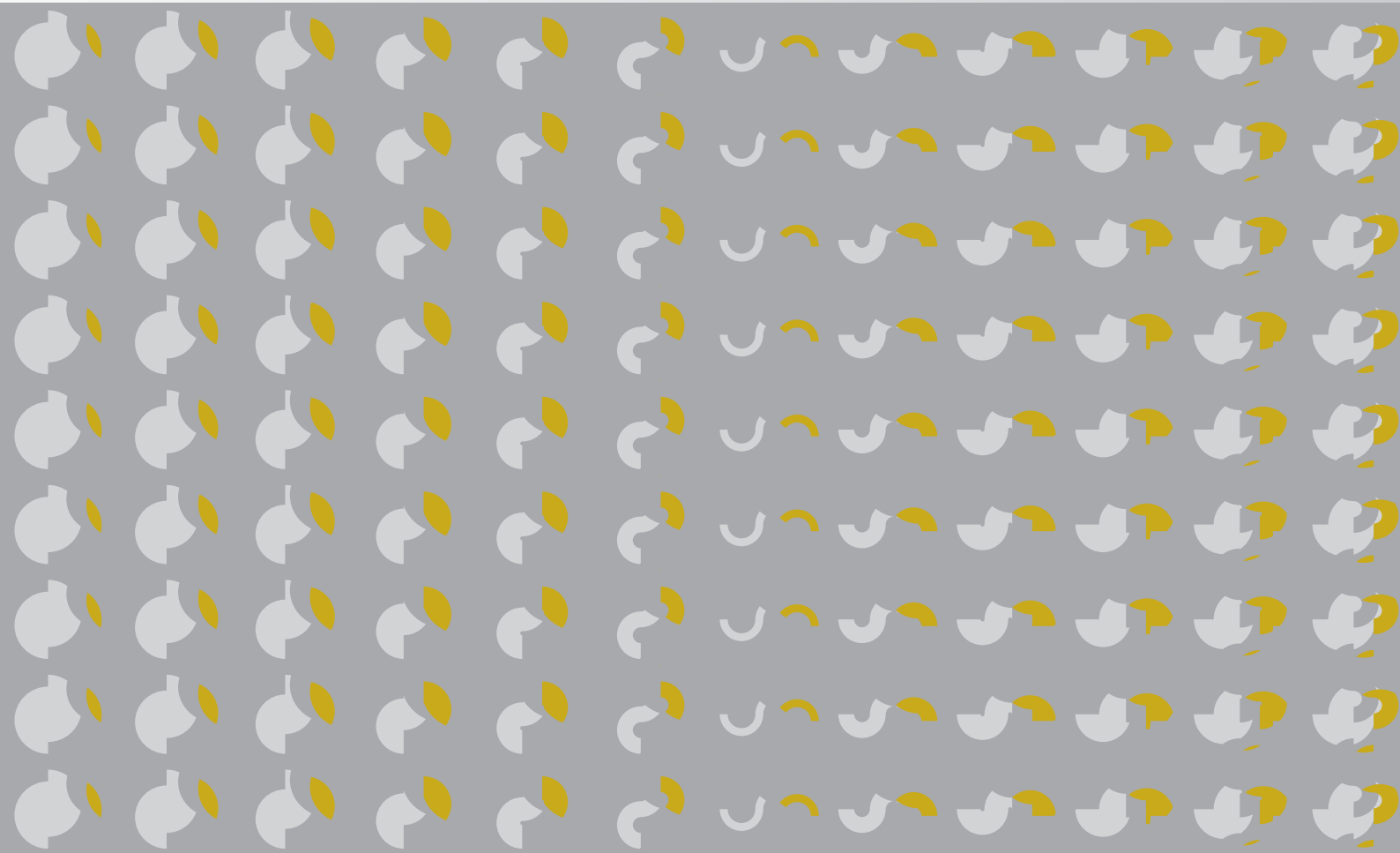



swissmedic

Annual Report 2015



MISSION

OUR

COMPETENCE:

FOR THERAPEUTIC

PRODUCTS

YOU CAN TRUST

(Guiding principles of Swissmedic)

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Foreword by Christine Beerli

New risks, new safety

Humanitarian challenges

2015 was an eventful and demanding year all over the world. Above all, we in Europe were made irrefutably aware of something that we always attempted to suppress: the brutal and cynical war raging in the Middle East is not happening somewhere far away, but right before our door and with very direct consequences for us and for our neighbours. The streams of refugees on the Balkan route, the disturbing images of shipwrecked people in the Mediterranean and reports of horrific terror attacks around the globe have shocked and unsettled us. In an age in which we as a society feel the need for safety more than seldom before, so much appears to be spiralling out of control.

“A great future has been predicted for extremely complex preparations, but the authorisation process entails a lot of work and requires highly qualified specialists.”

Medical advances

It may be somewhat comforting in this situation to know that, away from the attention of the media, there are previously life-threatening risks which have been reduced or virtually eradicated. Breakthroughs in medicine and pharmacy have made a number of once potentially fatal diseases less frightening and the rapid pace of progress in immunotherapy allows various types of cancer to be treated more effectively. Newly developed medicines mean that hepatitis C can now be cured with over 90 percent certainty and even the outcome of AIDS, “the epidemic of the century”, is no longer so inevitable thanks to new therapies. With early diagnosis and effective treatment, people with HIV have an almost normal life expectancy.

To ensure that this trend continues and new successes are achieved, innovative research and a strong regulatory agency are required.

Goals met

In 2015, Swissmedic, as an agency, achieved the goals defined in the service mandate and service level agreement. After the two years in the red envisaged in the financial plan and the budget, Swissmedic returned to the black in 2015. Maintaining this status in future will, however, pose a genuine challenge for a variety of reasons:

The medicines filed for approval are becoming increasingly complex. A case in point is the booming field of immunoncology, uses immunologically active biological substances to combat cancer. A great future has been predicted for these extremely complex preparations, but the authorisation process entails a great deal of work and requires highly qualified specialists.



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

“The Agency is well positioned and prepared to meet the challenges of the future.”

Growing requirements in the medical devices sector

We also face major challenges in the medical devices field. Over 500,000 different types of medical device are commercially available in Switzerland today, ranging from adhesive plasters to cardiac pacemakers. Here too, a growing number of increasingly complex products are coming onto the market. A large amount is expected of Swissmedic's market surveillance activities, and we are facing an influx of additional requirements as the EU enforces new regulations.

However, the Agency is well positioned and prepared to meet the challenges of the future. The Agency Council discussed future strategic goals at its annual strategy meeting and will factor in the findings of the newly introduced horizon scanning process when formulating these goals.

Changes in the Agency Council

Markus Dür, former member of the Cantonal Government of Lucerne, stepped down from the Agency Council at the end of 2015 following many years of exceptional and prolific service. The Agency benefited from Markus Dür's vast healthcare experience. With his crystal-clear, systematic way of thinking and debating, he was a significant contributor to the Agency Council's decision-making process.

The Federal Council appointed Vincenza Trivigno, State Chancellor of the Canton of Aargau, to the Agency Council. She took up her seat in the Agency Council in February 2016 and I very much look forward to a fruitful and interesting working relationship with her.

Christine Beerli, Chairwoman
of the Swissmedic Agency Council

Foreword by Jürg H. Schnetzer

Smart regulation

Perception

Hourly we are confronted with reports of mistakes, omissions, corruption and violence. The media hope to arouse our interest, our empathy, our concern.

We also face media stirs in the therapeutic products sector. When it comes to our safety, we grow sensitive.

On the one hand, everything seems possible: progress, innovation, breakthrough, spectacular successes. Yet on the other hand, we hear and read that something doesn't work either in general or in a specific case, no improvement or cure, serious side effects, disillusionment.

“Opportunities evolve into unrealistic notions, risks that materialise turn into dramas. The path to the political agenda is short.”

Opportunities and risks

The information society is exposed to both phenomena. Opportunities and risks are emotionalised and transported: opportunities evolve into unrealistic notions, risks that materialise turn into dramas. The path to the political agenda is short.

Where they see opportunities, parliamentarians – as representatives of the people – call for rapid access to innovation, reimbursable status and equal treatment. But when risks are identified, demands are immediately made for restrictions, more rules, stricter controls, even bans.

Traditional media and the new social media will contribute to increased regulation because opportunities and risks will make headlines as either a sensation or a blunder. This means that rare but spectacular constellations will also have to be regulated for all eternity.

Public value

Intelligent regulation begins with establishing which rules of the game have proven their worth, can be enforced without a commotion, and satisfy international best practice.

Intelligent regulation also takes account of political priorities and spheres of activity that need to be addressed in the interests of the population. And it goes without saying that expense and return, i.e. public value, should be in an acceptable ratio.



The ordinance regime to date has been largely based on guidelines from the previous century, when the authorisation of therapeutic products was still regulated at Cantonal level. The revised Therapeutic Products Act and the work being done on updating the related ordinances provides a unique opportunity to develop a modern, clear and broadly accepted body of rules.

“We are prepared to generally cut red tape and ensure smart regulation.”

Cutting red tape

Swissmedic and its Agency Council have drawn up a strategic roadmap. The Federal Office of Public Health as lead government department was involved in the proposal process. We have an intensive, literally pioneering phase ahead of us, accompanied by the equally intensive rigours of day-to-day business and project work.

We are prepared to generally cut red tape and ensure smart regulation where political consensus determines the requisite degree of safety, effectiveness and quality for therapeutic products.

Jürg H. Schnetzer
Director of Swissmedic

Activities during the year

Incidents involving medical devices – increased monitoring of hospitals

Under Art. 15 of the Medical Devices Ordinance, professional users and manufacturers are required to report incidents involving medical devices to Swissmedic. Hospitals are under an obligation to set up an internal quality assurance reporting system and designate a suitably qualified person to make the mandatory reports to Swissmedic. Analyses conducted by Swissmedic have shown that certain hospitals are failing to meet the reporting requirement or only satisfying it to a very inadequate degree. In 2015, Swissmedic responded by demanding that hospitals with a very poor compliance record take corrective action.

Referral procedures for hormonal contraceptives concluded

Two referral procedures for combined hormonal contraceptives were concluded in 2015. They entailed a product information update for 84 contraceptive pills. The increased risk of thromboembolism with certain contraceptives was added to the product information and references to potential additional benefits (such as effectiveness against acne) were deleted. Healthcare professionals were informed by circular and notices in industry publications. This is intended to underline how important it is that doctors make a careful risk/benefit assessment before issuing a prescription and that they also brief patients fully.

International campaign against counterfeit medicinal products

Operation PANGAEA VIII, an international week of action targeting illegal sales of medicinal products, attracted a record 111 participating countries. Working with customs officials and Antidoping Switzerland, Swissmedic inspected almost 600 shipments, confiscating those whose contents posed a significant health risk. The recipients of the released shipments also received an information letter warning them of the risks from such products.

VISION

**AWARENESS
OF RISKS AND
CO-OPERATION:
A FACTOR FOR
SUCCESS**

(Guiding principles of Swissmedic)

Shortage of medicinal products

Out of stock! When the required medicine is unavailable

Time and time again, a particular medicinal product is to be obtained nowhere in Switzerland – sometimes it's a vaccine that isn't available. How is this possible?

Lara is just two months old. She is due to be vaccinated against tetanus, whooping cough, diphtheria, polio and bacterial meningitis. But when her GP goes to order the five-way vaccination, his supplier tells him that the vaccine is currently out of stock. The doctor is livid. In his anger, he writes to Swissmedic: "It is simply unacceptable that Swissmedic is so obstinate with regard to the authorisation of vaccines. This is putting the health of Switzerland's children in jeopardy."

The doctor's annoyance is understandable. But the reproach that he levels at Swissmedic is unjustified. It is indeed true that every vaccine needs to be authorised before it can be sold. The manufacturer is required to file an application and furnish evidence that the vaccine is of impeccable quality and its benefits outweigh its risks. In the last 10 years, Swissmedic has approved over 90% of such applications.

However, supplies of vaccines can run short when production defects occur. Prior to distribution, every batch must be released by a therapeutic products authority. Laxity in the control of vaccines could put far more people in jeopardy than a vaccine shortage. As history teaches us, 77 infants died from a contaminated tuberculosis vaccine in the Lübeck vaccination disaster of 1921. In 1955, several hundred thousand children in the USA were infected by a faulty polio vaccine. This resulted in over 50 cases of permanent poliomyelitis plus five deaths. Thanks to more rigorous regulations and controls, such vaccine tragedies are virtually unknown today.

Switzerland (along with numerous other countries) experienced quite a different case of drug shortage in 2008, when the anticoagulant heparin was suddenly no longer available.

This was because around 100 people in the USA had died due to heparin supplied from China that had been contaminated by an impure ingredient. It goes without saying that manufacturers immediately stopped sourcing their raw stock from China, but because over half their global requirements of this particular heparin ingredient were produced there, supply bottlenecks resulted. For a period, heparin was extremely scarce in Switzerland, and the Swiss authorities were powerless to resolve the shortage.

A Swiss newspaper ran the following headline in 2014: "No anti-syphilis drugs – epidemic looming". Because there were so few cases of syphilis in Switzerland (350 in 2013), it was no longer worthwhile for manufacturers to apply for Swiss authorisation for their products. In the meantime, the number of syphilis cases in Switzerland has climbed to over 1,000, but the necessary antibiotics often have to be imported from abroad. Why doesn't Swissmedic simply force companies to supply their products in Switzerland? The answer is quite simply that Swiss law does not provide for such coercive measures.

"Swissmedic is responsible for ensuring the safety of therapeutic products, but not their supply."

Whether five-way vaccination, anticoagulants or antibiotics, there will repeatedly be shortages of medicinal products. In the vast



“Manufacturers will in future be required to hold stocks of basic vaccines as well as supplementary vaccines for infants and adolescents.”

majority of cases, Swissmedic does not have the power to intervene. Swissmedic is responsible for ensuring the safety of therapeutic products, but not their supply. In other words: Swissmedic is tasked with making sure that the medicines on the market are of impeccable quality and safe, but not that all medicines are available on the market at all times.

Swissmedic can only take action on vaccines if they are available abroad, in which case it will approve an application for their controlled import.

Ultimately, most shortages of medicinal products are due to commercial factors. Since production is expensive and complex, there are very few vaccine manufacturers. And these few manufacturers endeavour to produce as efficiently as possible. They close down factories and concentrate production on one single location. If a problem occurs at this production site, the company has no alternative location to fall back on. Doctors and patients end up bearing the brunt of the ensuing international supply bottleneck.

But the authorities are not merely passive bystanders. The growing difficulty in securing vaccine supplies was addressed by an analysis conducted together with the Federal Office for National Economic Supply (FONES). It was agreed to include vaccines in an early warning system for therapeutic products

as well as to stockpile vaccines. Manufacturers will be required in future to hold stocks of basic vaccines – e.g. against hepatitis B, tetanus and diphtheria – as well as supplementary vaccines for infants and adolescents – for instance, against measles, mumps and rubella. Reserves of antibiotics and other particularly vital therapeutic products will also need to be kept in quantities sufficient to cover Switzerland’s requirements for four months. The amendment is expected to enter into force in autumn 2016.

Veterinary medicinal products also in short supply

Shortages of veterinary medicinal products can also occur. This is problematic in the case of antibiotics of first choice, which are then replaced by preparations that are more critical in terms of antibiotic resistance.

Penal law

Unexpected early-morning visitors

Anyone who acts in violation of the Therapeutic Products Act will meet the full force of Swissmedic's Penal team. They are empowered to carry out house searches and even make arrests.

It's seven o'clock in the morning and a doorbell rings somewhere in western Switzerland. The occupant opens the door. His surprise is written all over his face. He was clearly expecting someone else. Standing at his door are a Swissmedic team and two Cantonal police officers. During the subsequent search of the man's home, they seize computers and other evidence because he is suspected of selling non-authorized medicinal products to clinics.

Eight investigators-in-charge currently work in Swissmedic's Penal division. They have powers comparable to those of a Cantonal or Federal prosecutor. They can carry out house searches, seize goods and even arrest suspects. There was one such incident last October in a clinic by Lake Zurich that was allegedly injecting patients with illegal therapeutic products.

"I only do that for serious violations. And only if our suspicions are well-founded and we have sufficient circumstantial evidence."

Every house search conducted by Swissmedic must be ordered by Director Jürg Schnetzer personally. "I only do that for serious violations. And only if our suspicions are well-founded and we have sufficient circumstantial evidence." This was the case 14 times in 2015. The investigations that follow a house search can last many months. On

average it takes around two years before a ruling is handed down (or proceedings are stayed). Proceedings frequently end with a summary penalty order or ruling from Swissmedic. In most cases, the goods in question are confiscated and a fine is issued. Prison sentences, on the other hand, can only be imposed by a Cantonal court. In 2015, Swissmedic initiated 13 summary penalty orders against a total of 18 persons. Two cases were referred to the courts.

In spring 2015, Swissmedic and officers of the Aargau Cantonal police raided a laboratory manufacturing anabolic steroids and erectile stimulants. Shortly before, Swissmedic had searched a pharmacy in eastern Switzerland that was producing illegal preparations from animal cells. Patients were reportedly being injected with these preparations with the promise that they could cure cancer and multiple sclerosis.

Penal decisions to be published

Representing a key innovation, the Penal division plans to start publishing information on its penal decisions online in 2016. Registered journalists will be able to view the decisions so they can report on them.



“Anyone out there violating therapeutic products legislation should be in no doubt that Swissmedic is like a watchdog that doesn’t growl or bark, but which certainly bites when it appears.”

Swissmedic’s rationale here is to improve transparency and enhance prevention. The aim is to deter potential perpetrators by letting them know what consequences they would face. Or as Swissmedic Director Jürg Schnetzer puts it: “Anyone out there violating therapeutic products legislation should be in no doubt that Swissmedic is like a watchdog that doesn’t growl or bark, but which certainly bites when it appears.”

However, Swissmedic is only responsible for cases where therapeutic products are being illegally manufactured, imported, exported or sold wholesale. The administration or use of illegal therapeutic products in clinics falls under the jurisdiction of the Cantonal authorities.

For information on risks and side effects...

The package insert used to be enough. Nowadays a lot of patients want to know more about their medication. Despite the Internet, there is often no substitute for a face-to-face discussion with a doctor or pharmacist.

Anyone who has seen the severely handicapped Céline is unlikely to forget her. She was 16 when she was prescribed a fourth-generation oral contraceptive. Shortly afterwards she suffered a pulmonary embolism and, as a result, is today seriously disabled. When Céline was put on the pill, oral contraceptives were known to increase the risk of potentially life-threatening pulmonary embolism, including in otherwise healthy young women. However, it was not known that this risk is twice as high with fourth-generation pills compared with common first and second-generation contraceptives. While the risk of pulmonary embolism is still very small, when it does happen, it is a tragedy for the victim and her family.

But where can patients obtain this kind of information? They can, of course, check on the Internet before seeing their doctor. On www.swissmedicinfo.ch, for instance, she will find the package insert as well as information for healthcare professionals. But this information can never replace a personal consultation with a doctor to clarify medical specifics.

This is because when Swissmedic experts authorise a medicine, they base their decision on a risk/benefit analysis, which, in turn, draws on clinical trials conducted on selected patients or users. To be able to prescribe a woman the right pill, a doctor needs not only product information, but also extensive information on the patient in question. How old is she? Is this the first time that she has taken the pill? Does she smoke? Is she overweight? Only when these and numerous other questions have been clarified can the right pill be prescribed (or none at all).

Unfortunately, the reality today is sometimes different. Contraceptives are prescribed with no or only a cursory consultation. Women frequently do not associate the pill with serious side effects, but tend to focus instead on the positive “secondary” outcomes, such as clearer skin or weight control. Evidently, the risks to users can only be reduced to a feasible minimum after a thorough prior consultation.

What can Swissmedic do to improve product information? For one, the Agency constantly monitors whether there are any new scientific findings on a preparation. If there are, any such information must be adapted for doctors and patients. Newly discovered risks and side effects have to be flagged up and explained. This is an ongoing task that never stops until a medicinal product is taken off the market.

For this process to work, it is essential that side effects are reported by healthcare professionals and collated and evaluated by Swissmedic. Known under the heading of pharmacovigilance, this is one Swissmedic's most crucial tasks. Individual risks and side effects frequently only manifest themselves when the preparation is on the market and being used by a large number of patients. When such a risk is discovered, the therapeutic products authority must act jointly with the manufacturer to issue a warning and, if necessary, restrict use of the medicine.

“Women frequently do not associate the pill with serious side effects.”



“Individual risks and side effects often only manifest themselves when the preparation is on the market.”

Today's patients want to know more and more about the pills they are swallowing. This is a good thing. Well-informed patients are also able to recognise warning symptoms, react sooner and seek out a doctor if, for instance, a thrombosis occurs. That can save lives.

Inform, but don't confuse

Package inserts are a key source of patient information. But they are frequently not easy for laypeople to understand. This is because choosing the right wording for a package insert presents a genuine dilemma. While as much information as possible needs to be provided, patients should not end up being afraid of the medication as this may deter them from taking it regularly. The problem is not limited to Switzerland. Efforts are underway at international level to make package inserts easier to understand. Potential options being discussed include a clear summary at the end of the insert or increased use of pictographs. Swissmedic staff are participating in the relevant working groups.

The Agency also regularly organises meetings with patient and consumer organisations to discuss the related issues. There is a great deal of work ahead here for Swissmedic over the next few years. So let's get down to it, for the benefit of all patients.

Outlook

2016 summit

The heads of medicines regulatory authorities from around 25 countries and regions (including the USA, China, Japan, Canada, Brazil, South Africa, the EU and Russia) come together once a year for a summit. At the most recent conference (November 2015) it was agreed that in 2016 Swissmedic would host the 11th summit, also incorporating the meeting of the International Coalition of Medicines Regulatory Authorities (ICMRA). The three-day conference will take place in Interlaken from 11 to 13 October 2016. The summit presents a unique opportunity to discuss not only the challenges currently facing medicines regulatory authorities, but also global endeavours to harmonise strategies. And it also provides a forum for numerous bilateral meetings within a brief timeframe.

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. Under the revised Act, laboratories that conduct or want to start conducting microbiological tests for the identification of communicable diseases will be subject to exclusive monitoring by Swissmedic. Microbiological laboratories now require an establishment licence from Swissmedic and will be inspected periodically to monitor compliance with the statutory provisions.

As a consequence of this amendment, certificates of recognition previously issued by the Federal Office of Public Health have lost their validity. The authorisation procedure has also been simplified in that the involvement of Cantonal authorities is no longer provided for. The amendment affects microbiological laboratories which

- Conduct diagnostic and epidemiological tests (patient diagnostics);
- Carry out microbiological tests to rule out a disease communicable by blood, blood products or transplants (screening);
- Provide microbiological testing of environmental samples (environmental analytics).

These laboratories must satisfy the requirements of the Ordinance on Microbiological Laboratories (SR 818.123.1).

The revised Act assigns additional tasks to Swissmedic in a new area outside the monitoring of therapeutic products. Since the costs of performing these tasks will only be partly offset by the Federal contribution, Swissmedic will largely have to defray them by levying procedural fees.

VALUES AND CONDUCT

QUALITY
EFFICIENCY
TRANSPARENCY
RESPECT
INTEGRITY
COMMITMENT
LOYALTY

(Guiding principles of Swissmedic)

Facts and figures

Business statistics as at end 2015

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)	241
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Manufacturing of medicinal products (without a licence for wholesale distribution)	95
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Wholesale distribution of medicinal products:

Import of medicinal products	553
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Wholesale trade of medicinal products	833
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Export of medicinal products	431
------------------------------	-----

Foreign trade with medicinal products	371
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Laboratories with a Swissmedic licence to carry out microbiological or serological tests on blood, blood products or transplants for the identification of transmissible diseases, with a view to transfusion, transplant or processing	39
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Blood transfusion services or hospitals with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	27
---	----

Controlled substances

Establishment licences for handling controlled substances	360
---	-----

Laboratories with FOPH recognition

Microbiological and serological laboratories inspected by Swissmedic	100
--	-----

Number of authorisations by type of product as at end 2015

Therapeutic products code

Number of authorised medicinal products

Synthetics human	4,990
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Biotechnologicals	304
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Vaccines	68
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Blood products	88
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Radiopharmaceuticals	36
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Generators	4
------------	---

Bacterial and yeast products	27
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Allergens	345
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Transplants: tissue products	2
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Phytopharmaceuticals	659
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Homeopathics	639
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Ayurvedic medicinal products	1
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Anthroposophics	424
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Tibetan medicinal products	6
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Veterinary medicinal products	719
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Total	8,312
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Number of authorisations by dispensing category as at end 2015

Dispensing category/Authorised medicinal products

A	Dispensed once only on medical or veterinary prescription	1,715
B	Dispensed on medical or veterinary prescription	3,799
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	43
C	Dispensed after expert advice from medical personnel	602
C/D	Dispensed after expert advice from medical personnel/Dispensed after expert advice	24
D	Dispensed after expert advice	1,927
E	Dispensed without expert advice	169
Total		8,312

Homeopathic and anthroposophic medicinal products without indication authorised by the notification procedure as at end 2015

Single products	11,194
Combined products	1,064

Swissmedic as an agency

Staff headcount at year end	424
Full-time positions at year end	352
Total women	55.7 %
Total men	44.3 %
Staff working part time (part time is defined as working up to 89% of a full-time post)	45.8 %
Average age of staff	47.5 years
Women	46.0 years
Men	49.3 years
Language distribution:	
German	85.1 %
French	12.2 %
Italian	2.7 %
Rhaeto-Romanic	0 %
Fluctuation rate	5.9 %

Market access

Marketing authorisation

Authorisation overview

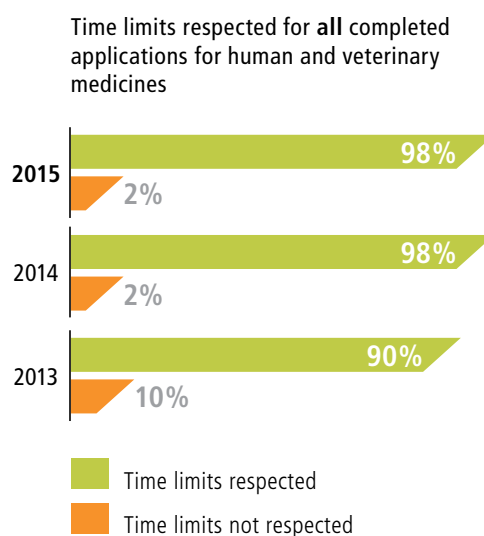
The Marketing Authorisation sector is involved in all phases of a medicinal product's life cycle. As early as during the development phase of a medicinal product, firms can obtain scientific advice with regard to the various aspects of a development programme. The main task of the Marketing Authorisation 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 14,819 applications were submitted in 2015, while 14,925 applications were finalised. As in the previous year, 98% of applications were finalised on schedule.
- Of the 23 scientific advice meetings, 13 pre-submission meetings and eleven clarification meetings requested in 2015, 28 were answered in writing, while face-to-face meetings took place in 19 cases.
- In the course of cooperation with the Clinical Trials department (Licensing division), the Preclinical Review department undertook 11 assessments for the approval of clinical trials, while the Quality Review department undertook 28.

Time limits

In 2015, 96% of applications for the first marketing authorisation of innovative medicinal products (ZL1A) were completed within the prescribed time limits. 82% of applications for non-innovative first marketing authorisations (ZL1B) were completed on schedule (if the delayed CHM applications – ZL1B – submitted prior to 2015 are excluded, the figure for this category rises to 97%). 100% of applications under the fast-track authorisation procedure and for the authorisation of new active substances (NAS) were completed on time. The corresponding percentages for the different types of variation were close to 99%.



Authorisation of human medicinal products (HAM)*

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 2015, Swissmedic received 295 applications for first authorisations of innovative medicinal products and major variations thereto, and 252 applications were completed.
- Of the 28 medicinal products with new active pharmaceutical ingredients that were authorised for the first time (32%), nine were completed by means of the fast-track procedure.
- Of the 277 applications for non-innovative first authorisations, 57 concerned co-marketing products.
- Three requests for the parallel importation of a medicinal product were submitted in 2015.

Human medicinal products with a new active pharmaceutical ingredient authorised in 2015

ATC	Active pharmaceutical ingredients	Product name	Application
Alimentary tract and metabolism	Dulaglutidum	Trulicity®, solution for injection in pre-filled syringe for single-use	Improvement of blood glucose control in adults with type 2 diabetes mellitus.
	Naloxegolum	Moventig®, film-coated tablets	Opioid-induced constipation.
	Netupitantum	Akynzeo®, capsules	Prevention of acute and delayed nausea and vomiting associated with moderately and highly emetogenic chemotherapy.
	Racecadotrilum	Vaprino®, capsules	Symptomatic treatment of acute diarrhoea in adults.
	Rifaximinum	Xifaxan® 550 mg, film-coated tablets	For the reduction in recurrence of episodes of overt hepatic encephalopathy in patients with hepatic cirrhosis.
Anti-infectives for systemic use	Daclatasvirum	Daklinza®, film-coated tablets	Chronic hepatitis C (in combination with other medicinal products).
	Simeprevirum	Olysio®, hard capsules	Chronic hepatitis C (in combination with other medicinal products).
Antineoplastic and immunomodulating agents	Apremilastum	Otezla®, film-coated tablets	Active psoriatic arthritis and moderate to severe plaque psoriasis.
	Carfilzomibum	Kyprolis®, powder for solution for infusion	Treatment, in combination with lenalidomide and dexamethasone, of adult patients with recurrent multiple myeloma who have received at least one prior therapy.

* The performance indicators regarding marketing authorisations are shown on page 35.

Ceritinibum	Zykadia [®] , capsules	Locally advanced or metastatic ALK-positive non-small cell lung cancer (NSCLC) previously treated with crizotinib.	
Cobimetinibum	Cotellic [®] , film-coated tablets	In combination with Zelboraf for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation.	
Idelalisibum	Zydelig [®] , film-coated tablets	Chronic lymphocytic B-cell leukaemia (B-CLL), follicular lymphoma.	
Lenvatinibum	Lenvima [®] , capsules	Thyroid carcinoma.	
Nintedanibum	Ofev [®] , soft capsules	Idiopathic pulmonary fibrosis (IPF).	
Nivolumabum	Opdivo [®] , concentrate for solution for infusion	Locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy.	
Panobinostatium	Farydak [®] , hard capsules	Treatment of multiple myeloma.	
Peginterferonum Beta-1A	Plegridy [®] , solution for injection in a pre-filled syringe	Multiple sclerosis.	
Pembrolizumabum	Keytruda [®] , powder for concentrate for solution for infusion	Unresectable or metastatic melanoma in adults who show progression after treatment with ipilimumab and, if BRAF V600 mutation-positive, a BRAF or MEK inhibitor.	
Pirfenidonum	Esbriet [®] , hard capsules	Idiopathic pulmonary fibrosis (IPF).	
Ramucirumabum	Cyramza [®] , concentrate for solution for infusion	Adenocarcinoma of the stomach or gastro-oesophageal junction.	
Secukinumabum	Cosentyx [®] , powder for solution for injection	Moderate to severe plaque psoriasis in adults previously treated with systemic therapies, including ciclosporin, methotrexate or PUVA.	
Sonidegibum	Odomzo [®] , capsules	Advanced basal cell carcinoma (BCC) that is not amenable to curative surgery or radiation therapy.	
Vedolizumabum	Entyvio [®] , powder for concentrate for solution for infusion	<ul style="list-style-type: none"> • Treatment of adults with moderately to severely active ulcerative colitis previously treated with tumour necrosis factor alpha (TNF) inhibitors. • Treatment of adults with moderately to severely active Crohn's disease (second-line treatment as for ulcerative colitis above). 	
Blood and blood-forming organs	Cangrelorum	Kengrexal™, powder for solution for infusion	Percutaneous coronary intervention (PCI) and "bridging".
	Edoxabanum	Lixiana [®] , film-coated tablets	<ul style="list-style-type: none"> • Prevention of stroke • Prevention of systemic embolism • Treatment and prevention of venous thromboembolism (incl. DVT and PE)
Cardiovascular system	Sacubitrilum Valsartanum	Entresto [®] , film-coated tablets	Reduction of the risk of cardiovascular mortality and morbidity in systolic heart failure.
Nervous system	Safinamidum	Xadago™, film-coated tablets	Idiopathic Parkinson's disease.
Miscellaneous	Ferri Oxyhydroxidum Saccharum Amyla	Velphoro [®] , chewable tablets	Hyperphosphataemia in adult patients with chronic kidney disease on dialysis treatment (haemodialysis, peritoneal dialysis).

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 2015 and issued 75 recommendations regarding marketing authorisation applications. The majority of them concerned new authorisations or additional indications for medicinal products.
- In addition, 37 expert reports for the purpose of full assessments and 46 reports on individual aspects were provided by the HMEC experts.

Number of HMEC recommendations relating to marketing authorisation applications



Extensions and discontinuations

The marketing authorisation for a human medicinal product is always issued for a five-year period. The authorisation holder must then 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 modified.

Activities

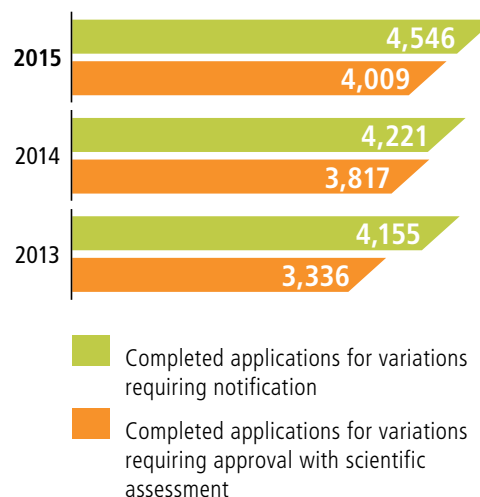
- In 2015, a total of 1,671 applications to extend the marketing authorisation were submitted, and 1,701 applications were completed.
- In addition, 199 applications for the discontinuation of a product and 23 applications for the discontinuation of a dosage strength of a product were received in 2015. 195 applications for the discontinuation of a product and 24 applications for the discontinuation of a dosage strength of a product were completed.

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 4,557 variations requiring notification were submitted in the year under review; 4,546 notifications were completed.
- Regarding modifications requiring approval, 4,066 applications were submitted and 4,009 were completed.



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:

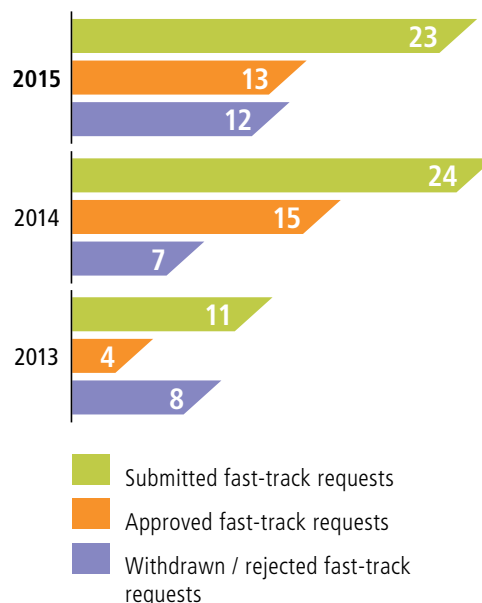
- expected successful treatment in the case of a serious illness,
- lack of other treatment possibilities with medicinal products or unsatisfactory treatment option,
- the use of the medicinal product indicates a significant therapeutic benefit.

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.

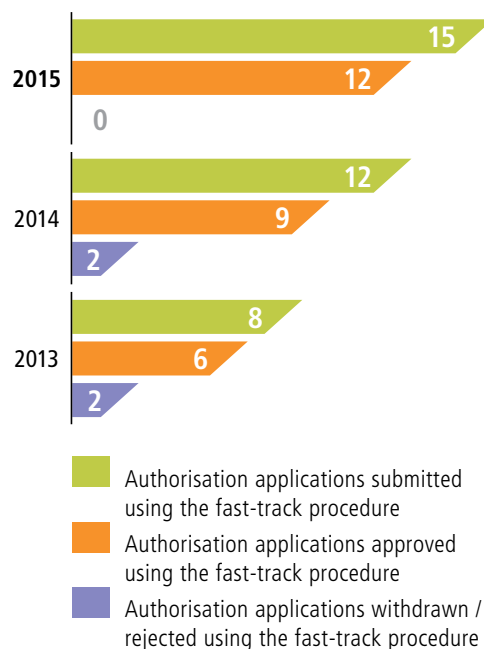
Activities

- In 2015, 23 requests for the fast-track procedure were submitted. 13 of these requests were approved and 12 were rejected or withdrawn by the applicant.
- A total of 15 authorisation applications using the fast-track procedure were submitted. 12 applications were approved, and none was rejected or withdrawn by the applicant.
- All of the applications submitted using the fast-track procedure were completed on time.

Fast-track requests



Applications using the fast-track procedure



The Procedure with Prior Notification (PPN)

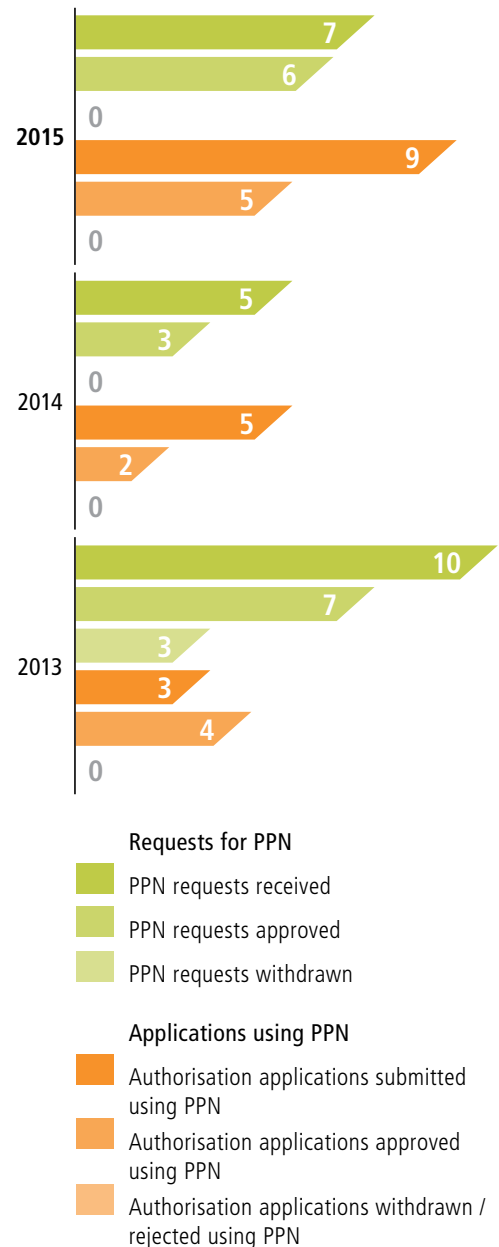
Since 1 January 2013, Swissmedic has offered applicants the option of having the assessment carried out 20% more rapidly, provided that they give prior notification of the submission date of their application (notification 5 - 8 months or, from 1 January 2016, 3 - 6 months before the planned submission 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 submitted PPN requests, six were approved. One request is currently still being processed.
- In 2015, nine authorisation applications using the PPN were submitted and five were approved; three further submissions are already planned.
- All of the applications submitted using the procedure with prior notification were completed on time.



Applications under Article 13 TPA

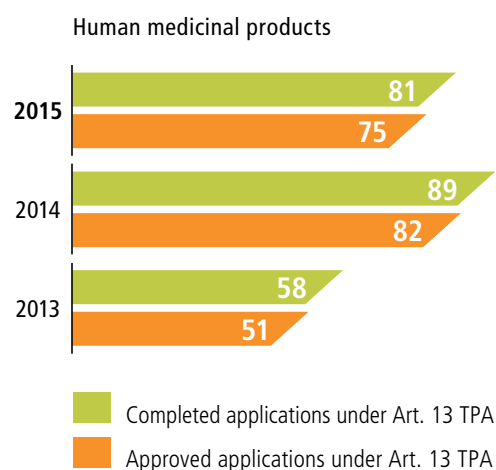
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose if the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

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

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

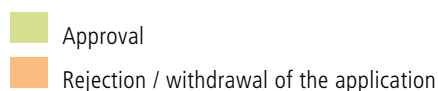
Activities

- Of the 81 authorisation applications under Art. 13 TPA that were completed in 2015, 75 were approved (92.6%), five were withdrawn and one was rejected.
- Of the 81 completed applications, nine involved "known active pharmaceutical ingredients with innovation", 27 "known active pharmaceutical ingredients without innovation", six "known active pharmaceutical ingredients of complementary and herbal medicines", five "major variations" including one additional indication, and 34 variations requiring approval.



Human medicinal products

	2013		2014		2015	
New notification of a new active substance	0	2	0	1	0	0
Known active pharmaceutical ingredients with innovation	1	2	8	2	7	2
Known active pharmaceutical ingredients without innovation	26	0	32	0	24	3
Known active pharmaceutical ingredients of complementary and herbal medicines	2	2	1	0	6	0
Variations requiring approval	20	1	33	0	34	0
Additional indications			1	0	1	0
Other major variations	2	0	5	2	3	1
Other applications	0	0	2	2	0	0
Total	51	7	82	7	75	6



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

- A total of 28 products were awarded orphan drug status in 2015 out of 34 applications received.
- Six products were newly authorised as orphan drugs. Further orphan indications were approved for six previously authorised orphan drugs. The status was discontinued for one product.

Paediatric medicinal products

Since the entry into force of EU Regulation EC 1902/2006 and the Food and Drugs 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 in 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 provides for 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 within the framework of paediatric clinical trials were considered important. Annual planning will continue to take account of inspections to assess compliance with GCP.

Activities

- The submission of a paediatric investigation plan (PIP) remains voluntary in Switzerland. A PIP (EU) was however submitted in 2014 with many applications for innovative products. This information is valuable for the evaluation of the application.
- The submission of PIPs proved helpful with regard to the notification of paediatric clinical trials. A total of 15 paediatric trials were authorised in 2015.

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 are authorised in Switzerland by Swissmedic. One process authorised for the treatment of platelet concentrates is employed in blood transfusion services throughout Switzerland, while a second authorised process for the treatment of platelets is not currently employed in Switzerland. A third process, authorised for the treatment of transfused plasma, is currently used in just one blood transfusion service.

- Three requests relating to authorisation conditions associated with these process authorisations, particularly the assessment of Periodic Safety Update Reports (PSUR), variations or extensions, were processed on schedule.

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

- One transplant product was authorised by Swissmedic in 2015. This means that two authorised transplant products are currently available in Switzerland (one skin equivalent and one product based on chondrocytes).
- Swissmedic held 13 company meetings (scientific advice, presubmission or clarification meetings) on transplant and gene therapy trials.

Complementary and herbal medicines

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.

Complementary medicinal products

Complementary medicinal products encompass homeopathic, anthroposophic and Asian medicinal products. With regard to marketing authorisation, Swissmedic takes into account the fact that the considerable value placed on complementary medicine is anchored within the Swiss Constitution. For this product group, and in addition to medicinal products stating an area of use (indication), a wide range of medicinal products without an indication are authorised. When authorising medicinal products without an indication, a greatly simplified authorisation procedure is usually applied. In addition to quality and safety, the focus is above all on tolerability.

Activities

- Swissmedic completed six applications for the first authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication.
- Five products without an indication were authorised using the simplified procedure under Article 17 para. 2 of the Ordinance on Complementary and Herbal Medicines.
- 38 applications for simplified authorisation without an indication involving a reduced dossier were completed. 16 of these products were authorised and 22 applications were rejected or withdrawn.
- A total of 133 products without an indication were newly authorised using the notification procedure. 86 of these were single products, 47 were combined products. A further 83 products were rejected or withdrawn.
- Almost all the backlog of unprocessed applications in the CHM department was cleared in 2015.

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

- As in 2014, no herbal medicinal products with a new active pharmaceutical ingredient were authorised in 2015.
- 36 applications for first authorisation of non-innovative herbal medicinal products were completed. 20 of them concerned co-marketing products.

Asian medicinal products

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

Activities

- The revision of the TAS list and the assessment of the quality documentation for Asian medicinal products has been initiated. This means that product notifications for Asian medicinal products without an indication should be possible in 2016.

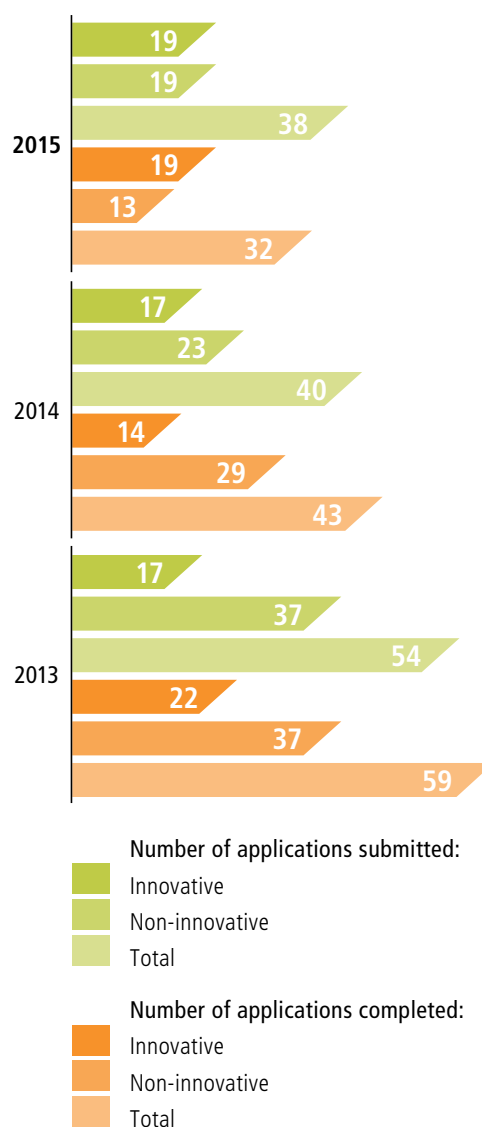
Veterinary medicinal products

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 live-stock concerns their effect on the safety of foodstuffs. Within the authorisation procedure, the currently valid standards specified in legislation on foodstuffs are used to specify the level of possible residues from a veterinary medicinal product that are tolerated in foodstuffs such as meat, milk, eggs or honey when a product has been administered to cattle, poultry or bees.

Activities

- In the year under review Swissmedic consolidated its scientific expertise in veterinary medicinal products in one place by focusing authorisation and market surveillance activities on the Veterinary Medicines department. This step increases efficiency by creating internal synergies and also involves beneficial collaboration with external agencies.
- 19 applications for innovative first authorisation and major variations were submitted, and 19 applications were completed.
- Of these 19 completed applications, six concerned the first authorisation of a medicinal product with a new active pharmaceutical ingredient, including one application for time-limited authorisation. Four of these were approved and one medicinal product was granted time-limited authorisation.
- All of these applications were processed within the prescribed time limits.



Veterinary medicinal products with a new active pharmaceutical ingredient authorised in 2015

ATC	Active pharmaceutical ingredients	Product name	Application
Anti-parasitic products, insecticides, repellents	Fluralaner	Bravecto ad us. vet., chewable tablet	Ectoparasiticide for systemic use in dogs.
	Spinosad	Comfortis ad us. vet., chewable tablet	Ectoparasiticide for systemic use in dogs and cats.
	Afoxolaner	NexGard ad us. vet., chewable tablets for dogs	Systemic treatment of flea or tick infestation in dogs.
Respiratory tract	Betamethasone acetate Florfenicol Terbinafine	Osurina ad us. vet., Osurina ad us. vet., ear gel for dogs	Treatment of acute otitis externa and acute deterioration of recurrent otitis externa associated with florfenicol-susceptible bacteria and terbinafine-susceptible fungi.

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

- Dr. Barbara Knutti was appointed chair of the VMEC in 2015.
- At its four meetings in 2015, the VMEC assessed ten applications for authorisation or a variation of the authorisation.

- During the meeting on 12 February 2015, there was an exchange of views on issues connected with the review of authorisation applications with Dr. Gabriel Beechinor, Director of Veterinary Sciences at the Irish Health Products Regulatory Agency (HPRA).

Extensions and discontinuations

Authorisations for a veterinary medicinal product are issued for five years. The authorisation holder must then 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

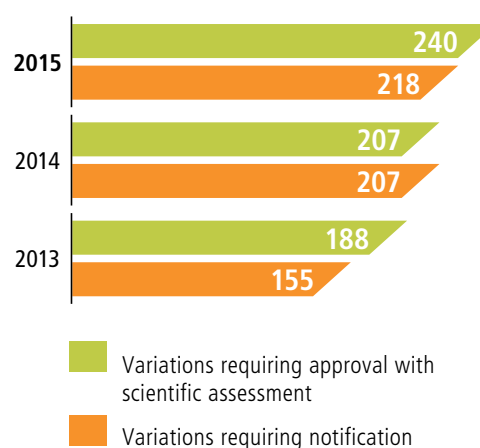
- In 2015, authorisation was extended for 100 products.

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 2015, 240 variations requiring approval and 218 variations requiring notification were completed.



Minor Use – Minor Species (MUMS)

Veterinary medicinal products that are only used for minor species or rarely occurring indications are difficult to place on the market because of the low turnover. From a clinical point of view, however, these products are necessary so that every animal can receive the appropriate treatment. Swiss legislation on therapeutic products provides the possibility for Swissmedic to permit facilitated authorisation procedures for these products. A distinction is made between recognition of MUMS status and the subsequent authorisation of a veterinary medicinal product as a MUMS product.

Activities

- A total of three MUMS statuses were issued in 2015.
- One application for a “known API with innovation” and one application for “time-limited authorisation” with MUMS status were approved.

Applications under Article 13 TPA for veterinary medicinal products

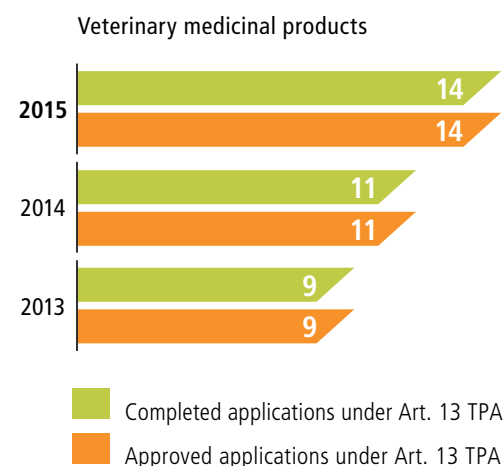
If an applicant requests authorisation or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with comparable medicinal product control, Swissmedic takes account of the results of the trials conducted for this purpose if the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

- All 14 authorisation applications for veterinary medicinal products under Art. 13 TPA that were completed in 2015 were approved.
- Of the 14 completed applications, three involved “known active pharmaceutical ingredients with innovation”, three “known active pharmaceutical ingredients without innovation”, four “major variations” including two additional indications and four variations requiring approval.



Veterinary medicinal products

	2013		2014		2015	
Known active pharmaceutical ingredients with innovation	0	0	2	0	3	0
Known active pharmaceutical ingredients without innovation	2	0	5	0	3	0
Variations requiring approval	6	0	4	0	4	0
Additional indications	1	0	0	0	2	0
Other major variations	0	0	0	0	2	0
Total	9	0	11	0	14	0



Appeals procedure regarding the authorisation of medicinal products

Appeals against official decisions issued with regard to the authorisation procedure may be lodged with the Federal Administrative Court within 30 days. The decision of the said court may be contested before the Federal Supreme Court.

Activities

- In 2015, four appeals were lodged with the Federal Administrative Court against official decisions taken by the Agency in connection with product authorisations. Two appeals were dismissed. The remaining cases are still pending. 13 decisions by the Federal Administrative Court were contested before the Federal Supreme Court. These cases are also still pending.
- Of the proceedings still pending before the Federal Administrative Court, judgement has been passed on 14. All the appeals were rejected.

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
	2015	Total 2015
Marketing authorisation procedures (all application categories), proportion of procedures completed within the prescribed time limits	≥95 %	98 %
First marketing authorisations of innovative medicinal products (ZL1A); proportion of procedures completed within the prescribed time limits	≥95 %	96 %
First marketing authorisations of non-innovative medicinal products (ZL1B); proportion of procedures completed within the prescribed time limits	≥95 %	82 %*
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 %	97 %
Administrative variations (ZL3B); proportion completed within the prescribed time limits	≥95 %	99 %
Fast-track authorisation procedure	100 %	100 %

* The time limits in 2015 for ZL1B applications were respected in 97% of cases when the delayed CHM applications submitted before 2015 are excluded.

Special activities and events

- As in the previous year, a benchmarking study of authorisation applications carried out in collaboration with industry stakeholders compared the overall times needed by companies and authorities in Switzerland, the EU and the USA to process applications (time from submission of the application to the official decision = total throughput time). The benchmarking study focused on major applications, specifically new notifications (new active substances and known active pharmaceutical ingredients with/without innovation) and major variations (new indications and other major variations). The total throughput times were generally longer in Switzerland than in the EU or USA. This is partly attributable to Swissmedic's longer time lines, which are a reflection of its resources, and partly to the longer company response times compared to other countries. Gratifyingly, Swissmedic's compliance with time limits has increased in all application types and the time needed by Swissmedic to process applications as a proportion of total throughput time has dropped. Furthermore, the previous year's positive result in the fast-track authorisation category was repeated in 2015. On average, Swissmedic was once again faster in authorising these new innovative drugs in 2015 than the EMA and the FDA.
- Responsibilities for veterinary medicinal products were reviewed in collaboration with representatives of the Federal Food Safety and Veterinary Office (FSVO) and Federal Office of Public Health (FOPH). Swissmedic retains responsibility for authorisation, vigilance and special licences. The FSVO's responsibilities include treatment guidelines, coordination with Cantonal Veterinary Officers and the ISVET database. Expertise in veterinary medicinal products was removed from Safety of Medicines and Authorisations and amalgamated in the Veterinary Medicinal Products department.
- Adaptations were made to several regulatory processes. Thus, following the conclusion of the two-year pilot phase for the procedure with prior notification (PPN), the experience gained by stakeholders and Swissmedic with this new procedure was evaluated. The most important adaptations concerned a shortened prior notification period and a more flexible procedure when switching from the fast-track procedure to a procedure with prior notification. The revised information sheet, to which other new additions have been made, entered into force on 1 January 2016. The instruction has been updated to reflect the current status resulting from the incorporation of the new Article 27a of the TPLO, which governs the simplified authorisation of radiopharmaceuticals containing active substances that are not or were not contained in any other medicinal product authorised by Swissmedic. The revised guidance document on radiopharmaceuticals and associated information sheets entered into force on 1 April 2015 after a six-month transitional period.
- Official approvals of variations requiring notification are no longer issued by registered letter. Instead electronic approval is immediately issued to authorisation holders via the Swissmedic Portal. The processing of these applications is now much faster thanks to the automation of various steps and the increased number of parallel activities within Swissmedic. Authorisation holders no longer have to submit two sets of hard copy for paper-based applications. Digitalisation and electronic processing by Swissmedic have made the extra copy that used to be required unnecessary. These are examples of the contributions made by Swissmedic to reduced bureaucracy and simplified procedures.
- In connection with an OECD/G8 initiative, and with the backing of the State Secretariat for Education, Research and Innovation (SERI), international researchers and representatives of the pharmaceutical industry met in Lausanne for a second time with Swissmedic, other leading drug regulatory authorities and the FOPH to discuss innovative developments in Alzheimer's/dementia and market access to these innovations.



Licensing

Licensing of medicinal and transplant products

Establishment licences for medicinal products

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

Activities

- At the end of 2015, 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 2015, the number of licences issued for the first time, extended or amended was 678, i.e. back on the increase following the declining trend in recent years.

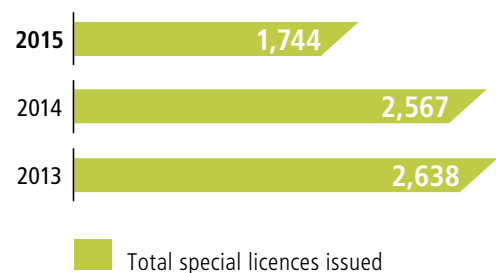
Performance indicator	Target	Result
Establishment licences; proportion of procedures that were completed within six months	95 %	100 %

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 2015, the number of special licences granted fell considerably following the simplification of the procedure for radiopharmaceuticals. Only 300 special licences were granted in this category versus almost 800 in 2014.



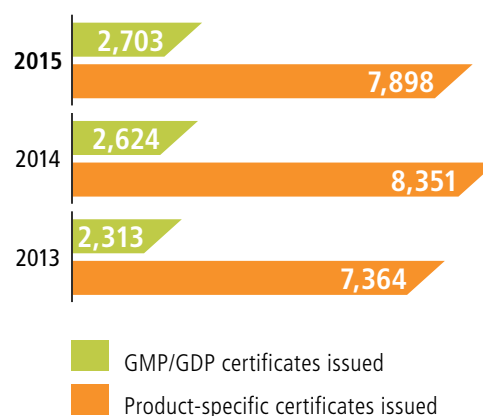
Performance indicator	Target	Result
Special licences; proportion of procedures that were completed within 24 hours	100 %	99 %

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

- An order form is now available for companies. Swissmedic automatically processes the information contained in the order form and converts it directly into the format specified by the WHO. A structured order form is available for companies. The information in the request form is processed electronically at Swissmedic and converted directly into the CPP format defined by the WHO.
- The number of GMP/GDP certificates has increased steadily for many years.
- The number of product-specific certificates remains at a stable high level.



Performance indicator	Target	Result
GMP/GDP certificates; proportion of procedures completed within 14 days	95 %	99 %

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 2015, 360 companies were in possession of an establishment licence for handling controlled substances. At 148, the number of processed applications for modifications, renewals or the start of operations was slightly down on the previous year.
- 7747 import and export permits were issued for international trade, 98% of which were issued electronically.
- Swissmedic analysed 21 individual substances and applied to the Federal Office of Home Affairs for their inclusion in the relevant Ordinance (BetmVV-EDI).

Performance indicator	Target	Result
Import and export permits for controlled substances; proportion of procedures completed within 10 working days	95 %	98 %

Clinical trials with medicinal products and transplant products

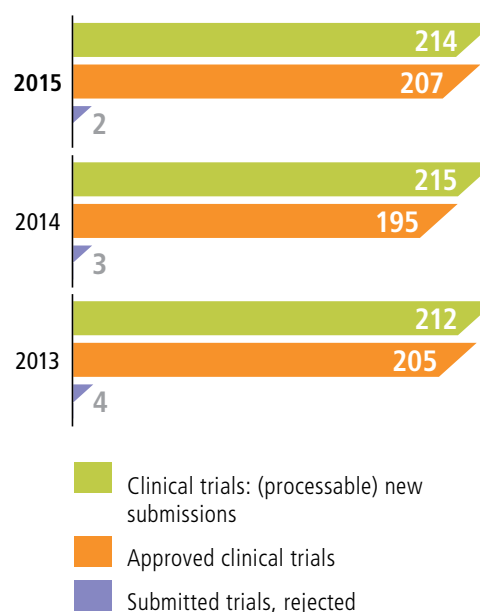
Clinical trials are used to systematically gather information on medicinal products when used in humans. Swissmedic verifies whether the quality and safety of the test product is guaranteed. Clinical trials may only be carried out in Switzerland if they have been approved by an Ethics Committee and by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

Activities

- Swissmedic received 227 applications for clinical trials with medicinal products (excluding transplant products and gene therapies) in 2015. Only 214 of these applications could be processed, as the rest were either incomplete or fell outside the remit of the Clinical Trials division. In total, 207 clinical trials were approved, including 54 in category B and 153 in category C. Two of the applications in the latter category concerned a first-in-human trial. Two clinical trials were rejected and three were withdrawn by the sponsor during evaluation. The other applications are currently being processed.
- Swissmedic processed 2,410 other requests or notifications relating to clinical trials of medicinal products (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, End-of-trial Reports, as well as 75 reports of suspected unexpected serious adverse reactions (SUSAR).
- To be able to approve clinical trials involving gene therapy (GT/GMO), Swissmedic needs position statements from the Federal Office of Public Health, the Swiss Expert Committee for Biosafety and the Federal Office for the Environment. In 2015, Swissmedic received ten applications for clinical trials, including six involving GT/GMO products and four involving transplant products (TpP). A total of eight trials were approved, as were 45 amendments, including 34 with GT/GMO products. All of these were category C trials, i.e. they involved products administered to humans for the first time.

- Swissmedic also 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 grey areas of the new law. In connection with these efforts, Swissmedic took part in three meetings organised by the FOPH agency responsible for coordinating research involving humans.

Medicinal products excluding transplant products and gene therapy



Performance indicator	Target	Result
First submissions of clinical trials; proportion of notifications assessed within 30 days	95 %	98 %

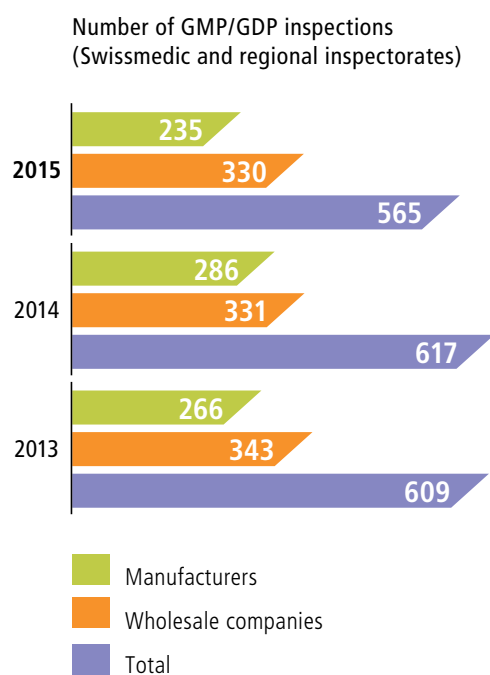
Inspections

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 2015, the Swissmedic inspectorate carried out 77, the regional inspectorates 488 GMP/GDP inspections of manufacturers and wholesale companies, giving a total of 565 inspections.
- The inspections carried out by the Swissmedic inspectorate concerned the following areas: transplant products 12%, blood transfusion services 35%, pre-approval inspections 4%, "for cause" inspections 18%, pharmaceutical sector inspections 31%. More intensive enforcement of company monitoring led to Swissmedic carrying out twice the number of ad hoc inspections due to complaints or suspected infringements of the law ("for cause" inspections).
- Various technical interpretations were revised with a view to harmonising the Swiss inspectorate system, with particular emphasis on the two documents that interpret the new GDP guidelines from 2016.
- After a brief interruption the previous year, Swissmedic was once again involved in inspection programmes organised by partner authorities outside Switzerland in 2015. In this context, 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) and a blood transfusion service in Indonesia was inspected with the WHO. Swissmedic also took part in several assessments of partner authorities within the framework of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). Following a reorganisation, the PIC/S now has a new structure, with most of the work being done in subcommittees. Cooperation within the new structure of the PIC/S has proved to be effective.



Performance indicator	Target	Result
Licensing inspections; degree to which the annual plan was achieved	100 %	100 %

GCP and GVP inspections

All 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 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 results of the trials satisfy 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

- In 2015, Swissmedic carried out 18 GCP inspections of clinical trials involving medicinal products submitted for authorisation in Switzerland.
- The Agency also carried out six GVP inspections in Switzerland and accompanied one GVP inspection in Germany.
- Swissmedic took part in two GCP inspection programmes and one GVP inspection programme under the PIC/S Convention. Within this framework, Swissmedic accompanied two GCP inspections carried out by foreign authorities in Canada and Austria. Two of the six GVP inspections carried out in Switzerland were also part of the PIC/S programme.
- Furthermore, Swissmedic provided expert support for two GCP inspections carried out in Switzerland by the FDA and the EMA.
- In 2015, the GCP/GVP inspectors again participated in the EMA's GCP inspectors working group.
- They performed four GCP inspections in the field of clinical trials with standardised transplants and gene therapy.
- Eight pharmacovigilance inspections were carried out jointly with the Licensing division and Swissmedic accompanied one pharmacovigilance inspection carried out in Switzerland by foreign authorities.

Performance indicator	Target	Result
GCP/GVP inspections; degree to which the annual plan was fulfilled	100 %	100 %

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

- Switzerland's GLP units were audited by a team of inspectors from Spain and Japan within the framework of the On Site Evaluation (OSE) programme of the Organisation for Economic Co-operation and Development (OECD). The last assessment of this kind was carried out in 2001. The evaluation report was discussed during the meeting of the OECD GLP Working Group in April 2015 and accepted. The Swiss GLP programme complies with all OECD requirements.
- Within the framework of its monitoring activities, the Swissmedic GLP unit carried out nine inspections, one of which involved the expansion of a testing area and another a final inspection. This test facility withdrew from the programme at the end of April 2015.
- The first inspection of a further test facility was carried out at the end of November.

Performance indicator	Target	Result
GLP inspections; degree to which the annual plan was fulfilled	100 %	100 %

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 microbiological and serological laboratories, transplants and genetic examinations on humans. Swissmedic also carries out some of the inspection activities in the therapeutic products sector for the Principality of Liechtenstein.

Activities

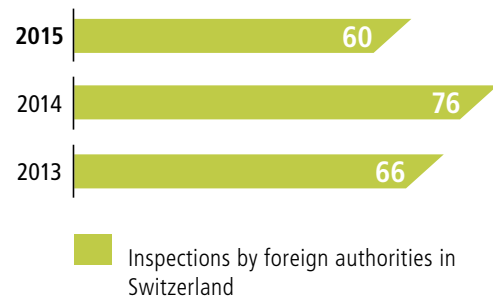
- In 2015, Swissmedic carried out 31 inspection procedures for the FOPH and one for the Principality of Liechtenstein.
- The Federal Council decided to implement the revised Federal Act on Combating Communicable Human Diseases (Epidemics Act) with effect from 1 January 2016. It approved two ordinances at the same time. Under the new Act, Swissmedic will assume full responsibility for the implementation activities relating to the monitoring of microbiological laboratories previously performed on behalf of the FOPH. The module agreement with the FOPH on which these activities were based expired at the end of 2015.

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 2015, foreign authorities carried out 58 GMP inspections at pharmaceutical companies in Switzerland. The inspecting authorities were the USA, with 24 inspections, Korea with eight, Turkey with five, Brazil, Kazakhstan and Kenya with three each, Iran, Mexico and Russia with two each, and Belarus, China, Taiwan, Libya, the Gulf Cooperation Council (GCC) and Uganda with one each.
- Swissmedic also accompanied two GCP inspections carried out by foreign monitoring authorities (FDA and EMA) in Switzerland.



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 April the European Court of Justice ruled that it may be justified to ban homosexuals from giving blood, but only if there is a high risk of infectious diseases such as HIV being transmitted. Moreover, it must also be clear that there is no real alternative to a ban on donating blood. Such alternatives could be effective methods for testing donated blood or questioning the donor in detail about

high-risk sexual behaviour. The Federal Council subsequently noted in its responses to two political initiatives that the blood transfusion centres are liable for the safety and quality of their products in their role as pharmaceutical manufacturers, but they have the option at any time of requesting Swissmedic to modify the approved procedures on the basis of scientific argumentation. The Swiss Transfusion organisation intends to prepare an application during 2016 to have the exclusion of men who have sex with men (MSM) from giving blood changed.

- The occurrence of cases of West Nile Virus (WNV) in nearby foreign countries led some regional blood transfusion services to temporarily introduce general or targeted polymerase chain reaction (PCR) testing for WNV. The Blood Transfusion Service of the Swiss Red Cross also regularly adapted the donor suitability criteria in order to minimise the risk of transmitting other communicable diseases such as dengue or Chagas.

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

- Under the Mutual Joint Audit Scheme of the European Directorate for the Quality of Medicines & HealthCare (EDQM), the Laboratory section (OMCL) underwent three days of intensive inspection in March 2015. The six auditors from the EDQM and various European OMCLs inspected the implementation of the ISO/EN 17025 standard requirements, use of the OMCL Network guidelines and compliance with the requirements of the OMCL QM system. The outcome of the audit was good.
- In November 2015, the OMCL held the first training course on the analysis of illegal and counterfeit biologicals. Participants from 12 European OMCLs and the EDQM spent two days learning about new methods in mass spectrometry and the use of databases to evaluate analytical results.
- Investigations into the causes of an increase in cases of haemolysis during administration of intravenous immunoglobulins continued in collaboration with the Market Monitoring of Medicinal Products and Safety of Medicines sections. Cooperation with the Paul Ehrlich Institute focusing on broadly supported pharmacovigilance data enabled a correlation to be identified between the cases of haemolysis that have been observed and the content of anti-A/anti-B isoagglutinins in various immunoglobulin products. These findings and possible approaches to reducing the risks associated with the use of immunoglobulin products were published (TRANSFUSION 2015;55:p13-p22).
- The Laboratory section (OMCL) trains apprentice laboratory technicians for chemical and biological laboratories. Three apprentices successfully completed their training in 2015.



Analysis conclusions for new marketing authorisations and market monitoring

	2013	2014	2015
Authorisation procedure: number of medicinal products examined	33	54	37
Market monitoring: number of medicinal products examined	1,763	1,980	1,333
Other (pharmacopoeia, round robin tests)	–	375	526
Total	1,796	2,409	1,896

Batch assessments and plasma pool analysis

	2013		2014		2015	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU)	635	117	701	74	748	65
Notifications	319	149	312	169	321	135
Plasma pool analyses	1,950	–	2,337	–	2,375	–
Product analyses as WHO reference laboratory	–	35	–	16	–	13

Performance indicator	Target	Result
Batch releases; proportion of assessments completed within the prescribed time limit	98 %	100 %

Appeals procedures regarding licences

Appeals against decisions in connection with the licensing procedure may be lodged with the Federal Administrative Court within 30 days. The decision of the said court may be contested before the Federal Supreme Court.

Activities

- Five appeals were lodged before the Federal Administrative Court against official decisions by the Agency in connection with licences in 2015. One appeal was not admitted, the others are pending.
- Two appeal proceedings that were already pending before the Federal Administrative Court or the Federal Supreme Court were dismissed.

Special activities and events

FOPH and Swissmedic campaign on cell therapy

The FOPH and Swissmedic have largely completed the campaign initiated in 2014 to eliminate dubious treatments and the production of fresh cells. In particular, three appeal proceedings against the measures instigated by Swissmedic are still pending. The initiative comprised an information campaign about the legal framework applicable to this area and a review of a total of 35 services being provided by clinics and other healthcare professionals. The campaign drew a great deal of international attention, especially in Asian countries where Swiss clinics heavily advertise these treatments.



Market surveillance

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

Medicinal products

Medicinal product vigilance

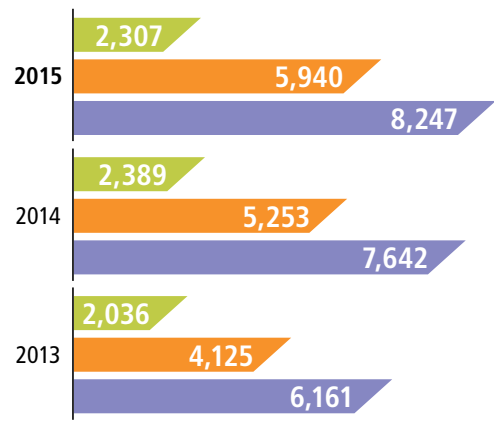
Swissmedic records safety signals associated with medicinal products, vaccines, labile blood products and veterinary medicines based on reports of adverse drug reactions (ADR) from within Switzerland. If the investigations confirm a new risk, Swissmedic initiates the necessary measures.

Pharmacovigilance

Within the framework of the pharmacovigilance network, the reports 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 8,247 reports of suspected adverse drug reactions (ADR). 2,307 of them were sent by the six regional pharmacovigilance centres (RPVC), 5,940 by the industry. As in previous years, there was again a sharp rise in the number of reports received (7.1%), due mainly to an increase in the volume reported by companies. The number of follow-ups to ADR reports is now also being recorded as a big increase in the number of reports was observed during the year and they are labour-intensive (2,156 follow-ups).
- A total of 26 signals concerning 87 medicinal products were generated from the ADR reports received from Switzerland, and these were investigated in detail.
- Roughly 70% of the reports from companies were submitted to Swissmedic electronically, using the pharmacovigilance gateway. A further nine companies were given access in 2015. With one more joining in January 2016, there are now 16 companies using the gateway, all with large reporting volumes.
- Healthcare professionals can use the online reporting portal EIViS (Electronic Vigilance System) that was launched in October 2014 to report ADRs online to one of the regional pharmacovigilance centres. In 2015 Swissmedic received 115 reports from healthcare professionals via the portal. Pharmaceutical companies without gateway access to the Swissmedic database can also send their reports to Swissmedic electronically via EIViS. As of the end of the year, 62 companies were actively using EIViS.



Number of reports of adverse reactions to human medicinal products:

- Regional pharmacovigilance centres
- Pharmaceutical companies
- Total

- All ADR reports received by Swissmedic are collated and processed in the national VigiFlow database. This database no longer meets all the requirements for a modern pharmacovigilance tool. Swissmedic therefore intends to replace VigiFlow with a modern Adverse Event Reporting System (AERS) by the end of 2017. A specification for the system was developed and the WTO call for tenders for the new database tool was issued on 8 December 2015.

Performance indicator	Target	Result
Serious adverse reactions: proportion of assessments carried out and transmitted to the companies within 15 calendar days	95 %	99 %

Haemovigilance

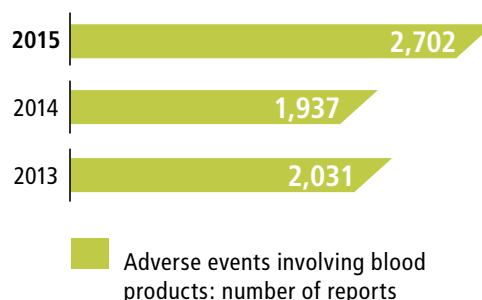
The purpose of haemovigilance is to increase the safety of blood and blood components (erythrocyte concentrates, platelet concentrates (PC), plasma for transfusion) and the entire transfusion process. Periodic evaluation of the haemovigilance data provides information on the nature and magnitude of transfusion risks in Switzerland.

Evaluation of reports shows where measures to reduce risk are needed and documents the impact of measures that have already been taken. This includes the promotion and implementation of proactive measures to increase transfusion safety both in individual blood transfusion services and hospitals and at national level.

Activities

- A total of 2,702 reports were received in 2015. 52% of them described transfusion reactions such as allergic and febrile reactions and antibody formation. Transfusion errors were the subject of 1% of the reports, while 42% described “near misses”, cases in which a transfusion error was avoided.

- The haemovigilance officers working at hospitals play a central role in the Swiss haemovigilance system.
- Evaluation of the haemovigilance data has confirmed the favourable safety profile of pathogen-inactivated platelet concentrates (in use throughout Switzerland since 2011). In particular, there was no evidence of a potentially increased risk of transfusion-associated acute lung injury (TRALI), a life-threatening adverse effect. The data were presented at an international congress (AABB Symposium 2015).



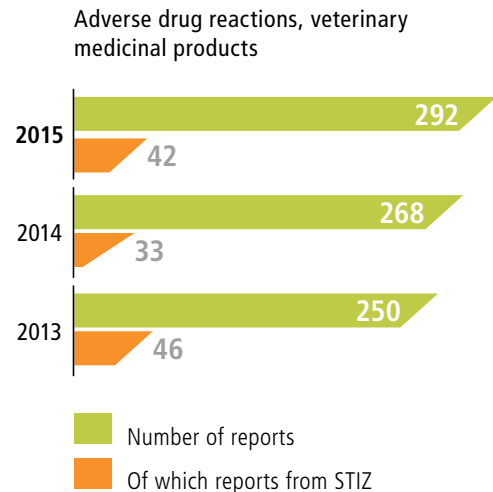
Performance indicator	Target	Result
Report on new findings	1	1
Training courses for haemovigilance officers	2	3

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

- Reports on adverse reactions (ADR) to veterinary medicinal products from 2014 were evaluated. A report on the evaluation was published in the journal Swiss Archive of Veterinary Medicine (Müntener et al., Schweiz. Arch. Tierheilk., 57: 601-605, 2014). The species most frequently affected were dogs, followed by cats and cattle. As in previous years, the most frequently reported reactions involved mainly antiparasitic or anti-infective medicines, followed in third place in 2014 by products containing hormonally active substances.
- The number of adverse reactions to veterinary medicinal products reported to Swissmedic increased by 9% on the previous year to 292. Forty-two of these reports were passed on to Swissmedic by Tox Info Suisse.
- Once again, ADR reports in 2015 primarily involved dogs and cats, followed in third place by cattle. The distribution by therapeutic category is comparable to that recorded in 2014. Eight signals were generated from the 292 reports. Five of them involved products for use in farm animals.



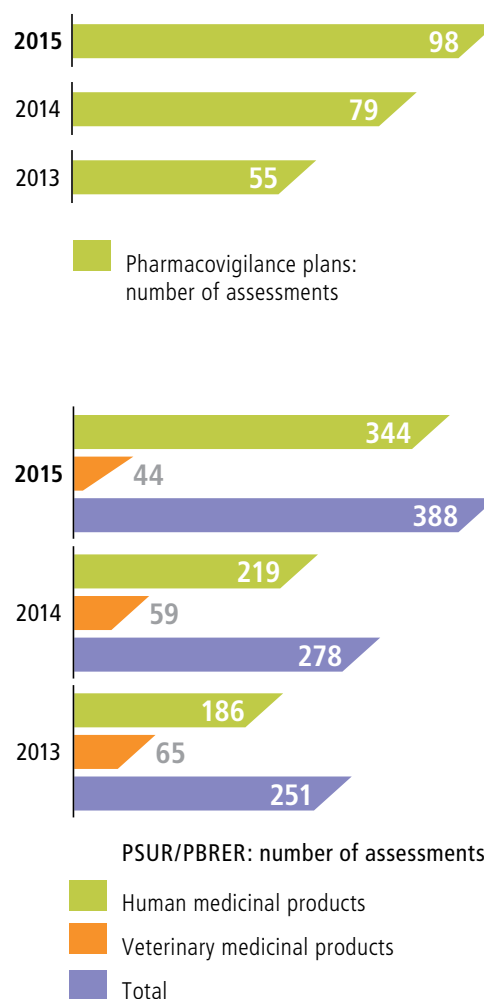
Performance indicator	Target	Result
Report on new findings	1	1

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

- Evaluation of pharmacovigilance plans is one of the main areas of activity relating to the safety of medicines. Such plans were evaluated as part of 98 applications for first authorisation and major variations of innovative medicinal products.
- In 2015 Swissmedic started a pilot phase in which summaries of the pharmacovigilance plans for two selected new authorisations were published on its website. The aim is to increase transparency and the knowledge about these products that is available to professionals using the site.
- A total of 344 periodic safety and efficacy reports (PSUR/PBRER) on human medicinal products after authorisation and 131 updated pharmacovigilance plans submitted with a PSUR/PBRER were evaluated. The short assessment process with systematic prioritisation made it possible to reduce the average time taken.
- Swissmedic processed 171 safety signals concerning medicinal products, of which 87 came from Switzerland and 84 were identified from international sources.



Performance indicator	Target	Result
Number of signals identified from the reports	120	171*

* Signals involving several authorisation holders were counted more than once

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

- In addition to an update of the information for healthcare professionals and patient information of all combined hormonal contraceptives in the course of a review procedure, the information about further medicinal products was updated following intervention by Swissmedic.
- In 12 cases healthcare professionals were informed about new risks relating to medicinal products in circulars approved by Swissmedic (DHPC).
- Swissmedic published information drawing attention to the risk of serious complications following accidental overdose of low-dose methotrexate as a result of daily instead of weekly administration.
- Swissmedic also drew attention to the risk of significant heart rhythm disturbances associated with simultaneous administration of Harvoni® with amiodarone or Sovaldi® and daclatasvir with amiodarone.

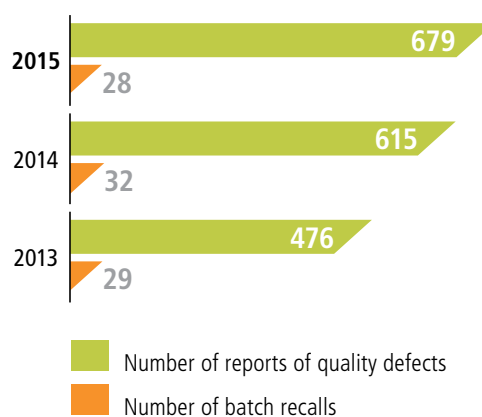
Performance indicator	Target	Result
Number of completed procedures (including reviews)	30	38

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

- Compared with 2014, there was again a 10% increase in the number of quality defects reported. A total of 679 reports were submitted. Switzerland was affected by 454 of them.
- Official decisions to carry out 28 batch recalls were taken.
- One medicinal product had to be recalled down to the patient level because of the risk of skin irritation, burns or inflammation. A concentrated hand disinfection product was incorrectly packaged with the patient information for a product containing the same active substance but sold as a ready-to-use product diluted by a factor of about 20.
- Mix-ups are repeatedly a reason for recalling medicinal products from the market. Two different dosage strengths of one product were thought to have been mixed up, for example. Another case involved capsules with unknown contents, which led to a recall down to the retail level. A case discovered by a doctor, in which different types of tablets appeared to have been packaged together, proved puzzling until it was discovered that the patient had transferred the tablets to another container at home.
- 22 applications to temporarily place on the market products produced for other countries were approved, the aim being to overcome supply shortages of medically important products.

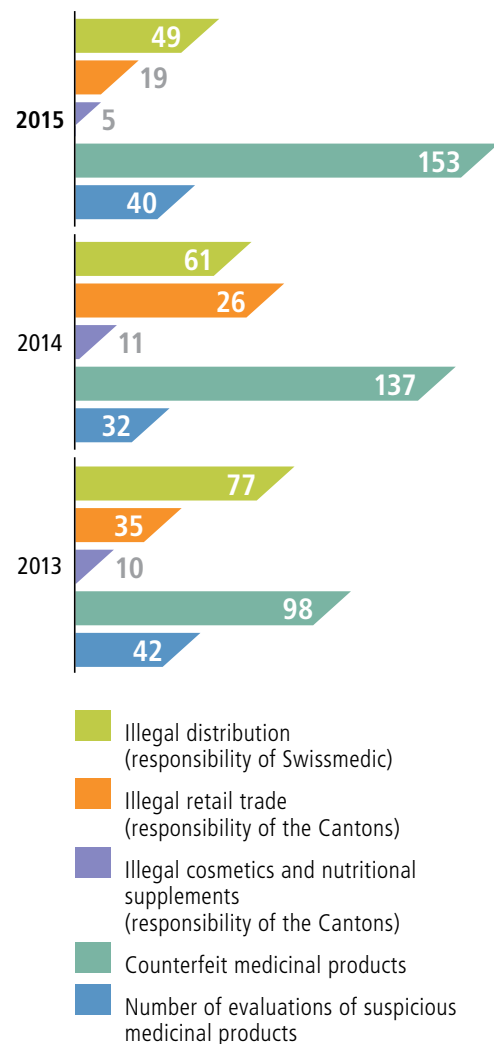


Measures against illegal medicinal products

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 2015, Swissmedic received 319 reports on illegal activities related to medicinal products. Of them, 49 concerned illegal distribution with a link to Switzerland.
- Some 24 cases were transmitted to the Cantons for further follow-up, since they concerned the retail trade of illegal products that do not come under the legislation on therapeutic products.
- Switzerland was involved in only 15 of a total of 153 reports of counterfeiting.
- Some 1094 unauthorised imports of medicinal products led to administrative proceedings being initiated.
- A press release about the number of illegal imports of medicinal products was issued at the start of the year. It emphasised the worrying trend in imports of overdosed erectile stimulants, which often lead to considerable adverse effects.
- Laboratory analysis was used to test illegally imported slimming aids for chemical constituents. It was striking that a large proportion of products advertised as natural contained dangerous substances such as sibutramine, which is banned in Switzerland and the EU. Swissmedic took these alarming findings as an opportunity to issue a further warning to the public about ordering medicinal products on the internet.

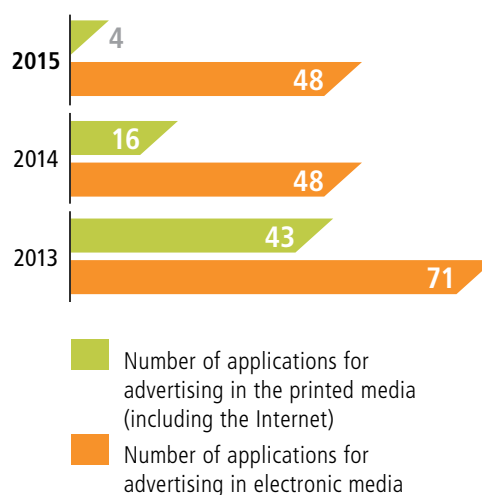


Control of advertising

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.

Activities

- Of the 52 applications submitted for prior control, only four involved printed media. The decline in submissions of printed media advertising analgesics, sleeping aids and sedatives, laxatives and anorectics is due to the change in practice introduced in mid-2015; prior control is now only mandatory if potential for dependence or abuse is mentioned in the medicinal product information. The other 48 applications involved advertising in electronic media such as television commercials, radio spots or e-boards.
- In 2015 Swissmedic had to follow up a greater number of gross infringements of the Therapeutic Products Act and the Advertising Ordinance with respect to advertising to healthcare professionals. A total of 13 administrative proceedings were initiated for infringements of advertising legislation relating to advertising to professionals and to the public. An official objection was issued in eight cases.
- Preliminary work on the revision of the Therapeutic Products Advertising Ordinance (TPAO) was done in conjunction with the FOPH. The aim of the revision is to take into account developments in the dissemination and use of electronic media.



Performance indicator	Target	Result
Prior control of advertising: proportion of cases where a preliminary decision was taken within 4 weeks of receipt of application	80 %	81 %

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

Performance indicator	Target	Result
First actions taken within 10 days for priority 1 reports	100 %	100 %
First actions taken within 30 days for priority 2 reports and within 90 days for priority 3 reports	90 %	92 %
Number of presentations, publications and circulars to raise awareness among stakeholders	12	9

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 2015, appeals were lodged with the Federal Administrative Court against seven official decisions by the Agency in connection with the market monitoring of medicinal products. Most of them concerned the illegal import of medicinal products and the advertising of medicinal products. In three cases, the appeals were not admitted by the court. One appeal was dismissed. For the others, the judgement is still outstanding.
- Of the appeals already pending before the Federal Administrative Court or the Federal Supreme Court, judgements were passed on five cases. Three appeals were dismissed. One appeal was not admitted, one appeal was approved in part.

Special activities and events

Better product information for contraceptive pills

The risks associated with combined hormonal contraceptives (CHC) have been known since they were authorised. In response to new findings about the risk of in some cases life-threatening deep vein thrombosis, a review was carried out to examine, update and harmonise the information for healthcare professionals and patient information for all 84 CHC that have been authorised. In a parallel procedure involving 33 CHC for which a beneficial effect on acne in some cases was claimed, this information was deleted as it had led to incorrect prescribing. The attention of healthcare professionals was drawn to this subject once again in a DHPC written by Swissmedic and in the publications issued by the professional associations, reminding them of their responsibility with respect to taking a careful history and prescribing and dispensing CHC.

Increase in quality problems and supply shortages

In 2015 there was a further increase in the number of reports of quality defects and applications to import medicinal products produced for other countries in order to overcome supply shortages. Since quality problems are often indicative of systemic (GXP) problems, Swissmedic intensified ad hoc inspections in response to complaints or suspected infringement of the law ("for cause" inspections) in order to clarify shortcomings of this type on the spot and request corrective action. Swissmedic is involved in the expert pool for the new reporting platform created by the Federal Office for National Economic Supply in October 2015 and in this way receives prompt information about supply shortages, enabling it to efficiently assess applications to import foreign products.

Pharmacovigilance

Since 2002, Swissmedic has been collaborating closely in pharmacovigilance with the pharmacology units at the university hospitals in Berne, Basel, Zurich, Geneva and Lausanne, as well as the regional hospital in Lugano. The RPVC provide their services on behalf of Swissmedic. Changes in recent years led to the old agreements being terminated with effect from 31 December 2015. An in-depth legal evaluation revealed that the services fall under public procurement requirements by virtue of their volume and are subject to tender via the WTO process. The tendering process started in April 2015 and the outcome was published on 3 July 2015. All existing RPVC submitted a bid and were considered. The new agreements entered into force on 1 January 2016.



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 the 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.

Placing on the market

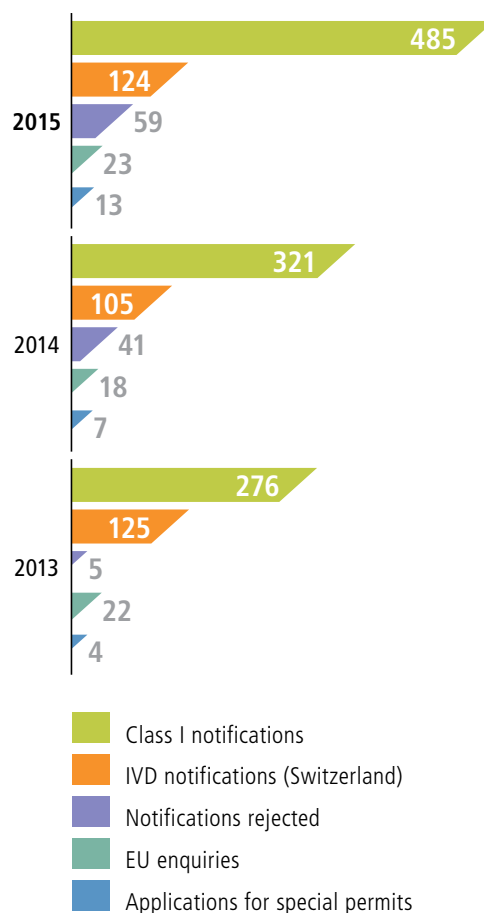
Manufacturers of medical devices associated with greater risks must bring in officially recognised notified bodies for the conformity assessment. Notification is mandatory for certain medical devices, and for these Swissmedic receives the notifications, carries out random checks on their classification,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

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 as needed in ad hoc working groups such as the Software Group.

Activities

- Compared with the previous year, reports on Class I medical devices increased 50% to 485. This class covers devices such as reusable surgical instruments, adhesive plasters and rolling walkers.
- The number of reports on medical devices relating to in vitro diagnostics (IVD) also increased slightly to 124.
- In 59 cases, Swissmedic rejected notifications of medical products from firms because of incorrect categorisation or classification, or because the product did not fall within its area of responsibility.
- In 2015, Swissmedic took part in 23 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 2015, 13 applications for special permits were reviewed, ten of which were approved.



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

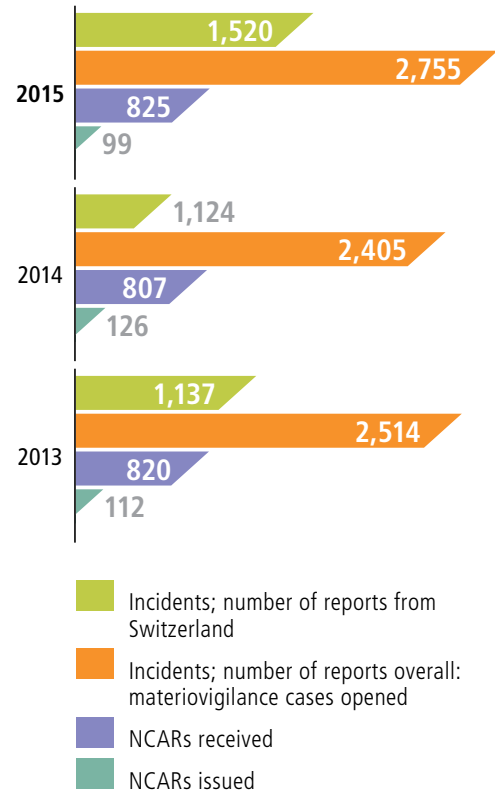
- The number of requests for mutual assistance from European partner authorities more than tripled compared to the previous year, reaching 151.
- Swissmedic issued 16 requests for mutual assistance to its European partner authorities, more than twice as many as in the previous year.
- Intensified monitoring of the CABs led Swissmedic to take part in internationally accompanied audits of these CABs again in 2015, an activity that included the review of product documentation.

Materiovigilance

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

Activities

- Of the 2,755 materiovigilance cases reported, 1,520 involved incidents in Switzerland. This represents a further year on year increase.
- In 713 cases, the implementation of corrective safety measures in Switzerland was monitored. A total of 99 reports on defective medical devices (National Competent Authority Reports, NCARs) were drawn up for the attention of foreign authorities, and Swissmedic received 825 NCARs from the European partner authorities.
- In 622 cases, a public safety report was published on the Swissmedic website for the information of users.
- In 2015, 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.



Performance indicator	Target	Result
Reports requiring urgent action; first measures taken within 10 days	100 %	100 %

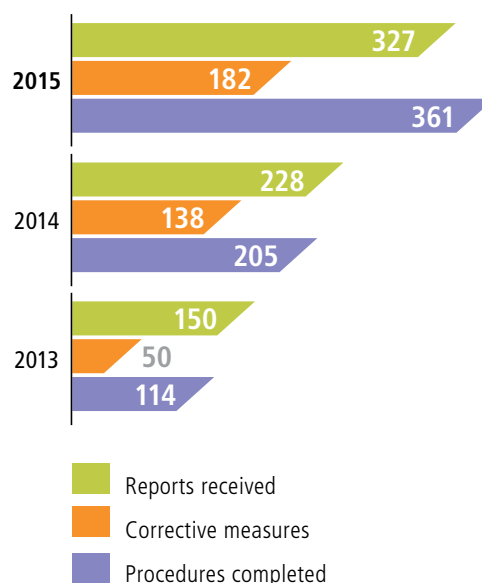
Market controls

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 to 327 in 2015.
- In 182 of the cases opened as the result of the reports, corrective measures were imposed, for example modification of the product descriptions or halting distribution.
- In 2015, 361 notifications were completed.
- There was again a sharp increase in notifications, as a result of which they were processed even more stringently according to the risk involved. Targeted allocation of resources and optimisation of report-handling processes enabled some of the increase to be absorbed. In 2015 it was consequently also possible to complete substantially more reports and take more corrective measures than the year before.

- Several administrative proceedings that had been ongoing for many years were also completed in 2015, enabling a backlog of work to be cleared.



Performance indicator	Target	Result
First activities for priority 1 cases initiated within 10 days	100 %	100 %
First activities for priority 2 cases initiated within 30 days	90 %	100 %
First activities for priority 3 cases initiated within 90 days		

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 5% to 38 in 2015.
- Three ongoing clinical investigations were inspected during the year under review.

Performance indicator	Target	Result
Approval of clinical investigations; proportion assessed within 30 to 60 days	95 %	92 %

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

- Swissmedic carried out monitoring audits at both of the CABs still active in the area of medical devices in Switzerland.

- In 2015, Swiss experts took part in two inspections of authorities in Europe that designate notified bodies.
- In the year under review, Swissmedic carried out four 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.

	2013	2014	2015
CAB inspections (excluding ISO 13485)	4	3	6
Joint assessments	4	2	2
On-site inspections of clinical investigations	2	0	3
Hospital audits (reprocessing, maintenance and reporting system)	0	2	4
Inspections by foreign authorities*	30	54	40
Inspections of market controls	1	6	8

* (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

- A total of 2,575 export certificates were issued in 2015. In nearly 99% of cases this service was provided within 30 days.

Export certificates



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. The decision of the said court may be contested before the Federal Supreme Court.

Activities

- In 2015, no appeals were lodged against an official decision of the Agency in connection with the market monitoring of medicinal devices.
- No further appeals are pending before the Federal Administrative Court or the Federal Supreme Court.

Special activities and events

Increased surveillance of the CABs

The stricter requirements applicable to the notified bodies, or CABs, involved in market access for medical devices mean that numerous medical products have to be re-certified throughout Europe. This also affects market monitoring and led to an even greater need for international coordination (increase in requests for mutual assistance).

Mandatory reporting for hospitals

In 2015 Swissmedic took action against hospitals that are not complying adequately with their reporting requirement and requested corrective measures.



Standards

Legal matters

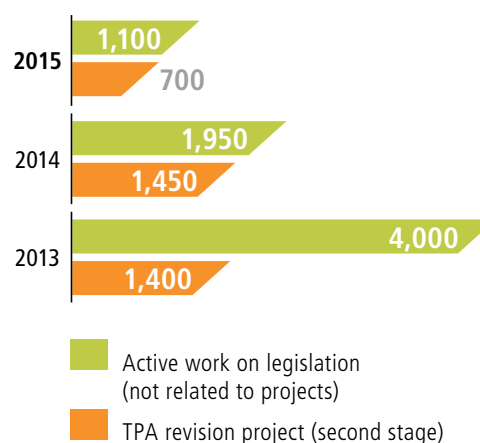
Legislation

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 integrated within this legislative work as the competent enforcement authority. The enactment and revision of the implementing ordinances of the Swissmedic Agency Council (ordinances of a technical nature) is however among the competences of Swissmedic.

Activities

- With the entry into effect of Implementing Regulation (EU) 920/2013, the designation and supervision of notified bodies in Europe was adapted to the stricter requirements. To implement these requirements in Switzerland, the FOPH worked closely with Swissmedic, SECO and the FDHA to produce the necessary revision of the Medical Devices Ordinance and enact it with effect from 14 April 2015. This ensured that medical products are subject to the same high quality and safety requirements in Switzerland as in Europe and that Swiss medical products continue to have free access to the EU market.
- As in 2014, the focus in 2015 was on the parliamentary consultation on the regular revision of the Therapeutic Products Act (second stage). After two rounds of consultation in the National Council and one consultation in the Council of States it was possible to resolve most of the differences that still existed between the two Councils. Swissmedic attended all these meetings with the FOPH, the lead entity responsible for preparing the legislation. The parliamentary reconciliation process will continue in 2016.
- Since the regular revision of the TPA (TPA2) is in the final phase of parliamentary consultation and made very few demands on the working groups responsible for the draft act, requiring instead only a small number of individuals, fewer human resources were required in 2015.

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

Activities

- In 2015, Swissmedic – together with Swiss experts from industry, universities, pharmacies (in the community and hospitals) and the authorities – devoted a total of 11.9 person years to specialised work in this area. 62% of this work was done by the Swiss Agency for Therapeutic Products. A total of 131 people from Switzerland were mandated to work in the various national and European committees and groups working on the pharmacopoeia.
- In 2015, Supplements 8.3, 8.4 and 8.5 of the Ph. Eur. came into effect.
- In addition, Supplement 11.2 of the Ph. Helv. was published and came into effect on 1 October. One important new development in this Supplement concerns the rules of Good Manufacturing Practice for small quantities of medicinal products. The addition of a specific appendix for the manufacture of sterile medicinal products represents a substantial contribution to ensuring the quality of medicines prepared in hospital and community-based pharmacies on the basis of an official formula. In addition, various texts were adapted to reflect the state of the art in science and technology and the wording of the Ph. Eur.

Technical standards for medical devices

If medical devices comply with the valid harmonised standards published in Europe, they are considered to be in conformity. Every year Swissmedic publishes references in the Federal Gazette under which the list of technical standards registered by Swissmedic can be consulted; 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

- The list of harmonised standards published annually in the Federal Gazette was replaced definitively by a reference to the corresponding website of the EU Commission.
- In 2015, Swissmedic was active in two national standards committees and one technical committee, whose purpose is to check proposals for international standards concerning medical devices.

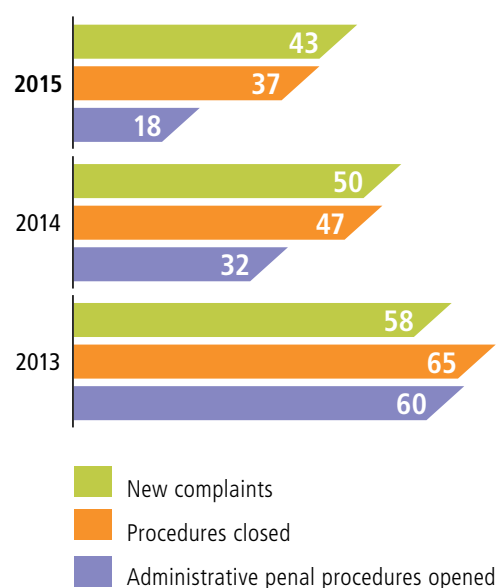
Penal law

General developments

Swissmedic is mandated to carry out a considerable proportion of the penal prosecutions associated 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 43 new complaints and closed 37 cases. It opened 18 administrative penal proceedings. The further fall in these figures in 2015 marks the continuation of the trend observed in recent years, whereby the complaints received by Swissmedic are increasingly relevant and concern meaningful cases.
- Several procedures, each at a different stage, required considerable resources. In the pre-trial phase of one case alone, for example, no fewer than 43 people, including 18 from Swissmedic, were involved in six searches conducted on the same day. This necessitated prior investigations and considerable preparation. Several complex investigations resulted in final reports, imposed penalties or referrals to the courts.
- Swissmedic's experience of international cooperation in criminal matters enables it to respond to requests from third countries for aid in its field of activity. In 2015, Swissmedic responded to five requests received from Germany, France, Serbia and Italy. In one case, Swissmedic took over a case referred to it by Germany and also obtained a conviction for activities that occurred in Switzerland. Finally, one request for international cooperation on criminal matters was addressed to Germany.
- The evaluation of the results of the consultation procedure set up with a view to ratifying the Medicrime Convention is ongoing.
- A strategy has been put in place to ensure that decisions issued by Swissmedic in criminal matters are publicised accordingly. Registered journalists will be able to view the decisions so they can report on them. Swissmedic's rationale here is to improve transparency and enhance prevention. The aim is to deter potential perpetrators by letting them know what consequences they would face.

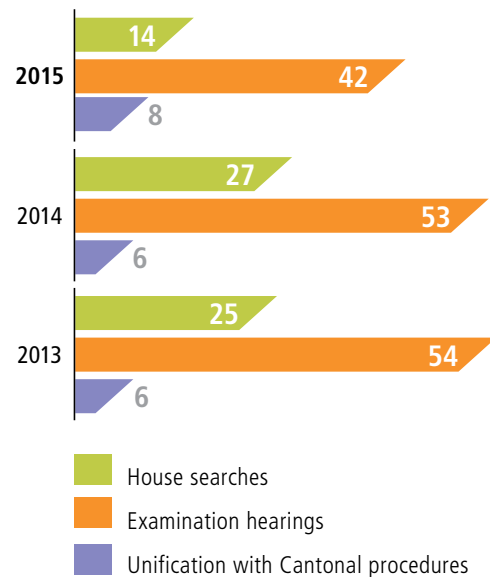


Investigative measures

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 2015, Swissmedic carried out 14 house searches and 42 hearings.
- Three appeals against coercive measures were lodged with the Federal Criminal Court (FCC) in 2015. One appeal was dismissed following its withdrawal. The FCC admitted one of the other appeals because the search criteria (key words) for the operation of computer equipment had not been communicated to the parties in advance and because the link between the items seized following the said operation and the subject matter of the proceedings had not been adequately demonstrated. The third appeal is still pending. The FCC also refused to admit one appeal submitted in 2014. Three requests to remove the seals affixed to documents seized during searches were submitted. These are also pending. Furthermore, the FCC rejected one request to remove seals submitted in 2014 because the link between the person concerned and the suspected offences was too weak.
- Swissmedic dealt with five incoming requests for international cooperation in criminal matters, two from Germany, one from Italy and one from France. In one case, Germany referred one procedure to Swissmedic for completion. In the opposite direction, one request was made to Germany.
- Eight 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; RS 415.0).

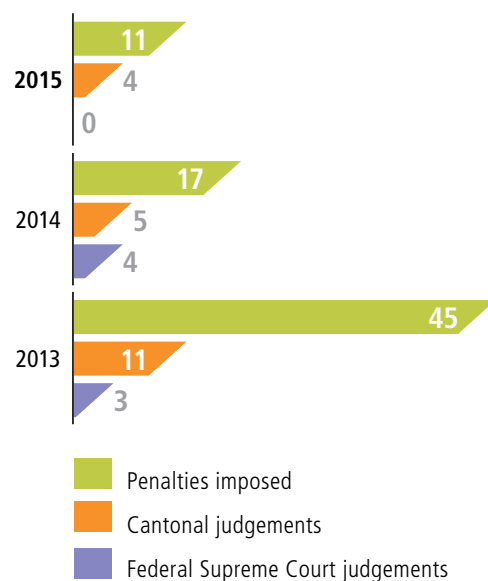


Decisions / judgements by Swissmedic and by courts

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

- 16 individuals were affected by the eleven penalties that were imposed. Six cases concerned illegal trading, including illegal import. In two of these cases, Responsible Persons were also deemed to have violated their obligations. Two cases involved the illegal manufacture of medicinal products, two the placing on the market of non-compliant medical devices and two violations of duties of diligence. Swissmedic also dismissed eleven cases, one following the death of the defendant, one because the perpetrator could not be found and nine cases where the suspicion was not confirmed or there was insufficient substantiation. Some of the individuals were involved in the initial stages of large-scale proceedings, and subsequently exonerated as the investigations progressed.
- The Cantonal courts issued decisions in two cases, one as the court of first instance and one as the court of second instance. In the first case, a court handed down a conviction at the request of Swissmedic. In the other case, a Cantonal court decided that compensation was payable by the Canton and Swissmedic following an acquittal issued in 2014. Furthermore, a Cantonal public prosecutor refused to admit a complaint referred by Swissmedic relating to a refusal to admit a request by a prosecutor following a complaint.
- A court of first instance decided that the above-mentioned complaint involved a case of illegal manufacture and illegal trading that jeopardised human health. The head of the company continued to produce and market, without authorisation, a product that was claimed to combat serious illnesses, whereas neither the dosage nor the pharmaceutical form were realistic for the purported treatments. The court imposed a day-based financial penalty of 250 days at 30 Swiss francs suspended for two years, a fine of 2000 francs and ordered the company to pay damages of almost 220,000 francs. Since this decision is the subject of an appeal, the case will continue in 2016.
- Two complex and far-reaching cases were referred to the Cantonal courts. They will be heard in 2016.



Stakeholder management

Information

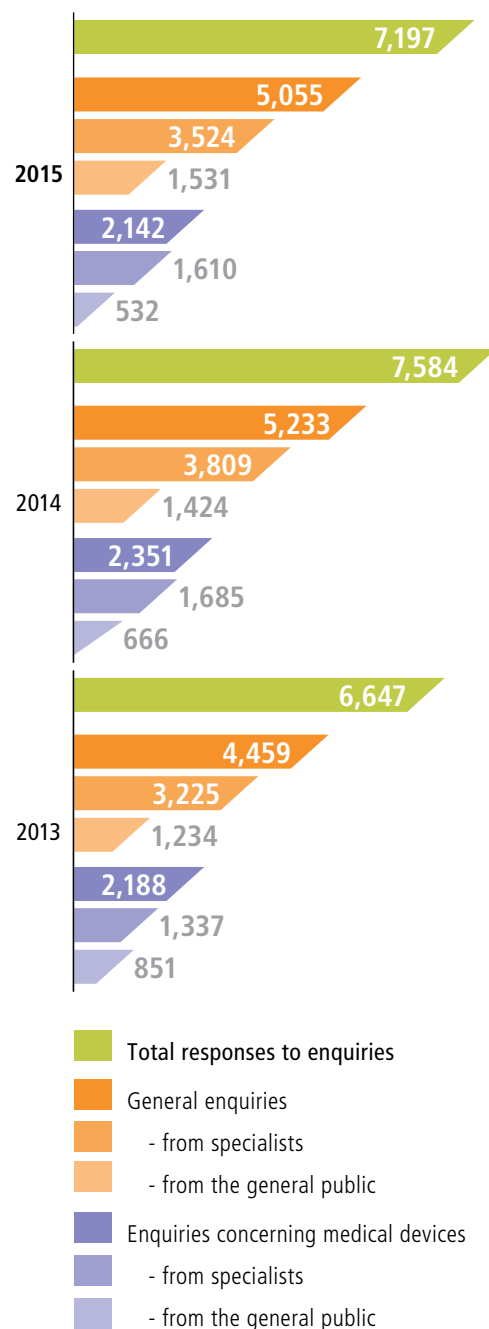
Swissmedic provides fast, targeted information on new findings concerning therapeutic products that could constitute health hazards. In addition to safety-relevant information, new authorisation decisions or major changes to medicinal product information are of considerable interest.

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

- In 2015, Swissmedic saw a slight decline in general as well as medical device enquiries.
- A large number of enquiries concerned the topic of stem cells, the submission of applications in electronic formats (edoc/eCTD), clinical trials and delimitation questions.
- A total of 97% of all enquiries were answered within ten calendar days.



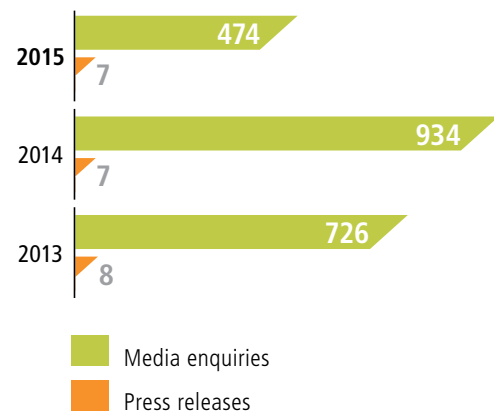
Performance indicator	Target	Result
General enquiries: percentage of responses sent within 10 days	95 %	97 %

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.

Activities

- The total of 474 media enquires received was lower than in the previous year.
- Providers of purported fresh cell therapies attracted a lot of media attention, with several camera crews even flying in from China to interview Swissmedic.
- Numerous enquiries came in on the topic of blood transfusions, more specifically regarding the current lifelong exclusion of men who have had sexual contact with men from donating blood.
- Matching the previous year's number, Swissmedic issued seven press releases in 2015. These included warnings against illegal therapeutic products and information on the banning of 21 further designer drugs.
- The media showed a great deal of interest in the scandal surrounding manipulated clinical trials by Indian company GVK Biosciences and the subsequent action taken by Swissmedic.
- Six house searches and arrests in connection with suspected therapeutic products offences in the Cantons of Zurich, Thurgau and Aargau created a stir at the end of September.
- The Federal Supreme Court decision that the Zur Rose pharmacy in Steckborn (Canton Thurgau) requires a prescription to sell OTC drugs over the Internet also prompted media enquiries.

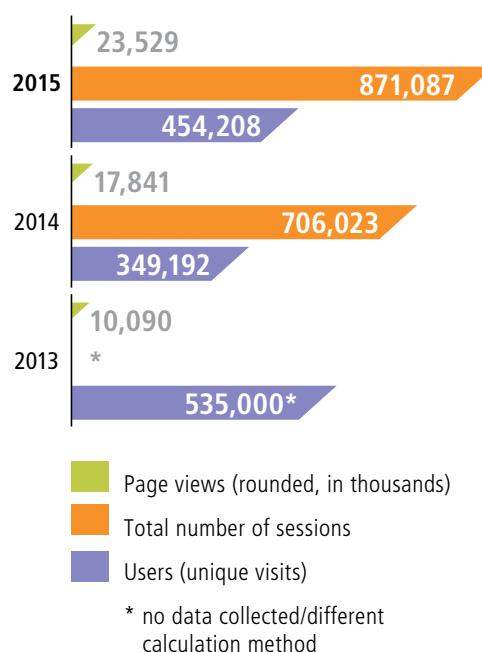


Publications

Swissmedic has a legal mandate to inform the public about specific events relating to therapeutic products. Announcements about new first authorisations of medicines, authorisation withdrawals, and amendments to regulatory requirements are published in the monthly 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

- Once again, two issues of "Vigilance News" containing topical articles on the safety of medicinal products were published on the Swissmedic website during the year.
- The Agency's haemovigilance annual report provided information on the early detection of new risks and quality defects in the use of blood and labile blood products.
- Swissmedic published 23 safety-related notices on medicinal products (mainly Direct Healthcare Professional Communications, DHPCs) on its website.
- The weekly publications on safety measures for medical devices contained 619 user information circulars.
- Nine specific safety notices were issued in connection with the use of medical devices.
- The Swissmedic website recorded a 30% -plus user increase in the year under review. In the meantime almost 16% of visitors access the website using mobile devices, compared with 10% in 2014.
- What is more, the Clinical Trials division (KLV) continually updates instructions for the submission of clinical drug trials, as well as a support document in the form of questions & answers.



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

- 12 events were held for external stakeholders in 2015. The main purpose of the Swissmedic events is to spotlight topics of current interest as well as facilitate an exchange between the Agency and stakeholders. As a forum for addressing participants' questions and concerns, the Swissmedic events are instrumental in helping the Agency reach its strategic objectives.

- **Swissmedic International Symposium, 3 and 4 September 2015**

Greater transparency in the authorisation process is something that Swissmedic's stakeholders want and care about. The Authorisation division organised workshops with representatives from the authorities to learn from their experiences with the publication of evaluation reports on authorisation applications. Patients, healthcare professionals and industry representatives were also asked about their expectations regarding public evaluation reports. The most important outcome was that the risk/benefit assessment made by the authorities when assessing an authorisation application should be made more transparent.

- **Haemovigilance Workshop, 26 and 27 October 2015**

Adverse effects may occur when using blood and labile blood products, despite all the safety measures taken. The Haemovigilance unit's annual workshops provide a platform for sharing up-to-the-minute information and findings for the purpose of identifying and reducing transfusion risks. In collaboration with hospitals in Switzerland, Swissmedic contributes to optimising haemotherapy.

- **Swissmedic anniversary event: Swiss Pharmacopoeia 150 years old**

The first Pharmacopoea Helvetica was published in 1865. Swissmedic placed articles on the history of Switzerland's national pharmacopoeia in a variety of publications and on 27 October 2015 hosted a conference to mark its 150th anniversary. At the event, Swissmedic and experts from the pharmacopoeia network gave topical talks to commemorate the book. Some 100 attendees from dispensaries, hospitals, universities and agencies participated in training sessions at the conference and seized the chance offered by the festive part of the event to exchange ideas with experts and fellow professionals.

- **Swissmedic regulatory news from the Authorisation division, 8 December 2015**

Swissmedic staged its third information event under the heading "Regulatory news from the Authorisation division". Important changes were presented, industry and Swissmedic representatives shared their experiences on various subjects, and an outline of regulatory amendments timetabled for 2016 was given. Attracting over 300 participants in 2015, the continual increase in attendance figures confirms the significance that the industry attaches to the event.

- Other events included the two-day data integrity training course for inspectors, which attracted participants from outside Switzerland, five training sessions on ELViS (the electronic portal for reporting suspected adverse drug reactions) and a working visit to share experience with and give training to hospital haemovigilance officers.

- Swissmedic organised a half-day training block on the topic of transfusion safety at the National Swisstransfusion Conference. As well as giving hospitals an opportunity to present their quality assurance systems to one another, the event offered a forum for discussing avoidable transfusion risks and the significance of hepatitis E for transfusion safety.

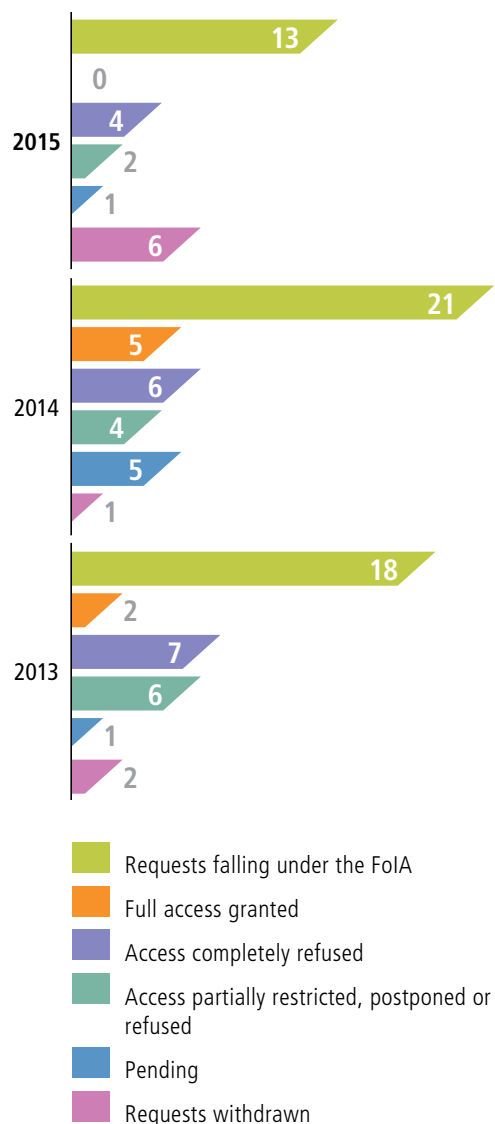
- Swissmedic chaired two events at the 2015 Annual Meeting of the German Society for Transfusion Medicine and Immunohaematology, which was held in Switzerland, and also gave a separate presentation of Swiss haemovigilance data.

Transparency

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

Activities

- Swissmedic received 13 requests falling under the FoIA, a considerably lower number than in previous years



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 2015, two appeals were lodged with the Federal Administrative Court against official decisions taken by the Agency in connection with access to official documents. Both cases are still pending.
- Of the appeals already pending before the Federal Administrative Court, one was approved.

Collaboration

Collaboration between Swissmedic and its various stakeholder groups is defined under the two principles national collaboration and international collaboration. In accordance with both its legal and its service mandate, 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 specified in its legal mandate, the service mandate and the service agreement. 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

Activities

- **Working group on patient and consumer organisations**

The platform set up in 2014 to share information with representatives of patient and consumer organisations and improve their involvement continued its work in 2015 and met quarterly. Various key regulatory topics were discussed, including requirements for the authorisation of and authorisation process for biosimilars, the legal basis and characteristics of patient information, as well as the new Human Research Act and initial experiences with its implementation. Furthermore, a representative of the Swiss Academy of Medical Sciences (SAMS) used the platform to present initial recommendations for the involvement of patients and patient organisations in Academy projects. The working group was established as a two-year pilot. At the end of 2015, 13 patient and two consumer organisations were represented.

- **Annual meeting of Cantonal Pharmacists on 13 March**

Swissmedic briefed participants on the status of the revision of the Therapeutic Products Act, on the ratification process for the Medicrime Convention and on the revision of the consultation procedure for the Therapeutic Products Advertising Ordinance (TPAO). The Agency also presented the Electronic Vigilance System ELViS, an Internet portal for reporting suspected adverse drug reactions. The market surveillance coordination group also reported on various projects, such as the revision of information sheets on medical devices for the general public and the establishment of an interdisciplinary working group on quality assurance in the transfusion chain.

- **Regulatory Affairs round table meetings with industry association representatives on 11 March and 28 September**

The Agency discussed operational focal points at both meetings, e.g. changes to the procedure with prior notification, the status of work on the electronic document management system (DMS) and eGov portal projects, as well as the system for reporting suspected adverse drug reactions. Other topics included restricting the disclosability of evaluation reports to the parties involved, as well as assessment times for additional indications.

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 2015, Swissmedic continued to play an active part in the Middle European Organisation for Regulatory Affairs (MEGRA) further training course "Start-Up Schweiz" and in ETH Zurich's master's degree course in Medicinal and Industrial Pharmaceutical Sciences (MIPS). In response to a request, Swissmedic presented the Swiss authorisation system for the first time to participants on the Master of Drug Regulatory Affairs programme of the German Society for Regulatory Affairs (DGRA).
- Within the framework of the Certificate of Advanced Studies (CAS) course on health systems and health policy at Zurich University of Applied Sciences as well as the lectures on therapeutic products legislation at the University of Basel, Swissmedic presented the Agency and specific activities and/or various specialist divisions at half-day information events in Berne.
- Swissmedic's Clinical Trials division (KLV) gave 15 presentations to various interested organisations, and held a round table meeting with the SCTO (Swiss Clinical Trial Organisation) and swissethics.
- On 28 April 2015, a Swissmedic employee gave a talk entitled "Nationwide Implementation of Pathogen-Inactivated Platelet Concentrates in Switzerland" at the AABB Symposium on Implementation of Pathogen-Reduced Blood Components in Bethesda, Maryland, USA.

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, collabora-

tion with authorities from other countries and with international institutions facilitates the identification of risks at an early stage and the initiation of coordinated measures.

International network

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

Activities

- **Reform of the International Council for Harmonisation (ICH)**

Swissmedic was actively involved in the process of reforming the ICH. The constituting meeting of the new Assembly and Management Committee took place on 23 October 2015 under the new name of International Council for Harmonisation. The organisation is now an association under Swiss law with its domicile in Geneva. The first regular meeting under the new structure took place in December. Swissmedic has a seat on all ICH bodies as a standing regulatory member with decision-making powers.
- **International Pharmaceutical Regulators Forum (IPRF) in June and December**

At the first meeting in June 2015, Swissmedic was confirmed as chair and secretariat for a further year at the wish of all members. Two and a half years after it was founded, the IPRF is already making a key contribution to the progressive harmonisation of technical requirements within the context of authorising medicinal products. In order to define the general direction of initiatives for the next five years, at the December meeting the Management Committee launched a process for the development of a long-term strategy, the results of which are expected to be ready in June 2016.
- **WHO training and visits from international agencies**

At the request of the World Health Organization (WHO), Swissmedic carried out a training workshop on the assessment of biosimilars in April. The Agency also hosted members of the WHO Prequalification team who had come for a status update on the various IT projects. Delegations from the medicines regulatory authorities of Armenia, Australia, Germany, Israel and Tanzania visited Swissmedic in 2015 to discuss different areas of therapeutic products regulation and strengthen inter-agency contact.
- **IGDRP**

In the period under review, Swissmedic actively supported the activities of the International Generic Drug Regulators Programme (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 reports on five applications as at 31 December 2015. An initial exchange of experiences between agencies participating in the pilot is planned for the next IGDRP meeting in May 2016.
- **Cooperation under the mantle of the European Directorate for the Quality of Medicines (EDQM)**

Two Swissmedic inspectors were enrolled on the EDQM international inspection programme for manufacturers of active pharmaceutical ingredients. They took part in one inspection in Japan and two in China.

Swissmedic also made a key contribution to the drafting of the first European Good Practice Guidelines for Blood Establishments (published by the EDQM in 2015) and European guidelines for conducting risk-based inspections of blood establishments.
- **World Health Organization (WHO)**

Swissmedic has chaired the WHO Blood Regulators Network (BRN) since 2013. In addition to Swissmedic, the network includes six other significant therapeutic products authorities operating in the area of blood product regulation. Over the past few years, the network has been instrumental in establishing a crucial basis for certain therapeutic approaches to combating the Ebola epidemic in Africa.
- **International cooperation on GMP inspections**

Swissmedic participates in two EU-PIC/S Working Groups on GMP. One is working on the revision of Annex 1 (sterile products) of the GMP guidelines, the other on

drafting various guides on data integrity intended for industry and inspectors. Within the PIC/S framework, Swissmedic inspectors took part in joint group inspections, the evaluation of candidate inspectorates (Kazakhstan, Turkey) and the re-evaluation of one member (Malaysia).

As it does every year, Swissmedic organised its training course for GMP and GDP inspectors, which was attended by several inspectors from partner authorities. The 2015 course was devoted to a topical issue of global relevance, namely the problem of data integrity.

Development cooperation

Under the memorandum of understanding signed in January 2014, Swissmedic's work on two projects with the Bill & Melinda Gates Foundation (BMGF), the Swiss Agency for Development and Cooperation (SDC), the World Health Organization (WHO) and the East African Community (EAC) began to take concrete shape in the year under review.

Swissmedic took part in the Steering Committee meeting of the EAC Medicines Regulatory Harmonisation (EAC-MRH) Programme held in Kigali, Rwanda, in March 2015. Technical support measures in the four focal areas Information Management Systems (IMS), Medicines Evaluation & Registration (MER), Good Manufacturing Practices (GMP) and Quality Management Systems (QMS) were formulated at the meeting.

To be able to establish the amount of support needed in the area of IMS, Swissmedic – in conjunction with the WHO – conducted an evaluation of the fledgling systems. In the area of MER, a Swissmedic expert participated in an initial joint assessment of the EAC authorities in Uganda in October. His expertise enabled him to provide crucial input for the professional evaluation of dossiers.

A second project is aimed at establishing an authorisation process and a scientific advice process for preparations for the treatment of diseases mainly affecting people in southern Africa.

The authorisation process is based on Swissmedic's decades-old practice of issuing export permits for medicinal products that are not destined for the Swiss market. These procedures are to be made accessible to representatives of African regulatory authorities (primarily from East Africa) and the WHO. The associated processes were drawn up by a Swissmedic working group in 2015. In October 2015, the two drafts were presented at a round table meeting to the relevant stakeholders, who showed a fundamental interest in the

procedures. The draft processes are now being discussed in detail with partners EAC and the WHO. Authorisation applications for the two-year pilot phase can be submitted to Swissmedic from the beginning of 2016.

These projects are being partly funded under a grant agreement between the BMGF and Swissmedic signed in December 2015. At the same time, the SDC concluded a similar agreement with the WHO allowing the latter to continue supporting Swissmedic's endeavours to strengthen the regulatory authorities and promote harmonisation primarily in the East African Community. This ensures that Swissmedic's development cooperation efforts are financed through project funding and not from the regular Swissmedic budget – as stipulated by the Federal Council in the service mandate.

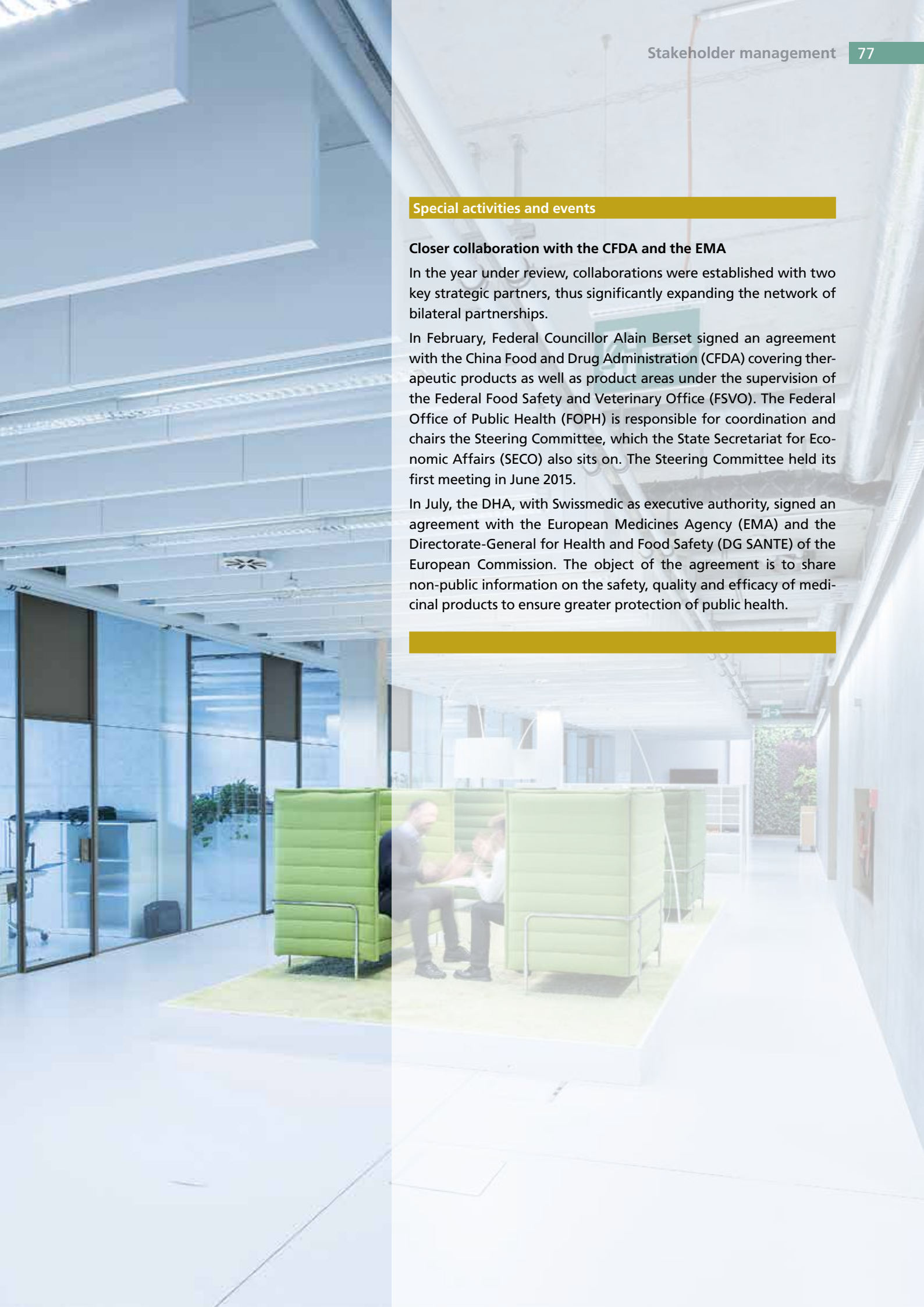
Special activities and events

Closer collaboration with the CFDA and the EMA

In the year under review, collaborations were established with two key strategic partners, thus significantly expanding the network of bilateral partnerships.

In February, Federal Councillor Alain Berset signed an agreement with the China Food and Drug Administration (CFDA) covering therapeutic products as well as product areas under the supervision of the Federal Food Safety and Veterinary Office (FSVO). The Federal Office of Public Health (FOPH) is responsible for coordination and chairs the Steering Committee, which the State Secretariat for Economic Affairs (SECO) also sits on. The Steering Committee held its first meeting in June 2015.

In July, the DHA, with Swissmedic as executive authority, signed an agreement with the European Medicines Agency (EMA) and the Directorate-General for Health and Food Safety (DG SANTE) of the European Commission. The object of the agreement is to share non-public information on the safety, quality and efficacy of medicinal products to ensure greater protection of public health.



Telematics/Information technology

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

- With the parliamentary consultation process on the revision of the Therapeutic Products Act not yet concluded, Swissmedic continued to pursue its existing IT strategy. At the end of 2015, initial analyses were made of the impact of the revised therapeutic products legislation on IT resources.
- The sourcing of SAP IT services was optimised. Technical and organisational interfaces with the Federal Office of Information Technology, Systems and Telecommunication (FOITT) as operating partner were made simpler and thus more efficient for both sides. A public call for tenders to expand the service portfolio marked a change in procurement strategy for SAP development and maintenance services.
- Methods and processes for assessing the cost effectiveness of IT projects were revised, with greater emphasis placed on systematically tapping into available potential. Project steering committees are now in a position to swiftly and consistently control a project's cost effectiveness throughout all phases.
- Projects roadmap planning was made more flexible. In the future, planned projects will be compared against one another and prioritised on four reference dates each year. The projects road map is to be adapted accordingly.

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

- Roll-out of the electronic data management system (DMS) was completed. Internal execution of the authorisation process and selected other processes is now largely paperless. A new scanning service for incoming post is in place for the digitisation of business cases submitted on paper. Approximately 1000 metres of paper files relating to therapeutic products already on the market are also being digitised.
- 2015 saw the launch of a project to expand eGovernment services further. By year end it was already in the implementation phase. The new service will enable applicants and reporters to file legally valid submissions and reports plus all the related documentation fully electronically. If requested, Swissmedic will also be able to send correspondence electronically, including electronically signed official decisions. Pilot operations are currently scheduled to begin in the 2nd half of 2016.
- Project initialisation work has already begun on several replacement and new investments planned for the next few years. These include the replacement of the website and intranet content management systems, the replacement of the vigilance reporting management system for medicinal products, and the planned new electronic data archiving platform.

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 fixed-line analogue telephone system was fully decommissioned in the year under review, and Swissmedic was integrated into the Federal Administration IT workplace systems and services. Besides digital telephones, staff now have a wide range of additional modern communication and collaboration features at their fingertips.
- All employees received new notebooks to replace the outdated IT workplace systems. Swissmedic's IT structure thus supports the growing need for mobility.
- More than 150 measures were implemented to extensively optimise the performance and functionality of the SAP ERP and CRM-based applications commissioned in 2013 and 2014 and improve process efficiency.
- The stability and performance of the recently launched document management system did not immediately achieve the desired quality. Initial corrective steps have eased the situation. Further necessary optimisation measures have been scheduled for 2016.
- The reworking of the release management processes means that the increasing system complexity and the associated availability risks can be addressed more effectively in future.
- Over 25 small projects were also run to maintain IT resources and enhance business functionalities.
- Procurement Management, which is part of the IT organisation, handled all public tenders within the stipulated deadlines and without encountering any objections.



Organisation

Swissmedic Agency Council

Current as at December 2015

Chairwoman: Beerli Christine, barrister

Conti Carlo, Dr. iur.

Dürr Markus, Dr. med. vet.

Guillod Olivier, Prof. Dr. iur.

Obrist Reto, Prof. Dr. med.

Suter Peter M., Prof. Dr. med.

Zanini Giovan Maria, pharmacist

Members of the Human Medicines Expert Committee (HMEC)

Current as at December 2015

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

Ordinary members

Bauer Matthias, PD Dr. med.

Castiglione Monica, Prof. Dr. med.

Cerny Andreas, Prof. Dr. med.

Dayer Pierre, Prof. Dr. med.

Schaffner Thomas, Prof. Dr. med.

Schild Laurent, Prof. Dr. med.

Vogt Markus, Prof. Dr. med.

Extraordinary members

Aicher Lothar, Dr. rer. nat.

von Ammon Klaus, Dr. med.

Bolli Richard, Dr. phil. II

Bonnabry Pascal, Prof. Dr. pharm.

Brutsche Martin Hugo, Prof. Dr. med.

Caldelari Reto, Dr. phil. nat.

Cavin Frédy, phil. nat.

Cerny Thomas, Prof. Dr. med.

Cotting Jacques Ernest, PD Dr. med.

Egger Matthias, Prof. Dr. med.

Erne Paul Josef Erwin, Prof. Dr. med.

FitzGerald Reginald Edward, Dr. phil. nat.

Frost Heiner, Dr. med.

Gassmann Peter, Dr. sc. nat.

Genton Blaise, Prof. Dr. med.

Giannopoulou-Politakis Catherine, PD Dr. med. dent.

Heusser Peter, Prof. Dr. med.

Hullin Roger, Prof.

Hüsler Jürg, Prof. Dr. phil. nat.

John Hubert, Prof. Dr. med.

Köföncü Evra, Dr. med.

Kraenzlin Marius Edgar, Prof. Dr. med.

Leniger Tobias, PD Dr. med.

Ludwig Christian, Prof. Dr. med.

Marbet German Albert, Prof. Dr. med.

Meier Beat, Prof. Dr. sc. nat.

Meier Christoph Rudolf, Prof. Dr. pharm.

Meier Rémy Friedrich, Prof. Dr. med.

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.

Schädelin Jürg, Dr. med.

Schär Peyer Beatrice, Dr. sc. nat.

Seger Reinhard A.; Prof Dr.med.

Sonderegger-Stalder Emanuel N., Dr. med.

Stötter Hans-Wolfgang, Dr. med.

Strik Werner, Prof. Dr. med.

Thomi Matthes Brigitte, Dipl. pharm.

Tramer Martin, Prof. Dr. med.

Wilks Martin F., Prof. Dr. med.

Wolf Ursula, Prof. Dr. med.

Wunder Dorothea, PD Dr. med.

Yerly Daniel, Dr. phil. nat.

Zangemeister Uwe, Prof. Dr. phil. nat.

Zimlich Klaus-Heinrich, Dr. rer. nat.

Advisory members

Hofmann Heinrich, Prof. Dr.-ing

Lämmle Bernhard, Prof. Dr. med.

Saller Reinhard, Prof. Dr. med.

Schmid Beat, Dr. sc. nat.

Streuli Isabelle, Dr.med.

Members of the Veterinary Medicines Expert Committee (VMEC)

Current as at December 2015

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

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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.

Wenker Christian, Dr. med. vet.

Wüthrich Andreas, Dr. med. vet.

Zinsstag Jakob, Dr. med. vet. Ph.D.

Auditors

Swiss Federal Audit Office

Our staff – our capital

Current as at December 2015

Executive Director

Schnetzer Jürg H.

Management Board

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

Our staff

Abegglen Julia, Aebischer Gilles, Aebischer Kathrin, Aeschbacher Monique, Ammann Doris, Amsler Lorenz, Antonov Janine, Appenzeller Campana Katrin, Bachmann Beat, Baeriswyl Gerda, Bailat Sylvie, Balzli Peter, Bapst Astrid, Barbu Mirela, Bärtsch Martin, Baumann Yvonne, Begert Beat, Bellac Caroline Laetitia, Bellwald Patricia, Berdoz José, Berger Christoph, Bernold Erika, 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, Bolte Claus, Borner Stefan, Boschung Andrea, Boschung Livia, Boss Doris, Boyle Charles, Brockmann Silke, Brunner Stefan, Bucheli Caroline, 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 Santuccion Antonella, Chatelain Barbara, Chételat Jean-Marie, Christen Tobias, Cina Susanne, Cokoja Adisa, Colangelo Elena, Coso Marija, Crottet Pascal François, Dähler Michaela, Dalla Torre Simon, Damke Beat, De Luigi Lucia, Decoudre Julia, Déverin Olivier, Dexheimer Petra, Diethelm Markus, Diggelmann Joy, Ditesheim Véronique, Djonova Julia, Drapela Aurélie, Drechsel-Weiss Bettina, Driess Stephanie, Dunkel-de Raad Saskia, Dürr-Kammer Eva, Eggenschwyler Doris, Egger Franziska, Ehrensperger Edmund, Ehrensperger Murri Eva, Endress Eva-Maria, Engel Marie-Helene, Erne Franz, Erny Samuel, Escandari Markus, Essen Renate, Essers Dirk, Eugster Urs, Eyal Eva, Fahrni Ursula, Faller Claudine, Federer-Oetliker Martina, Fehlmann Sabine, Felber Hanspeter, Feldmann Danila, Felser Andrea, 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, Gertsch Rolf, Gilgen Michael, Glauser Daniel, Gloor Eveline, Gosdschan Tobias, Gottofrey James, Graber Angelika, Gremminger Ilona, Grimm Friederike, Gross Bruno, Grubenmann Bruno, Grüter Eric, Guggisberg Stefan, Gugler Claudia, Gürtler Rolf, Gut Joseph, Gysin René, Häberli-Airoldi Isabelle, Haberstich Eva, Haenggeli Christine, Hägi Nicole, Hahn Spielmann Véronique, Haldemann Silvia, Hammel Mario, Häni Brigitte, Häuptli Daniel, Häuptli Thomas, Hausammann Georg, Heckenmeyer-Probst Clara, Hediger Ronald, Hellstern Oliver, Heneka Bilkis, Hernandez Perni Maria Engracia, Herren Daniel, Herrli Stefan, Herrmann Claudia, Hildebrand Pius, Hofmann Linda, Hofstetter Christiane, Horn-Lohrens Ottmar, Hottiger Thomas, Hotz Rolf, Huber Cornelia, Huber Elisabeth, Hügli Muriel, Hug-Michel Christine, Hürlimann Maria Gertrud, Jaggi Lukas, Jahn Katrin, Jaquet Françoise, Järman Stephan, Jaus Alexandra, Jenny Hans-Beat, Jentzsch Christoph, Jéquier Martine, Jermann Ronald, Johner Regula, Joos Monika, Joye Laetitia, Jungo Jacqueline, Junker Christian, Junker Denise, Juritz Stephanie, Jutzi Markus Philipp, Kapossy Katrin, Käser Sandra, Käsermann Donald, Keller Michel, Kemmler Hans, Keusen-Weyermann Katrin, Kindler Adrian, Klauss Gunnar, Kläy Barbara, Klenke Elisabeth, Klensch Odette, Kleppisch Thomas, Kneubühl Roger, Knöpfli Heinz, Kocher-Guggisberg Beatrice, Koeninger Franziska, Köhli Michael, Kopp Lukas, Krayenbühl Jean Christian, Krebs Franziska, Kreit Boris, Kühni Martin, Kummer Robert, Küng Christoph, Kunz-Greub Marianne, Künzle Werner, Kuster André, Kuster-Weber Iris, Lachat Séverine, Landgraf Cordula, Langos-Mabboux Manuela, Lany Catharina, Lapke Conwitha, Lauer Gabriele, Lavanchy Vincent, Le Stanc Pascale, Ledermann-Fahrni Barbara, Lehmann Markus, Lehmann Thomas, Leist Roman, Leu Martin, Leuenberger Alice, Leuenberger Hansjürg, Leuenberger-Bischoff Monika, Levy Guy, 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, Matthes Ingo, Meier Roger, Méroz Jean-Christophe, Meseguer Georges, Messerli Nicole, Messi Mara, Meusburger Madeleine, Meyer Rita, Meyer Simon, Meyer Ulrike Ursula, Meyer Urs, Minning Sabine Monique, Mion Alexander, Mooser Guido, Moreno Rafael,

Mosimann Lenzin Ruth, Müller Markus-Peter, Müller-Mook Renate, Munz Thomas, Mutti Sven, Nava Gabriela, Neeser Zaugg Rosmarie, Netsch Marco, Nick André, Niggli Urs, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Oberli Aurelia, Op den Camp Roel, Osswald Tschan Marco, Özsahin Hülya, Paniga Nicoletta, Pavelic Ferretti Danijela, 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, Ramelli Monica, Ramseier Isabelle, Rätz Katerina, Remund Thomas, Renaudin Michael, Renftle Wolfgang, Rethage Janine, Reusser Daniel, Richter Thomas, Rickenbacher Nadja, Rieder Barbara, Riedl Jutta, Riesen-Beer Sabine, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Rosolen Joël, Roth Daniel, Roux Catherine, Ruch Claudia, Rüfenacht Francine, Rumo Anton, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sängler Michael, Saurer Isabella, Scalise Claudia, Schaffner Nils, Schärer Christian, Schäublin Martina, Scheidegger Michelle, Scheidegger René, Schläpfer Jörg, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Egger Dorit, Schnyder Benno, Schnyder Franz-Lukas, Schnyder Renato, Schochat Thomas, Schöni Damian, Schönthal Cornelia, Schumacher Thérèse, Schütz Andrea, Schwab-Stampfli Rebekka, Schwartz Thomas, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Senessie Charles, Seyffert Bernadette, Sieg Anna, Sommer Andrea, Spohn Margot, Spörri Bernhard, Spring Andrea, Stacchetti Matthias, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stalder Barbara, Stämpfli Ursula, Stäuble Elisabeth, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Steinle Patrizia, Stoller Rudolf, Strack Guido, Straub Andrea Katharina, Studer Peter, Sulser Mario, Tanner Yvonne, Tanner Soland Eveline, Terkovics Attila Leo, Teuscher Françoise, Thiess Maria, Thomas Sabine, Thürig Soltermann Eva, Toma Valeriu, Tromp Jan, Tschalär Yolanda, Tschirren Markus, Utiger Christoph, van den Ouweland Frank, Vihertola Mari, Vilei Edy, von Mühlernen Eva, Vuilleumier Monika, Wacker Christoph, Wagner Jan, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Wälti Markus, Wälti Rudolf, Waser René, Weber Heidi, Wegenast Susanne, Wegmann Barbara, Weissmahr Richard, Weix Janine, Wenger Laure, Werder Carine, 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, Zabala Ruiz Arantzazu, Zaugg Kunz Sandra, Zbinden Raphael, Zemp Markus, Zenhäusern Gabriela, Ziak Martin, Ziehli Salvisberg Mariette, Zimmermann Esther, Zimmermann Marion, Züger Dominik, Zumbrunn Severin, Zurbuchen Andreas, Zürcher Jasmin, Zurkinden Tanja, Zwahlen Roland.

Income statement

(in KCHF)

	2015	2014
Procedural fees and income further to art. 69 TPA	40,112	38,708
Levies on sales	42,193	41,315
Other income	1,254	52
Federal contribution	13,958	13,900
Other operating income	158	171
Loss of revenues from procedural fees	-6,796	-6,614
Net income	90,880	87,531
Services for third parties	-1,468	-1,521
Personnel	-64,715	-63,679
Rental, maintenance, energy, transport and insurance	-2,407	-2,572
Administration	-5,370	-5,631
IT	-9,632	-8,898
Other expenditure	-125	-764
Amortisation	-5,885	-5,477
Total operating expenditure	-89,602	-88,541
Operating income	1,278	-1,010
Financial income	12	10
Financial expenditure	-263	-231
Financial result	-251	-221
Gain / Loss	1,027	-1,231
Statement of comprehensive income		
(in KCHF)		
	2015	2014
Gain / Loss	1,027	-1,231
Other income	2,712	-33,513
Actuarial losses (gains)		
Total comprehensive income	3,739	-34,744

Balance sheet

(in KCHF)

	as 31.12.2015	as 31.12.2014
Cash and cash equivalents	1,013	1,082
Receivables from sales and service	25,798	17,488
Other receivables	0	0
Prepaid expenses	42	22
Current assets	26,853	18,592
Fixed assets	3,170	3,681
Immovable property	74,032	75,396
Intangible assets	8,093	9,833
Capital assets	85,294	88,910
Total assets	112,147	107,502
Commitments on sales and services	5,507	5,380
Other commitments	29,208	29,049
Deferred income and short-term provisions	3,926	3,547
Short-term commitments	38,641	37,976
Firm advances	10,000	10,000
Provisions for loyalty bonuses	2,635	2,590
Provision for pension fund commitments (net)	71,020	70,824
Long-term commitments	83,655	83,414
Gain / Loss	1,027	-1,231
Reserves	10	1,241
Endowment capital	14,500	14,500
Accumulated actuarial losses	-25,686	-28,398
Own capital	-10,149	-13,888
Total liabilities	112,147	107,502

Product accounting

(in KCHF)

Products Product groups	Principal funding of products based on 2011-2015	Expenditure	Procedural fees income	Results
Legal foundations	Federal contributions	-5,294	0	-5,294
Technical standards	Fees	-3,371	0	-3,370
Total Standards products group		-8,665	0	-8,664
Information for the general public	Federal contributions	-3,346	1	-3,345
Information for the therapeutic products sector	Fees	-2,831	164	-2,667
Total Information products group		-6,177	165	-6,012
Marketing authorisation	Fees	-33,442	21,124	-12,318
Licences	Fees	-14,264	10,098	-4,166
Total Market Access products group		-47,706	31,222	-16,484
Medicinal products vigilance	Fees	-8,392	414	-7,978
Medical devices vigilance	Federal contributions	-3,012	0	-3,012
Market monitoring of medicinal products	Fees	-7,972	806	-7,166
Market monitoring of medical devices	Federal contributions	-2,836	0	-2,836
Total Market Surveillance products group		-22,212	1,220	-20,992
Penal law	Federal contributions	-2,554	181	-2,373
Total Penal Law products group		-2,554	181	-2,373
Services for third parties	Fees	-2,286	529	-1,757
Total Services for Third Parties products group		-2,286	529	-1,757
Total products		-89,600	33,317	-56,283
Levies on sales				42,193
Federal contributions				13,958
Other income				1,412
Other operating expenditure				1
Financial result				-251
Gain				1,027

Products funded mainly by the Confederation

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result-based product accounting
Legal foundations	-5,294	0	-5,294
Information for the general public	-3,346	1	-3,345
Medical devices vigilance	-3,012	0	-3,012
Market monitoring of medical devices	-2,836	0	-2,836
Penal law	-2,554	181	-2,554
Total products funded mainly by the Confederation	-17,042	182	-16,860
Total Federal contributions			13,958
Expenditure surplus			-2,902

Hallerstrasse 7

P.O. Box

CH-3000 Berne 9

P: +41 58 462 02 11

F: +41 58 462 02 12

www.swissmedic.ch
