of cases where a preliminary decision was taken within 4 weeks of receipt of the application

- Target
- Result

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

Performance indicator

First actions taken within 10 days for priority 1 reports

Performance indicator

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

Performance indicator

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

● Target ● Result

Appeals procedures regarding the market monitoring of medicinal products

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

Activities

- In 2016, appeals were lodged with the Federal Administrative Court against five official decisions by the Agency in connection with the market monitoring of medicinal products. Three appeals were not admitted, one appeal was rejected and another is pending.
- Of the appeals already pending before the Federal Administrative Court, two were dismissed. One appeal was dismissed.

Special activities and events: Market surveillance for medicinal products

Improvement of transfusion safety

The Therapeutic Products Act requires institutions that transfuse blood to establish a quality assurance (QA) system. The legislation defines neither the exact structure nor the scope of the QA system. In 2014, Swissmedic set up a working group comprising representatives of the Cantonal Pharmacists Association (KAV), Cantonal Doctors Association (VKS) and haemovigilance managers to produce a guideline for quality assurance in transfusion practice. The guideline describes what a QA system should regulate and what the minimum requirements are. Hospitals can also use it as a checklist for updating/refining their QA systems. The intention is for the guideline to be published in 2017 following consultation and approval by the Cantonal associations (KAV and VKS).

Improvement of the data quality of manufacturers' details

An analysis of the data available to Swissmedic about the firms involved in the manufacture of a medicinal product revealed large gaps. A project to improve this situation was initiated since, when international reports of GMP breaches are reported, a rapid evaluation must be carried out to determine which authorised medicinal products are affected by a quality problem. A major milestone was reached in June 2016 with the publication of a totally revised form for manufacturers' details. This gives the person responsible for batch release at the company's end a complete overview of the manufacturers involved and their status, and ensures that full details are sent with applications submitted to Swissmedic.

Optimised collaboration in pharmacovigilance

The new contracts introduced from 2016 for the services provided by the six Regional Pharmacovigilance Centres (RPVC) in connection with the documentation and evaluation of reports on adverse drug reactions have demonstrated their value. Reports from the RPVC are now processed in accordance with their importance for the identification of safety-relevant signals. At the same time, Swissmedic is now able to inspect the RPVC regularly, in the same way that it already inspects authorisation holders. Two such inspections took place in 2016.

Medical devices

Market monitoring of medical devices

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

Integration within the European system

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

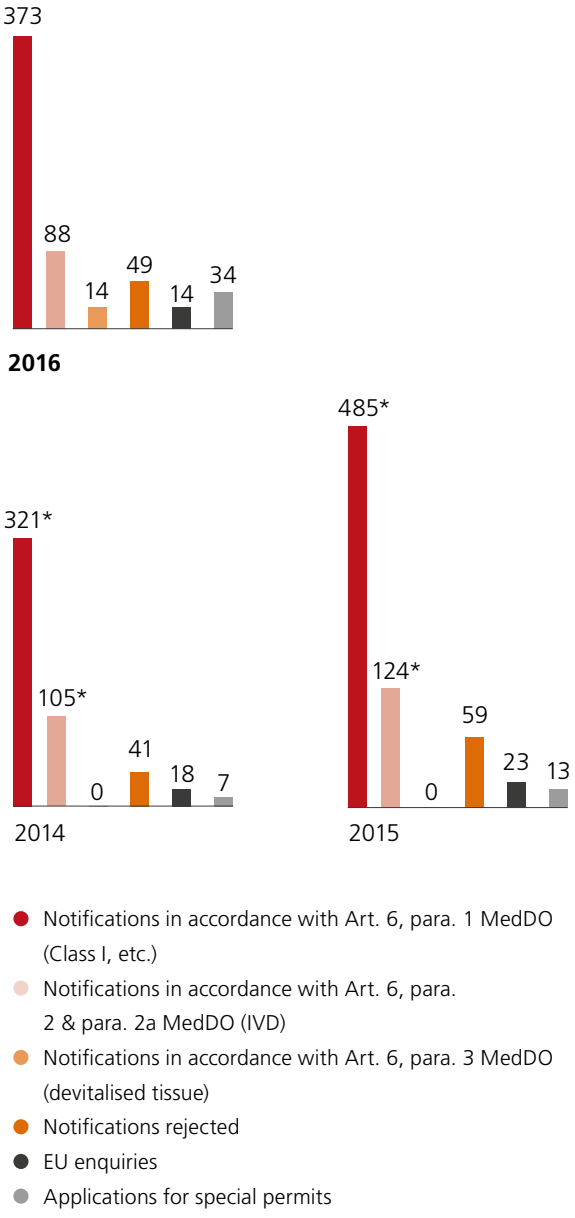
This European system provides the authorities of the contracting states with a shared database (EUDAMED) as an information system for market monitoring. CE-marked medical devices are considered as being compliant and may be distributed in all contracting states.Swissmedic took part in the meetings of high-level bodies of the Member States, i.e. meetings of the Competent Authorities Medical Devices (CAMD) and its working groups: the Compliance and Enforcement Group (COEN) and the Notified Bodies Operations Group (NBOG). Swissmedic is also active within the Medical Devices Expert Group (MDEG) of the European Commission and its working groups: Vigilance, Borderline and Classification, In Vitro Diagnostic Technical Group, Clinical Investigation and Evaluation (CIE), EUDAMED and in ad hoc working groups such as the Software Group as required.

Placing on the market

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

Activities

- In 2016, 373 notifications in accordance with Art. 6 para. 1 MedDO were received. They involved classic Class 1 medical devices, custom-made classic or active implantable medical devices, systems and treatment units. This class covers products such as reusable surgical instruments, adhesive plasters and rolling walkers.
- A total of 88 notifications in accordance with Art. 6 para. 2 and para. 2a MedDO were submitted for in vitro diagnostic (IVD) devices.
- Fourteen notifications in accordance with Art. 6 para. 3 MedDO were received for classic and active implantable medical devices which are made using or which contain devitalised human tissue.
- In 49 cases, Swissmedic rejected notifications of medical devices from firms because of incorrect categorisation or classification, or because the product did not fall within its area of responsibility.
- In 2016, Swissmedic took part in 14 EU enquiries on delimitation questions regarding the classification of devices.
- Swissmedic may issue special permits for the import of non-compliant medical devices if these devices are able to resolve a life-threatening situation for a patient. In 2016 the number of applications for special permits that were reviewed and approved rose to 34.



* The corresponding figures from previous years are comparable only to a certain extent since the criteria for recording them were modified slightly during 2016.

European market monitoring activities

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

Activities

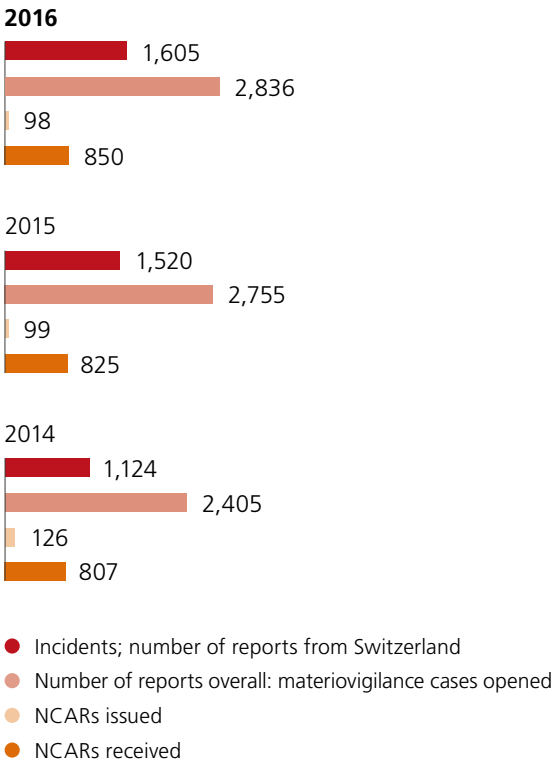
- The number of requests for mutual assistance from European partner authorities remained stable compared to 2015 at 150.
- In 2016, Swissmedic issued 18 requests for mutual assistance to its European partner authorities.
- Intensified monitoring of the CABs led Swissmedic to take part in internationally accompanied audits of these CABs again in 2016, an activity that included the review of product documentation. Both the notified bodies in Switzerland were also audited in this way in 2016.

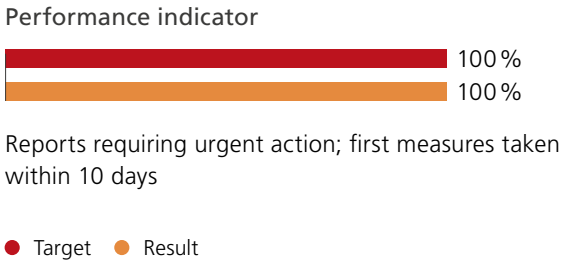
Materiovigilance

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

Activities

- A total of 1605 incidents were reported in Switzerland in 2016. This represents a further increase compared with the previous year.
- The implementation of corrective safety measures in Switzerland was monitored in 750 cases. A total of 98 reports on defective medical devices (National Competent Authority Reports, NCARs) were drawn up for the attention of foreign authorities, and Swissmedic received 850 NCARs from the European partner authorities.
- In 644 cases, a public safety report was published on the Swissmedic website for the information of users.
- In 2016, new cases of suspected incidents or concrete actions to be taken on pending cases were again discussed during monthly telephone conferences with the other European monitoring authorities.



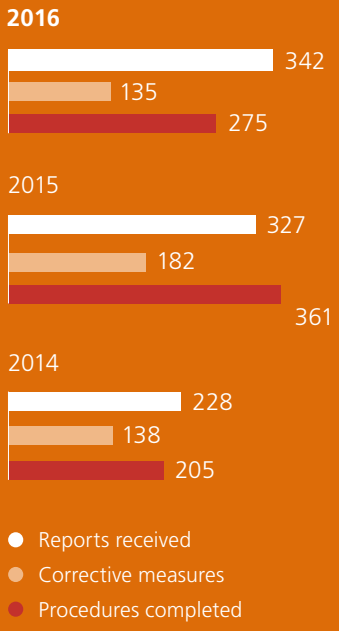


Market controls

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

Activities

- The number of reports on products suspected of being non-compliant rose slightly to 342 in 2016.
- Corrective measures, such as modification of the product descriptions or halting distribution, were imposed in response to 135 of the shortcomings.
- In 2016, 275 notifications were completed.
- The number of reports remains high, as a result of which they were processed stringently according to the risk involved.



Clinical investigations

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

Activities

- The number of applications for investigations with medical devices that are not yet authorised for the market rose by some 10 % to 34 in 2016.
- Six ongoing clinical investigations were inspected during the year under review.

Performance indicator

Approval of clinical investigations; proportion assessed within 30 to 60 days

Target Result

Monitoring of conformity assessment bodies (CABs) and inspections

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

Activities

- As part of market control activities, on-site inspections of nine Swiss firms were performed.
- In 2016, Swissmedic carried out a total of 12 inspections in hospitals in the areas of reprocessing, maintenance and reporting systems.
- Swissmedic co-ordinates inspections carried out in Switzerland by foreign authorities with the State Secretariat for Economic Affairs (SECO) and, if needed, accompanies the inspectors on site.

	2014	2015	**2016**
CAB inspections (including ISO 13485)	3	6	3
Joint assessments	2	2	2
On-site inspections of clinical investigations	0	3	6
Hospital audits (reprocessing, maintenance and reporting system)	2	4	12
Inspections by foreign authorities*	54	40	74
Inspections of market controls	6	8	10

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

Export certificates

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

Activities

- In 2016, 2677 export certificates were issued. In 99 % of cases this service was provided within 30 days.

2,677	2,575	2,379
2016	2015	2014

Appeals procedure concerning the market monitoring of medical devices

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

Activities

- In 2016, two appeals were lodged against official decisions of the Agency in connection with the market monitoring of medicinal devices. Both are pending.
- No further appeals from previous years are pending before the Federal Administrative Court or the Federal Supreme Court.

Special activities and events: Market monitoring of medical devices

Increased inspection activity

In 2016, Swissmedic specifically and substantially increased inspection activities relating to medical devices with the aim of boosting enforcement and improving product safety and hence patient safety.

Election to the CAMD Executive Group

The Head of the Medical Devices Department at Swissmedic was elected to the CAMD Executive Group at the Competent Authorities for Medical Devices (CAMD) Meeting held on 20 and 21 June 2016 in Amsterdam. Switzerland is now represented in the steering committee that is working towards better European cooperation and market monitoring for medical devices.

Reduction in the number of conformity assessment bodies

The Europe-wide intensification of market surveillance activities for medical devices that has been ongoing since 2013 is having tangible effects. The number of conformity assessment bodies (CABs) across Europe has decreased from approximately 80 to fewer than 60 in the past three years. In some instances the scope of designation of the Notified Bodies has also been restricted. This means than many manufacturers need a new CAB to certify their products. This is not an easy process and at the moment can take up to one year to complete. Swissmedic has addressed the problem and decided to follow the harmonised European approach, granting firms a period of 12 months in which they are required to have their products certified. The practical implementation of this decision was announced on the Swissmedic website in December 2016.

Standards

Legal matters

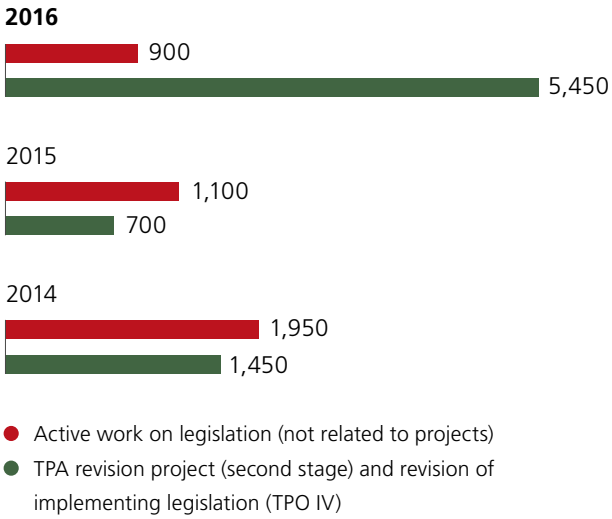
Legislation

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

Activities

- The EU began revising its medical devices legislation in 2012 and published the latest versions of the new Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR) in June 2016. These will no longer be directives but regulations which are directly applicable in the EU Member States. They are expected to enter into force in the first half of 2017. These provisions will become legally binding 20 days after publication and will come into force in stages within 6 months to 5 years for all EU Member States. Switzerland has to integrate the new regulations into Swiss law in good time if it wants to continue participating in the European internal market for medical devices and avoid technical trade barriers. At the same time, access to the EU's current and new databases and expert groups is indispensable for ensuring effective and efficient market surveillance in Switzerland.
  Maintaining equivalence of the provisions calls for far-reaching adjustments to Swiss law and ordinances and to the MRA. After an initial approximate analysis of the ramifications, a project group led by the FOPH and including Swissmedic and SECO personnel was initiated in June 2016. Project planning envisages a multi-stage approach to ensure timely implementation into Swiss law. Swissmedic is largely providing specialist input. Responsibility for adapting legal texts within the given schedule rests with the FOPH.
- The Ordinary Revision of the Therapeutic Products Act (TPA2) was adopted by parliament on 18 March 2016. The referendum deadline expired uninvoked on 7 July 2016. This marked the conclusion of an extensive legislative project, the dispatch for which the Federal Council had presented to parliament on 7 November 2012.
- The statutory amendments passed under TPA2 require numerous adjustments to the implementing legislation. At the end of March 2016, Swissmedic and the FOPH jointly launched a legislative project for the associated ordinances of the Federal Council and the Agency Council under the designation "Therapeutic Products Ordinance Package IV (TPO IV)". The public consultation procedure for the ten draft ordinances affected by TPO IV is scheduled to begin in spring 2017.

Human resources deployed to work on legislation (Hours worked rounded to the nearest 50)



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

Activities

- In 2016, Supplements 8.6, 8.7 and 8.8. of the Ph. Eur. came into effect.
- Various text sections in the Ph. Helv. were updated to reflect the state of the art in science and technology.
- Swissmedic – together with Swiss experts from industry, universities, pharmacies (in the community and hospitals) and the authorities – performed the necessary specialised work, amounting to a total of 8.7 person years. 59 % of this work was done by the Agency.
- A total of 133 people from Switzerland were mandated to serve in the various national and European committees and groups working on the pharmacopoeia. In the elections held every three years to appoint experts to the Ph. Eur. specialised committees and groups, 99 of the more than 700 posts were filled by Swiss experts. 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 responsible for the publications (signed off by the Executive Director) required by law in the area of medical devices (publication of standards in the Federal Gazette in accordance with Art. 4, para. 3 MedDO). The list of registered technical standards is updated regularly on the Swissmedic website.

The Agency also works in various national standards committees (SC) and technical committees (TC). These committees analyse the effects of new or revised international standards on medical devices with regard to Switzerland, and issue comments on them where needed.

Activities

- In 2016, Swissmedic was active in two national standards committees and one technical committee.

Special activities and events: Standards

European Pharmacopoeia Commission elects Swiss Chair

Responsibility for the elaboration of the Ph. Eur. lies with the European Pharmacopoeia Commission (COM), which is composed of the delegations representing the contracting parties to the Ph. Eur. The COM Chair is elected from among its members. The Head of the Pharmacopoeia division at Swissmedic was elected Chair for a term from June 2016 to June 2019, marking the first time in the over 50-year history of the Ph. Eur. that a Swiss national has held this office.

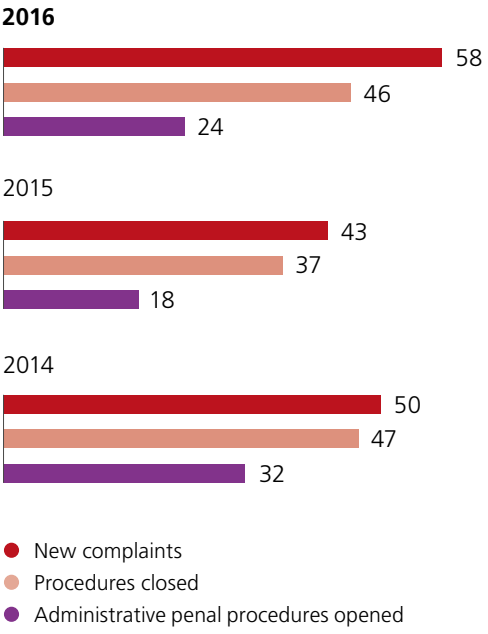
Penal law

General developments

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

Activities

- The Penal division received 58 new complaints and closed 46 cases. It opened 24 administrative penal proceedings. The workload can be described as stable, if high. The trend observed in recent years, whereby the complaints received by Swissmedic are increasingly relevant and concern meaningful cases, is again confirmed.
- In particular, several procedures required considerable resources in terms of the accounting work needed to ascertain the revenues generated illegally by the defendants and their businesses, all within international scenarios.
- Swissmedic received two requests for international co-operation in criminal matters from the United Kingdom and issued one request to Monaco and two requests to Germany. The processing of requests received or made during 2015 also continued.
- The evaluation of the results of the consultation procedure set up with a view to ratifying the Medicrime Convention continued. In parallel, work started on implementing the changes resulting from this ratification and the recent revision of the Therapeutic Products Act.
- In compliance with the strategy put in place to ensure that decisions issued by Swissmedic in criminal matters are publicised accordingly, three lists of decisions were communicated to accredited journalists, one for the whole of 2015, one for the period from January to April 2016, and one for the period from May to September 2016. This publicity prompted 18 consultation requests relating to the decisions and to several articles that both raised public awareness of the issue and helped prevent violations of the Therapeutic Products Act. Since the second list for 2016 was issued, Swissmedic has adapted its practice to the jurisprudence of the Federal Supreme Court (ATF 1C_123/2016 of 21 June 2016 ''Cresta Run''. Since this date, criminal orders have been announced even before their entry into force.

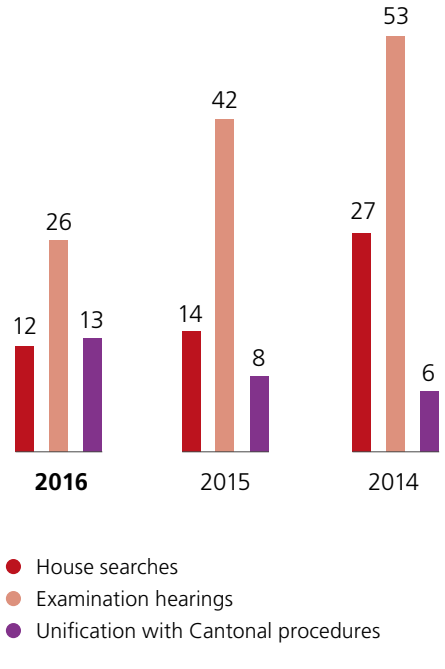


Investigative measures

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

Activities

- In 2016, Swissmedic carried out 12 house searches and 26 hearings.
- Four appeals against decisions by the Agency were lodged with the Federal Criminal Court (FCC) in 2016. One appeal – concerning seizure – was declared inadmissible due to late submission. The FCC rejected another appeal concerning a similar measure. The other two appeals, which concern a refusal to disqualify an employee of the Agency and a refusal to extend a time limit, are still pending. Two requests to remove the seals affixed to documents, one of which was attached in 2015, the other in 2016, were admitted. The Federal Criminal Court refused to admit two other requests submitted in 2015 because the first request, to affix seals, was submitted belatedly, while the other request had not been lodged by an authorised person. In the first case, an appeal lodged with the Federal Supreme Court was admitted because, contrary to what the Federal Criminal Court had believed, the request had actually been received within the permitted deadline.
- Swissmedic dealt with two incoming requests from the United Kingdom for international cooperation in criminal matters. In the opposite direction, two requests were issued to Germany and one to Monaco.
- 13 cases were the subject of procedural unification, i.e. the association of the prosecution with Cantonal proceedings. The cases concerned the illegal import of medicinal products in connection with dispensing and/or infringements of the Federal Act on the Promotion of Sport and Exercise (SpoPA; SR 415.0), as well as illegal trading in medicinal products. The progress made in this area reflects the good cooperation with the Cantons, which ask Swissmedic for information in its fields of expertise. In certain cases, these requests result in joint proceedings and procedural unification.

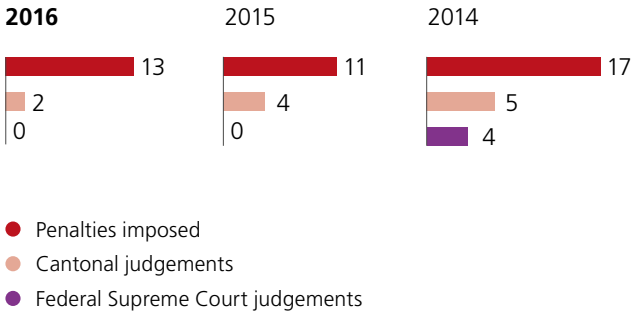


Decisions / judgements by Swissmedic and by courts

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

Activities

- 15 individuals were affected by the 13 penalties that were imposed. Nine cases concerned illegal trading, including illegal import. Three cases involved the illegal manufacture of medicinal products, and there was one case of illegal advertising. Four criminal orders were issued following objections submitted against penalties that had been imposed. Two concerned illegal trading, with violation of due diligence obligations, specifically by the Responsible Persons, and one concerning the manufacture and placing on the market of illegal medical devices. Swissmedic also dismissed four cases in which the suspicions were not confirmed or the evidence proved insufficient.
- A court of first instance issued a judgement in a case of forgery of documents and the marketing of an expired vital product. One appeal was lodged by Swissmedic because a job qualification was not accepted by the court. In an appeals procedure concerning a case of illegal manufacture and trading with consequent endangerment of human health, in which the court of first instance had imposed a day-based financial penalty of 250 days at CHF 30 suspended for two years, a fine of CHF 2,000 on the perpetrator, and ordered the company to pay damages of almost CHF 220,000, the defendant failed to attend the appeal hearing. He subsequently requested a new hearing, stating that his absence had been due to illness. His request was refused. The decision of the Court of Appeal can still be subject to an appeal to the Federal Supreme Court. Moreover, two applications for judgements were withdrawn during legal proceedings, which means that the criminal orders became final.
- One of the criminal orders that entered into force as a result involved the trading abroad of vital products without the required authorisations and the violation of due diligence obligations by the relevant specialist. The person responsible was fined a day-based penalty of 100 days at CHF 180, suspended for two years, a fine of CHF 8,500 and the payment of procedural costs of CHF 13,603.30. Three companies have also been ordered to pay damages of EUR 608,482 and GBP 80,490 and GBP 31,000 respectively.



Stakeholder management

Information

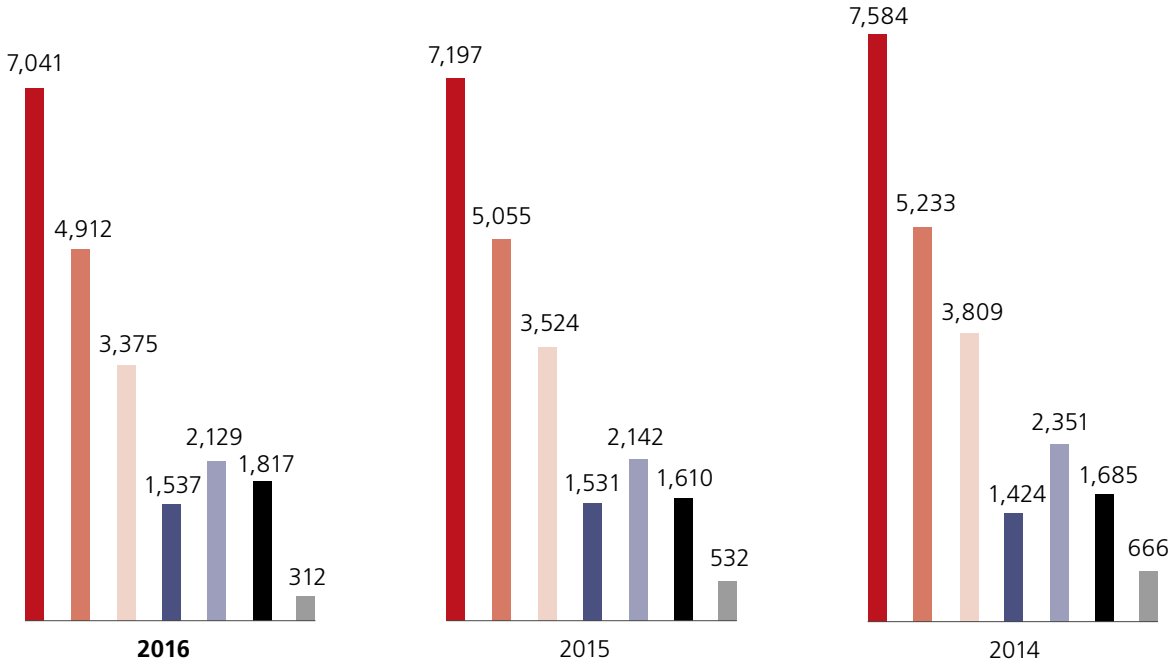
Swissmedic provides fast, targeted information on new findings concerning therapeutic products that could constitute health hazards. In addition to safety-relevant information, new authorisation decisions or major changes to medicinal product information are of considerable interest.

General enquiries

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

Activities

- Approximately as many enquiries were received in 2016 as in the previous year.
- Most of the general enquiries concerned the import of medicinal products, variations requiring notification and variations requiring approval, authorisations and, as in 2015, a large number of questions on delimitation.
- The main questions on medical devices related to release for sale, and sterilisation.
- In 2016, 97 % of general enquiries were answered within 10 calendar days.



Performance indicator

General enquiries: percentage of responses sent within 10 days

Target Result

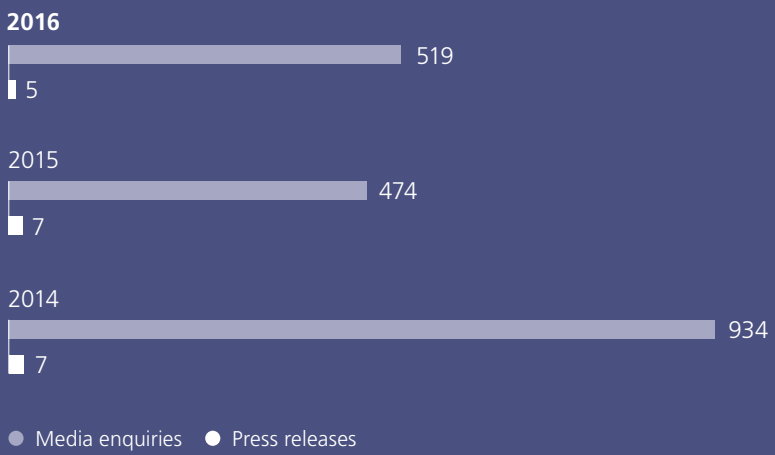
Press relations

Stakeholder groups want intelligible, reliable information – including via the press – on the benefits and risks of medicinal products and medical devices as well as on the tasks undertaken by the Swiss Agency for Therapeutic Products. Within the boundaries of the law, Swissmedic aims to provide transparency through a professional working relationship with the press and to play a role in ensuring the safety and health of people and animals in Switzerland.

Activities

- The Media Unit dealt with 519 enquiries from media representatives. Most enquiries came from Switzerland, and around seven percent from the rest of Europe and countries outside Europe – including one enquiry from Vanuatu, an island nation located in the South Pacific.
- Swissmedic posted five official media releases via the Federal Administration news portal. Warnings of the dangers of medicinal products illegally imported into Switzerland and one product recall down to patient level attracted particular media attention.
- Swissmedic representatives were quoted in the press on a wide range of topics. Over 30 interviews on current questions of therapeutic product safety, the authorisation of medicinal products and other key tasks undertaken by the Swiss Agency for Therapeutic Products were broadcast on radio and television.
- Media reporting covered a broad variety of subjects in the year under review, e.g.:

– Criminal prosecution of violations against therapeutic products legislation, in particular in connection with questionable stem cell treatments;
– The safety of medicines (with the focus on active substances contraindicated during pregnancy such as isotretinoin and valproic acid, reporting behaviour in connection with adverse drug reactions, and questions on shelf-life);
– Change in practice regarding the advertising of medicinal products (prior control only for medicines with potential for dependence or abuse);
– Increased regulation and surveillance of medical devices in Europe;
– New Guidelines on Good Distribution Practice of Medicinal Products;
– Temporary shortages of vaccine supplies;
– The change – advocated by Swiss Transfusion SRC – in blood donation criteria for MSM (men who have sex with men);
– The authorisation and surveillance of clinical trials with therapeutic products;
– A rise in purchases of limited medicines outside Switzerland owing to enormous price differences;
– The marketability of cannabis products.



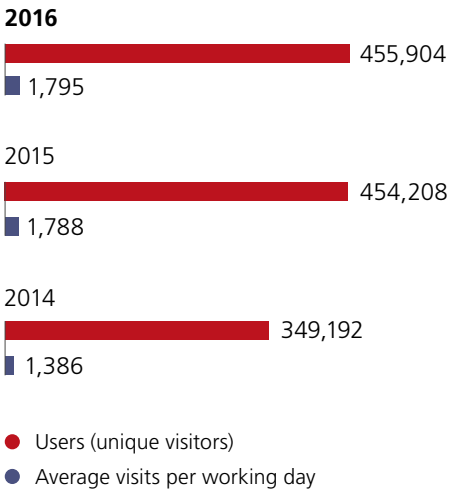
Publications

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

Activities

- The main multi-language publications include the Annual Report and the annual accounts, the monthly Swissmedic Journal, Swissmedic's Vigilance News, and the Haemovigilance Annual Report, which is now printed in electronic form only.
- The number of safety-related notices on medicinal products (mainly Direct Healthcare Professional Communications, DHPCs) published by Swissmedic on its website and via newsletter rose from 22 to 28 in the year under review.
- Similarly, the number of reports of public recalls and other safety measures (FSCAs) carried out for medical devices increased slightly to 627.
- The most common hits on the Swissmedic website were for the lists of authorised medicinal products, as well as for urgent communications on safety signals, the electronic version of the Swissmedic Journal, and updates on hormonal contraceptives.
- The number of users visiting the Swissmedic website at least once daily did not change considerably year-on-year. 20 % of visitors now access the website from mobile devices.
- Swissmedic will have to replace its web content management system (CMS) by the end of 2017. Following an extensive assessment conducted during the year under review, a decision was made in favour of the CMS currently used by the Federal Administration. The switchover to the new software is scheduled for October 2017. The relaunch will also entail adjustments to the information architecture to give visitors improved, user-friendly access to the Agency's various areas of activity.

Website statistics www.swissmedic.ch



Events

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

Activities

One event highlight followed another in 2016. Totalling 17, the number of events was on a par with the average for the past few years. It was, however, the international events organised by Swissmedic that made 2016 a special year.

- EMACOLEX, 7–9 September 2016
  The European Medicines Agencies Co-operation on Legal and Legislative Issues (EMACOLEX) is an informal working group of the European Heads of Medicines Agencies (HMA). Under the mantle of EMACOLEX, lawyers from the therapeutic products authorities of the EU Member States meet half-yearly to discuss current practice at the individual agencies as well as pronouncements on prevailing therapeutic products legislation and to confer on developments in the area of therapeutic products law. Canada's Therapeutic Products Directorate and Swissmedic each send an observer to these meetings. In 2016, under the Slovak presidency of the EU, Swissmedic had its second opportunity since 2006 to organise an EMACOLEX meeting.

- 1th Summit of Heads of Medicines Regulatory Agencies, 11–13 October 2016
  Swissmedic hosted the Summit of Heads of Medicines Regulatory Agencies in 2016. Further details can be found in the Activities during the year section.

- 2016 info & news from the Narcotics division
  The Narcotics division organised four workshops tailored to the information needs of people in the pharmaceutical industry who also work with controlled substances/preparations at a national and international level.

- 24th formal meeting of the Homeopathic Medicinal Products Working Group (HMPWG) 10–11 November 2016
  The Homeopathic Medicinal Products Working Group (HMPWG) is under the purview of the EU HMA. It serves as a forum for regulatory agencies to exchange regulatory and scientific information on the quality and safety of homeopathic medicinal products for human and veterinary use. It draws up guidelines for the requirements for the authorisation of homeopathic medicinal products. The group, which meets twice a year, is made up of representatives of the national regulatory agencies. Representatives of the European Commission and the European Medicines Agency (EMA) are also invited, as are observers from the EDQM, the EFTA countries, and the WHO. 37 people from 23 countries attended the meeting in Switzerland.

- Meeting on Market Surveillance and Quality Defects Handling 21–22 November 2016
  Hosted by Swissmedic for the second time, this international meeting offers a platform to share experiences made with the handling of quality defects in medicinal products. The objective of the meeting is to improve international networking and facilitate collaboration in order to ensure a faster response to quality defects with an international impact. The meeting was attended by 25 people from 15 different countries.

- Swissmedic Regulatory News from the Authorisation division 1 December 2016
  The information event "Regulatory News from the Authorisation division" has a firm place on the calendar for Swissmedic and its stakeholders. At the end of every year, Swissmedic presents important changes, industry and Swissmedic representatives share their experiences on various subjects, and an outline of upcoming regulatory amendments is given. Attracting over 350 participants in 2016, the continual increase in attendance figures confirms the significance that the industry attaches to this information event.

Other events included the two-day training course for inspectors on "How to inspect data integrity", which drew in participants from outside Switzerland, and various training sessions on ElViS, the electronic portal for reporting suspected adverse drug reactions.

Transparency

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

Activities

- Swissmedic received 19 requests falling under the FoIA, a slightly higher number than in the previous year.
- Two verbal mediations were held before the Federal Data Protection and Information Commissioner (FDPIC).

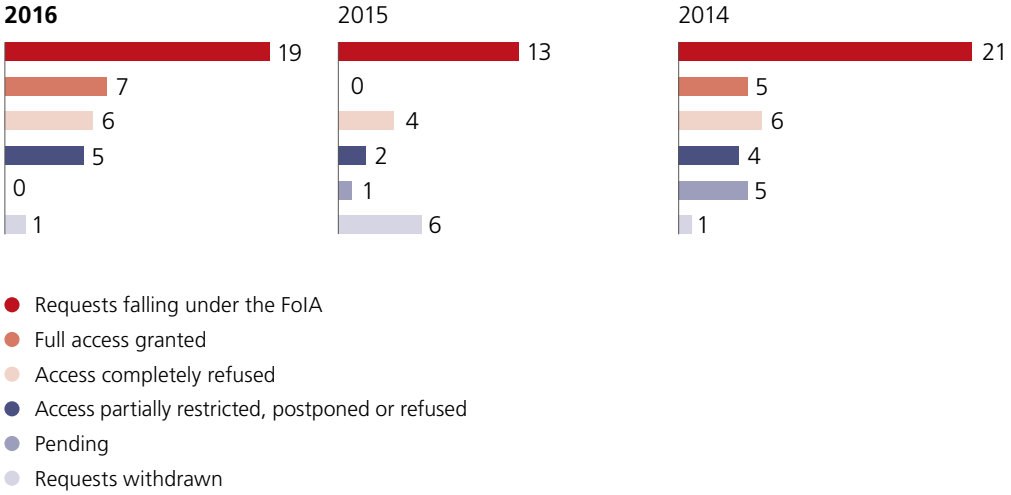
Appeals procedure regarding access to official documents

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

Activities

- In 2016, no appeals were lodged with the Federal Administrative Court against an official decision of the Agency in connection with access to official documents.
- Of the appeals already pending before the Federal Administrative Court, one was approved. The appealing party subsequently took the appeal to the Federal Supreme Court, which approved it in part.

Appeals procedure regarding access to official documents



Collaboration

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

National collaboration

National network

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

- Patients/consumers and their associations/organisations
- Healthcare professionals and their associations/organisations
- The therapeutic products industry and its associations/organisations
- Service providers from the therapeutic products industry
- Cantonal and federal authorities and parliament
- Media representatives (see section headed Press relations)

Activities

- Launch of EUPATI toolbox and founding of Switzerland's EUPATI platform
  On 3 February 2016, the European Patients' Academy on Therapeutic Innovation (EUPATI) launched a new training toolbox on medicines research and development. The toolbox is available to European patient groups, patient representatives and anyone wishing to learn more about the research and development process behind medicinal products. Swissmedic has been actively represented on the Regulatory Advisory Panel since the start of the EUPATI project in 2012 and is a supporter of the national platform EUPATI Switzerland, which also celebrated its founding event on 3 February 2016 in Bern.

- Regulatory Affairs round table meetings with industry association representatives on 7 March and 14 September 2016
  The aim of the periodic meetings between Swissmedic and industry association representatives is to share information and resolve technical issues. The Agency briefed both meetings in the period under review on relevant topics from all of its areas of activity, including the pilot phase of the patient/consumer organisations working group, cooperation with the European Medicines Agency (EMA), the change in practice at Swissmedic regarding the expiry of establishment licences, suspension of the manufacturer information update project, the benchmarking study of authorisation periods, and the status and next steps of the eGovernment project.

- Round table meeting with companies from the veterinary pharmaceuticals industry on 11 November 2016
  In collaboration with the Federal Food Safety and Veterinary Office (FSVO), Swissmedic staged an information event for companies distributing veterinary medicinal products (VMP) and veterinary vaccines in Switzerland. Authorisation holders operating in Switzerland were updated on current developments and changes, and VMP-specific questions and concerns were discussed. As is the case with the regulatory round table meetings for human medicinal products, this event is to be held regularly from 2017 on.

- Annual meeting of Cantonal Pharmacists on 14 April 2016
  Swissmedic briefed the annual meeting with representatives of the Swiss Association of Cantonal Pharmacists (KAV/APC) on various topics from the areas of legal affairs (including the revision of the Therapeutic Products Act and the therapeutic products ordinances), authorisations ("fresh cell therapy" campaign) and market surveillance (tighter inspections of medical devices, materiovigilance campaign to improve reporting in hospitals, implementation of the Falsified Medicines Directive). The KAV/APC raised the matter of the current recommendations regarding off-label use and outlined the treatment responsibilities of the different healthcare professionals.

- Swissmedic patient/consumer organisations working group
  The working group held a total of four half-day meetings in the period under review. The main emphasis was on the organisation and evaluation of a survey on attainment of the targets of the two-year pilot launched in May 2014. Based on the survey findings, the working group pilot phase is to be extended by two more years.

  In approving the extension, Swissmedic's Management Board is taking up the working group's proposal to continue the solid partnership that has been initiated and further intensify it over the next two years, for the particular purpose of incorporating the perspectives of the patient and the consumer more effectively into Swissmedic's defined processes.

External further training initiatives and specialist presentations

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

Activities

- In 2016, Swissmedic continued to play an active part in the Middle European Organisation for Regulatory Affairs (MEGRA) further training course "StartUp Schweiz" and in ETH Zurich's master's degree course in Medicinal and Industrial Pharmaceutical Sciences (MIPS) as well as the Master of Drug Regulatory Affairs programme of the German Society for Regulatory Affairs (DGRA).
- As part of the Certificate of Advanced Studies (CAS) course Management of Biotech, Medtech & Pharma Ventures at the Swiss Federal Institute of Technology Lausanne (EPFL) and the CAS Pharmaceuticals – from Research to Market at ETH Zurich, Swissmedic staff provided information on Swiss GMP legislation and on procedures for the various types of inspection.
- For the CAS course on health systems and health policy at the Zurich University of Applied Sciences (zhaw), Swissmedic put on half-day information events in Bern to present the Agency and its specific activities in the areas of authorising medicinal products and conducting market surveillance on medicinal products.
- At the 28th DIA EuroMeeting, held in Hamburg in 2016, Swissmedic staff gave talks on topics comparing Swissmedic authorisation decisions with EMA and FDA rulings, on international harmonisation, and on IGDRP.

International collaboration

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

International network

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

Activities

- International Council for Harmonisation (ICH)
  Collaboration under the ICH continues to be accorded high priority by Swissmedic. In autumn 2017, the Agency will be organising the first ICH conference in Switzerland. In the period under review, the updated guideline issued by the M4E(R2) Expert Working Group on the subject of "Enhancing the Format and Structure of Benefit-Risk Information" was approved by the Assembly in Step 4. Swissmedic is applying the revised guideline accordingly now it has been published on the ICH website.

  The 1996 ICH Guideline on GCP is one of the most important achievements of the ICH process. The ICH Assembly adopted an important amendment – ICH E6(R2) – that aims to encourage sponsors to implement improved oversight and management of clinical trials.

  To implement ICH E6(R2) in Switzerland, the reference to the Human Research Act in Annex 1 of the Clinical Trials Ordinance (ClinO) will have to be amended. This amendment is expected to be effected in the second quarter of 2017. Since Version R2 essentially synthesises existing requirements from other guidelines, Swissmedic will use it as a reference with immediate effect.

- International Generic Drug Regulators Programme (IGDRP)
  In the period under review, Swissmedic actively supported the activities of the IGDRP and took part in both meetings of the Steering Committee. Under the two ongoing information-sharing pilots using the EU's decentralised procedure (DCP) and the centralised procedure (CP) of the European Medicines Agency (EMA), Swissmedic had received the EU assessment reports on six applications as at 31 December 2016. To sum up, it can be stated that the EU and Swissmedic reports and the ensuing questions and conclusions were very similar. The pilot has therefore contributed to building mutual trust. At the end of the year, the "IGDRP Roadmap to 2020" was published on the IGDRP website. The Roadmap outlines plans and objectives for the next few years, as well as the strategic priorities for meeting the targets set.

- Australia-Canada-Singapore-Switzerland Consortium (ACSS Consortium)
  Swissmedic attended the two ACSS meetings held in 2016, both of which focussed on the Generic Medicines Work Sharing Trial. This concrete work sharing trial is modelled on the EU Decentralised Procedure (DCP), with Australia assuming the role of reference agency for the ongoing initial pilots, and Canada and Swissmedic conducting the peer review. The application for authorisation (new application) was received at the end of June 2016, and the assessment process should be completed in 2017. The aim of this pioneering pilot is to build mutual trust and to demonstrate and establish the possibilities for work sharing.

- International Pharmaceutical Regulators Forum (IPRF) in June and November
  The International Pharmaceutical Regulators Forum (IPRF) offers the participating international drug regulatory authorities a universal platform to exchange information, know-how and experiences. To ensure the forum enjoys effective strategic positioning over a longer timeframe, the Management Committee launched a strategy development process at the end of 2015. A draft version of the longer-term IPRF strategy was finalised at the first Management Committee meeting in June of the year under review, and this future business model was adopted at the second meeting in November. Swissmedic has held the chair of this international forum since it was founded, and also provided the IPRF Secretariat. Having occupied the role for three years, Swissmedic has now relinquished it. The US FDA now holds the forum chair, and the position of vice-chair has been filled by the Brazilian regulatory agency ANVISA.

- Strengthening individual bilateral relations
  Strategically, the focus of bilateral collaboration is on internationally recognised drug regulatory authorities with a regulatory system for medicinal products that is comparable to Switzerland's. Accordingly, activities with the European Medicines Agency (EMA) and the respective national authorities of the EU Member States were scaled up and given priority in the year under review. We have also intensified our dialogue with the China Food and Drug Administration (CFDA), with whom we entered into an agreement in 2015. The conclusion of two memoranda of understanding – one with the UK's MHRA (October 2016) and one with the Mexican COFEPRIS (November 2016) – has added two key international cooperation partners to Swissmedic's network of fellow agencies.

- World Health Organization (WHO)
  Swissmedic has assumed its second term as chair of the WHO Blood Regulators Network, which is comprised of seven leading international regulatory authorities that have responsibility for the regulation of blood products and support the WHO in the area of blood product safety. Priority measures implemented in the year under review were in connection with the spread of the Zika virus and outbreaks of the yellow fever virus. WHO guidelines on management of blood as essential medicines were drawn up and adopted in autumn 2016 by the WHO Expert Committee on Biological Standardisation.

- Cooperation under the mantle of the European Directorate for the Quality of Medicines (EDQM)
  Switzerland is represented in the Steering Committee on Blood Transfusion (CD-P-TS) and in the associated Expert Committee (CD-P-TS/GTS). The Expert Committee updates and revises the "Guide to the Preparation, Use and Quality Assurance of Blood Components", which is also binding on Switzerland with regard to donor suitability criteria. Switzerland also made a key contribution in this Expert Committee as a rapporteur on the "Good Practice Guidelines for Blood Establishments and Hospital Blood Banks Required to Comply with EU Directive 2005/62/EC". This document is recognised by the EU Commission and is enshrined with binding force in the EU Directives.

- Cooperation on GMP inspections
  As a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), Swissmedic participated in several ongoing projects concerning the preliminary evaluation of the GMP inspectorate of Kazakhstan and the evaluation of the Turkish GMP inspectorate (these two inspectorates are candidates for accession to the PIC/S) and various working groups (e.g. Working Group (WG) on Data Integrity, WG on Revision of GMP Annex 1, the latter in close collaboration with the EU's EMA). Swissmedic also continued to participate in various PIC/S subcommittees working on the harmonisation of GMDP and inspector training.

  Swissmedic is represented in one of the GMP working groups of the International Coalition of Medicines Regulatory Authorities (ICMRA). In this connection, work on the establishment of a "GMP Reliance Framework" pilot project by the GMP Inspections working group continued. The aim of this project is to reduce the number of inspections carried out abroad by sharing information between authorities. To achieve this goal, the working group works closely with the PIC/S.

Development cooperation

The memorandum of understanding signed in January 2014 between the Bill & Melinda Gates Foundation (BMGF), the FDHA and the FDFA is aimed at helping to improve and expedite access to healthcare and medicines in low-resource countries.

Under the support project for the East African Community Medicines Regulatory Harmonisation Programme (EAC-MRH), Swissmedic experts from the Clinical Review and Quality Review departments took part in the three EAC joint assessments. Assisting efforts to harmonise guidelines for EAC therapeutic products authorities, Swissmedic experts reviewed the draft texts and put their proposals to the meeting of the Technical Working Group in October 2016 in Dar es Salaam.

In the period under review, the Steering Committee of the EAC-MRH Programme met once in June in Entebbe, Uganda, and once in December in Nairobi, Kenya. Swissmedic's participation in the two meetings gave the Agency a general picture of the status of work, as well as an opportunity to discuss with EAC officers the technical support measures already taken and those planned in the four focal areas Information Management Systems (IMS), Medicines Evaluation and Registration (MER), Good Manufacturing Practices (GMP) and Quality Management Systems (QMS).

An authorisation process and a scientific advice process for preparations for the treatment of diseases mainly affecting people in southern Africa were established under a second project.

The authorisation process is based on Swissmedic's years-old practice of issuing export permits for medicinal products that are not destined for the Swiss market. This procedure is accessible to representatives of African regulatory authorities (primarily from East Africa) and the WHO. The draft processes for the pilot phase were published on the Swissmedic website in April 2016 and initial talks were held with interested stakeholders. Authorisation applications can be filed with Swissmedic.

Special activities and events: Stakeholder management

ICDRA Conference from 27 November to 2 December 2016 in Cape Town, South Africa

Representatives from international therapeutic products authorities, the WHO (World Health Organization) and interested stakeholders met in Cape Town, South Africa, for the 17th Pre-ICDRA and ICDRA. This was the first ICDRA to be held on the African continent. The 2016 conference under the heading "Patients are waiting: how regulators collectively make a difference" was dedicated to the crucial question of how to ensure access to safe and effective high-quality medical products for all patients worldwide, with a particular focus on Africa. Swissmedic played an active role in the conference, giving presentations on cooperation with the East African Community under the MoU with the Bill and Melinda Gates Foundation, on Swissmedic's strategy regarding collaboration with foreign authorities, on incentives in the area of paediatric medicinal products, and on the regulation of blood and blood products. At two panel meetings, Swissmedic also commented on ongoing global endeavours to promote harmonisation.

Telematics / Information

IT management

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

Activities

- The revised Therapeutic Products Act adopted in March 2016 requires significant adjustments to be made to Swissmedic's service provision processes prior to entry into force of the implementing provisions. The downstream process adjustments to the Swissmedic information systems represent a time-critical component of the overall implementation package. Correspondingly substantial resources were deployed to push ahead with the specialised engineering of the service provision processes under revision and with the planning schedule for adjustments to the information systems. The likely adjustments to the legal basis following consultation on the implementing provisions pose a particular challenge to planning and project management.
- Implementation of the international standardisation of therapeutic product data is gaining momentum in the wake of the new ISO standard Identification of Medicinal Products (IDMP). Over the next few years, the international vanguard of therapeutic products authorities will progressively commit the therapeutic products industry to submit its applications and notifications in an IDMP-compatible format. Implementing these standards will require sizeable investments in information system architecture and existing IT applications on the part of the therapeutic products industry as well as the therapeutic products authorities. Swissmedic instigated initial steps in 2016 to be able to take policy decisions in 2017 on adjusting the IT architecture and on procedures for IDMP implementation.
- The Federal Office of Information Technology, Systems and Telecommunication (FOITT) is updating its service offering for the website content of its service users. Swissmedic seized this update as an opportunity to examine various other solutions on offer and develop a revised sub-strategy for the mandatory publication of information and therapeutic product data going forward.

Solution development

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

Activities

- In the course of the fourth quarter of 2016, the new eGovernment solution for the full electronic processing of applications, reports and correspondence moved into the pilot phase. The solution, developed in close collaboration with representatives of the therapeutic products industry, is becoming increasingly popular with the companies taking part in the pilot run. From the second quarter of 2017, the solution will gradually be made accessible to all submitting companies before progressing to full regular operation.
- The national database for the processing and analysis of adverse drug reactions is not being developed further by the present provider and operator. A new, state-of-the-art solution sourced through public tender was evaluated and a feasibility study on integration into the Swissmedic information system architecture carried out. Implementation and migration are scheduled for the following year.

- The Medical Devices division began work on staggered renewal of the supporting information systems. The service provision processes will be migrated in stages to the Swissmedic SAP and DMS platforms. At the same time, the planning schedule factors in the need to update the legal basis.
- The Licensing division prepared the groundwork for moving from paper-based application processing to electronic handling. These processes are also to be migrated to the existing SAP and DMS platforms.
- In accordance with the updated legal basis for work time recording which came into effect on 1 January 2016, Swissmedic is also switching to a simplified model for tracking hours worked. Preparatory work has begun on replacing electronic time clocks and introducing SAP-based work time recording. Implementation and rollout are scheduled for 2017.

IT operations, use, maintenance and ongoing improvements

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

Activities

- The SAP platform user interface was modernised under a widescale product release. A similar upgrade was prepared for the complex SAP Portfolio and Project Management (PPM) planning module.
- In line with the FOITT's decision to expedite the transfer to Swissmedic of operating and maintenance services for the SAP platforms, SAP management tools for the SAP authorisation solution were configured and commissioned at Swissmedic.
- The intranet service provided by the FOITT will be terminated at the end of 2017. Design plans have been prepared for the configuration of a new intranet solution based on Swissmedic's SharePoint platform. Implementation is timetabled for the following year.
- Improvements to the Hallerstrasse property and the sale of the Erlachstrasse 12 property necessitated the extensive relocation of workplace systems, as well as structural adjustments to the network infrastructure. The work was completed on schedule.
- The entire fleet of multifunction printers was replaced with equipment from the procurement lot of the Federal Office for Buildings and Logistics.
- More than 100 individual measures were implemented to further optimise SAP and SharePoint platform-based electronic business processes or to adapt them to changing requirements.
- Swissmedic Procurement Management, which is part of the IT organisation, handled all necessary public tenders within the stipulated deadline and without encountering any objections. These included tenders for the provision of in-house language courses and for the supply of translation services.

Corporate Governance

Organisation

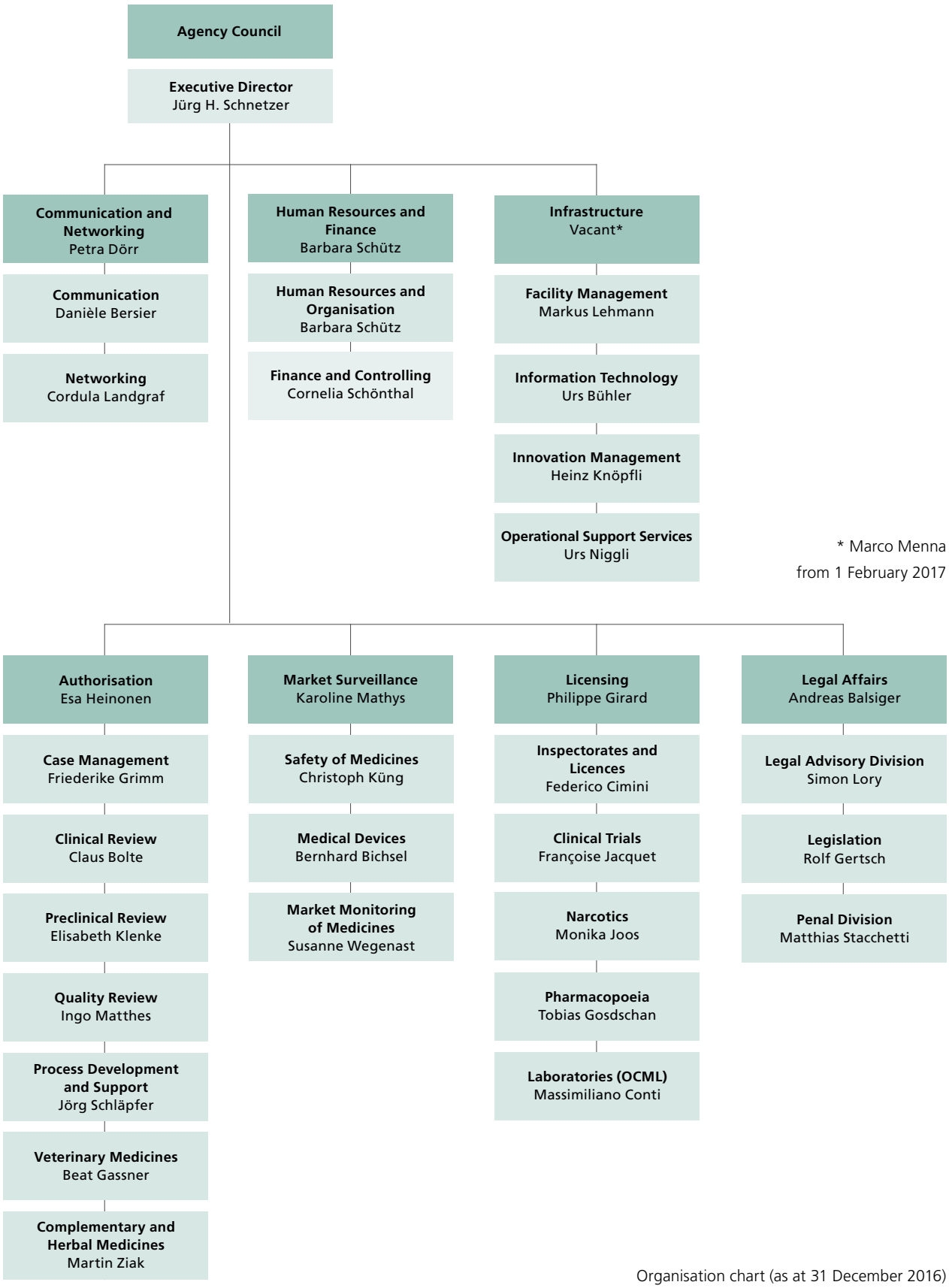
Swissmedic's activities are founded on therapeutic products legislation. The principal legal basis is the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA). Swissmedic is attached to the Federal Department of Home Affairs. As a federal public institute based in Bern,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

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

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

Tasks

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



* Marco Menna
from 1 February 2017

Organisation chart (as at 31 December 2016)

Revenues

Swissmedic is financed through fees and levies, payments from the federal government for services of public interest and through payments received for services rendered to third parties. To ensure that its control activities are efficient, the Agency is managed according to the principles of good business practice.

	Revenues in 2016	As a percentage of total revenues
Fees	CHF 31,645	35 %
Levies	CHF 43,321	49 %
Payments from the federal government	CHF 13,899	15 %
Payments received for services rendered to third parties	CHF 141	0,1 %

Agency Council

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

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

The Agency Council is comprised of the following members (as at 31 December 2016):

Member	In office since
Ms. Christine Beerli (C)	2006
Dr. Carlo Conti (VC)	2001
Prof. Reto Obrist	2010
Prof. Peter Suter	2010
Prof. Olivier Guillod	2014
Mr. Giovan Maria Zanini	2015
Ms. Vincenza Trivigno	2016

C = chair; VC = vice-chair

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

Chair
Christine Beerli, lic.iur.

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

Olivier Guillod, Prof. Dr. iur.

Director of the Institute of Health Law, University of Neuchâtel

Peter M. Suter, Prof. Dr. med.

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

Zanini Giovan Maria, Pharmacist

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

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

Carlo Conti, Dr. iur.

Attorney-at-law
Partner, WENGER PLATTNER

Reto Obrist, Prof. Dr. med.

Former chief physician for oncology, Valais Health Network

Vincenza Trivigno, lic. rer. pol.

State Chancellor, Cantonal Chancellery, Canton of Aargau

Management Board

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

Jürg H. Schnetzer

Executive Director

Other occupations and public offices held

Since 2012: none

Until 2011: Member of Council of Antidoping Switzerland (Foundation)

Andreas Balsiger Betts

Head of Legal Affairs - Member of Management Board

Other occupations and public offices held

None

Petra Dörr, Dr.

Head of Communication and Networking – Member of Management Board

Other occupations and public offices held

None

Philippe Girard, Dr.

Head of Authorisation - Member of Management Board

Other occupations and public offices held

None

Karoline Mathys Badertscher, Dr.

Head of Market Surveillance - Member of Management Board

Other occupations and public offices held

None

Barbara Schütz Baumgartner

Head of Human Resources and Finance – Member of Management Board

Other occupations and public offices held

Since 2016: Member of the Board of Directors of Localnet AG

Since 2010: Administrative Board of the Bern Pension Fund; employer representative

Since 2008: Member of the Board of Directors, Raiffeisenbank, Burgdorf Region

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

Remuneration

The expenses approved by the Federal Council for the Agency Council are capped at CHF 200,000 per year. In 2016 the remuneration paid to the Agency Council amounted to CHF 174,000, of which CHF 38,000 was paid to the Chair. Details of the remuneration for the members of the Agency Council are contained in the latter's business regulations, which are published on the Agency website.

The total remuneration paid to the Management Board was CHF 1,830,411. The Executive Director's salary was CHF 301,538.

Supervision by the owner

As a rule, three meetings (owner discussions) are held each year between the Federal Department of Home Affairs (FDHA) and the Swissmedic Agency Council. These meetings are chaired by the Head of the FDHA. They are also attended by the chair and vice-chair of the Agency Council, the Executive Director and individual members of the Management Board. Swissmedic submits a report to the FDHA on the attainment of the objectives specified in the service level agreement for 2016 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 2016 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 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-related 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

Members of the Human Medicines Expert Committee (HMEC)

Current as at December 2016

Chairman: Krähenbühl Stephan, Prof. Dr. med. et pharm.

Ordinary members

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

Extraordinary members

Aicher Lothar, Dr. rer. nat.
Ballmer-Weber Barbara, Prof. Dr. med.
Borner Markus, Prof. Dr. med.
Brutsche Martin Hugo, Prof. Dr. med.
Buser Katharina, Dr. med.
Caldelari Reto, Dr. phil. nat.
Cavin Frédy, phil. nat.
Cerny Thomas, Prof. Dr. med.
Cotting Jacques Ernest, PD Dr. med.
FitzGerald Reginald Edward, Dr. phil. nat.
Genton Blaise, Prof. Dr. med.
Giannopoulou-Politakis Catherine, PD Dr. med. dent.
Hullin Roger, Prof. Dr. med.
Hüsler Jürg, Prof. Dr. phil. nat.
John Hubert, Prof. Dr. med.
Kraenzlin Marius Edgar, Prof. Dr. med.
Ludwig Christian, Prof. Dr. med.
Meier Beat, Prof. Dr. sc. nat.
Meier Christoph Rudolf, Prof. Dr. pharm.
Messerli Jürg, Dr. med.
Möller Burkhard, Prof. Dr. med.
Munier Francis Louis Paul, Prof. Dr. med.
Nadal David, Prof. Dr. med.
Naegeli Hanspeter, Prof. Dr. med. vet.
Pfeifer Dina, Dr. med.
Pittner Heribert, PD Dr. med.
Rodondi Pierre-Yves, Dr. med.
Sappino André-Pascal, Prof. Dr. med.
Schär Peyer Beatrice, Dr. sc. nat.
Seger Reinhard A., Prof. Dr. med.
Sonderegger-Stalder Emanuel N., Dr. med.
Strik Werner, Prof. Dr. med.
Thomi Matthes Brigitte, Dipl. pharm.
Tramèr Martin, Prof. Dr. med.
von Ammon Klaus, Dr. med.
von Wolff Michael, Prof. Dr. med.
Wilks Martin F., Prof. Dr. med.
Wolf Ursula, Prof. Dr. med.
Yerly Daniel, Dr. phil. nat.
Zangemeister-Wittke Uwe, Prof. Dr. phil. nat.
Zimlich Klaus-Heinrich, Dr. rer. nat.

Advisory members

Angelillo Anne, Prof. Dr. med.
Hofmann Heinrich, Prof. Dr. ing.
Hunger Robert Emil, Prof. Dr. med.
Lämmle Bernhard, Prof. Dr. med.
Rabe Thomas, Prof. Dr. med.
Saller Reinhard, Prof. Dr. med.
Streuli Isabelle, Dr. med.

Members of the Veterinary Medicines Expert Committee (VMEC)

Current as at December 2016

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

Ordinary members

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

Extraordinary members

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

Our staff – our capital

Current as at December 2016

Executive Director

Schnetzer Jürg H.

Management Board

Balsiger Betts Andreas, Dörr Petra, Girard Philippe, Heinonen Esa, Mathys Badertscher Karoline, Schütz Baumgartner Barbara

Our staff

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

Pfäffli Chantal, Pfefferkorn Anita, Philippekin Frédéric, Pinsard François, Plüss Ruth, Polatti Daniela, Porporini Lucio, Prisching Andrea, Puliafito Anita, Pürro Michel, Putzke Jörg, Rached Eva, Ramelli Monica, Ramseier Isabelle, Rätz Katerina, Remund Thomas, Renaudin Michael, Renftle Wolfgang, Rethage Janine, Reusser Daniel, Richter Thomas, Rickenbacher Nadja, Rieder Barbara, Riesen-Beer Sabine, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Roost Matthias, Rosolen Joël, Roth Daniel, Roux Catherine, Ruch Claudia, Rüfenacht Francine, Rumo Anton, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sänger Michael, Satarasinghege Don Sandya, Saurer Isabella, Schaffner Nils, Schärer Christian, Schäublin Martina, Scheidegger Michelle, Scheidegger René, Schläpfer Jörg, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Eggler Dorit, Schnetzer Jürg Heinz, Schnyder Benno, Schnyder Franz-Lukas, Schochat Thomas, Schöni Damian, Schönthal Cornelia, Schumacher Thérèse, Schütz Andrea, Schütz Baumgartner Barbara, Schwab-Stampfli Rebekka, Schwartz Thomas, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Senessie Charles, Sieg Anna, Sommer Andrea, Sorg Regula, Spohn Margot, Spörri Bernhard, Spring Andrea, Stacchetti Matthias, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stämpfli Ursula, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Steinle Patrizia, Stoller Rudolf, Strack Guido, Straub Andrea Katharina, Studer Peter, Sulser Mario, Tanner Soland Eveline, Tanner Yvonne, Terkovics Attila Leo, Teuscher Françoise, Thiess Maria, Thürig Soltermann Eva, Toma Valeriu, Tromp Jan, Tschalär Yolanda, Tschirren Markus, Tschui Janie, Utiger Christoph, Van den Ouweland Frank, Vasileva Tsvetina, Vihertola Mari, Vilei Edy, von Mühlenen Eva, Wacker Christoph, Wagner Jan, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Walther Maya, Wälti Markus, Wälti Rudolf, Waser René, Wassmer Karin, Weber Heidi, Wegenast Susanne, Wegmann Barbara, Weissmahr Richard, Weix Janine, Werder Carine, Wernli Cédric, Weyermann Andrea, Weyermann Philipp, Whitehead Frances, Whitehead Margaret, Wieland Christa, Wildner Oliver, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wittwer Stefanie, Wullschleger Stefan, Wüthrich Cinderella, Wüthrich Karin, Wyss Brigitte, Wyss Martin, Wyss-Romanello Sabine, Zaugg Kunz Sandra, Zbinden Raphael, Zemp Markus, Ziak Martin, Ziehli Salvisberg Mariette, Zimmermann Esther, Züger Dominik, Zurbuchen Andreas, Zürcher Jasmin, Zurkinden Tanja, Zwahlen Roland

Income statement

(in KCHF)

	2016	2015
Procedural fees and income further to Art. 69 TPA	39,129	40,112
Levies on sales	43,321	42,193
Other income	296	1,254
Federal contribution	13,899	13,958
Other operating income	29	158
Loss of revenues from procedural fees	-7,484	-6,796
Net income	**89,190**	**90,880**
Services for third parties	-2,059	-1,468
Personnel	- 63,220	-64,715
Rental, maintenance, energy, transport and insurance	-2,672	-2,407
Administration	-4,460	-5,370
IT	-8,672	-9,632
Other expenditure	-277	-125
Amortisation	-5,563	-5,885
Total operating expenditure	**-86,923**	**-89,602**
Operating income	**2,267**	**1,278**
Financial income	10	12
Financial expenditure	-220	-263
Financial result	**-210**	**-251**
Gain / Loss	2,057	1,027

Statement of comprehensive income (in KCHF)	**2016**	**2015**
Gain / Loss	**2,057**	**1,027**
Other income Actuarial losses (gains)	-1,589	2,712
Total comprehensive income	468	3,739

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

Balance sheet

(in KCHF)

	at 31.12.2016	at 31.12.2015
Cash and cash equivalents	416	1 013
Receivables from sales and service	19,144	25,798
Other receivables	676	0
Prepaid expenses	79	42
Current assets	**20,315**	**26,853**
Fixed assets	3,644	3,170
Immovable property	74,897	74,032
Intangible assets	6,267	8,093
Capital assets	**84,808**	**85,294**
Total assets	**105,123**	**112,147**
Commitments on sales and services	5,828	5,507
Other commitments	19,589	29,208
Deferred income and short-term provisions	3,834	3,926
Short-term commitments	**29,251**	**38,641**
Firm advances	10,000	10,000
Provisions for loyalty bonuses	2,597	2,635
Provision for pension fund commitments (net)	72,956	71,020
Long-term commitments	**85,553**	**83,655**
Gain/Loss	2,057	1,027
Reserves	1,037	10
Endowment capital	14,500	14,500
Accumulated actuarial losses	-27,275	-25,686
Own capital	**-9,681**	**-10,149**
Total liabilities	**105,123**	**112,147**

Products funded mainly by the Confederation

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result-based product accounting
Legal foundations	-5,829	0	-5,829
Information for the general public	-3,295	0	-3,295
Medical devices vigilance	-3,035	1	-3,034
Market monitoring of medical devices	-2,920	34	-2,886
Penal law	-2,750	221	-2,529
Total products funded mainly by the Confederation	**-17,829**	**256**	**-17,573**
Total Federal contributions			**13,899**
Expenditure surplus			**-3,674**

Annual Report 2016

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swissmedic

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

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