swissmedic

Annual Report 2014

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The end of 2014 marked the conclusion of a four-year strategy period at Swissmedic. A brief review permits an insight into the foundation on which the Management Board and Agency Council (on the basis of the legal mandate and the guidelines for the service mandate) developed the new strategic objectives for 2015 to 2018.

Swissmedic has developed positively over the past few years, and the outcomes from the 2011-2014 strategy period are pleasing. The strategic objectives have been achieved to a very large extent.

The Agency is recognised both at home and abroad as a competent and efficient therapeutic products authority. It works with a very wide range of stakeholders (Like patient and consumer organisations, medical professionals, cantonal and federal authorities, the therapeutic products industry, international partners).

The distinct improvement in adherence to authorisation timelines as well as our extensive, audience-appropriate public information efforts make us quantifiable. You will find further information on this subject in the «Activities during the year» section of this report.

Our collaboration in the development and enforcement of international standards and the clear focus of the risk-based approach which we take in our core areas of operation are proof positive that Swissmedic can also hold its own on a global comparison.

Expenditure on investments and necessary staff increases is being absorbed by higher fees. Following two years of reporting a deficit (2013 and 2014), a return to profit is budgeted for 2015.

Swissmedic is and remains a learning organisation and an employer of choice. Continuous training ensures that the high level of professional competence of Swissmedic's employees is kept up to date.

To be equipped for the 2015-2018 strategy period, the Agency Council, in conjunction with the Management Board, drew up the new strategic objectives in the course of 2014.
Over the coming four years, Swissmedic aims to warrant the description **effective, transparent, reliable** and **strong**.

We will deploy our **resources even more effectively** precisely where they deliver the greatest benefit in terms of fulfilling our mandate. We aim to **vigorously promote transparency** to the full extent permitted by law. We will remain reliable and **consistently meet deadlines** – without compromising on the quality of the work we do in protecting the public. And we want Swissmedic to be perceived by the public as an **autonomous, effective and strong supervisory authority**.

The new strategic plan can be found on the Swissmedic website under *About us*/*Our strategy*.

Ms Anne-Sylvie Fontannaz, the Cantonal Pharmacist of Vaud, stepped down from the Agency Council at the end of 2014, having served on this body since 2001. I would like to thank her most sincerely for all her work and valuable professional input as well as an extremely pleasant and amicable working relationship.

Following their election by the Federal Council, Prof. Olivier Guillod from Neuchâtel and Mr Giovan Maria Zanini, Cantonal Pharmacist of Ticino, joined the Agency Council at the beginning of January 2015. I wish to extend a warm welcome to both gentlemen and look forward to working with them.

Christine Beerli
Chairwoman of the Swissmedic Agency Council

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

Swissmedic, the Swiss Agency for Therapeutic Products is a legally autonomous federal authority with health regulatory oversight in areas affecting safety and the economy.

The Agency's mandate is to ensure that the general public is only offered and administered high-quality therapeutic products that are safe and effective. One objective is to test and authorise new and innovative medicinal products quickly in the interests of patients. The benefits and risks of a new product are investigated and validated in a rigorous and intensive assessment process. Swissmedic is also responsible for supervising the therapeutic products industry, encompassing companies that manufacture, distribute or also export medicinal products and medical devices. This is to make certain that products either still satisfy the originally verified standards of effectiveness, safety and quality or that any modifications have been documented and can be retraced. Ultimately, this too is in the interests of patients, who expect to see swift action taken when defects and new risks are identified. Swift does not mean overhasty and, by extension, error-prone, it means prompt and focused, appropriate and consistent.

In the course of fulfilling its remit, Swissmedic is exposed to the highly divergent expectations of a wide variety of stakeholder groups. While calls for improvement are impartial and hardly controversial, self-serving interests are pursued in the political and media arena against a backdrop of economic considerations such as safeguarding innovation, securing rapid market access, optimising profits or cutting costs. Critics then start talking of "red-tape hurdles" and "formalism". Here we depend on the strategic safety barriers erected by policymakers, whose job it is to define areas of activity and objectives, enabling us to increasingly use private-sector, performance-based methods for operations and controlling. Statutory requirements and funding constitute the input, while the results of organised daily work activities represent the output.

If Swissmedic is to be respected as a modern agency, it must excel through performance, efficiency and effectiveness. Society's call for transparency is an opportunity for us to display our competence, commitment and integrity and to provide a rationale for our independence. Benchmarked against the policymakers' intentions, our level of effectiveness or target attainment within these areas of activity – in other words, the outcome – will be judged by the Confederation as owner. It can also exert an influence on funding for Swissmedic. The mechanics are obvious: those demanding less regulation are advocating fewer resources and facilitating economic progress; those scaling back resources are impacting the output, which has a direct bearing on the outcome, i.e. the degree of protection enjoyed by the population. A broad political debate is needed to balance out the safety, effectiveness and quality requirements to be satisfied by therapeutic products. That is precisely what the current revision of the Therapeutic Products Act is aiming to achieve. It is undeniably in the public interest to keep therapeutic product safety insulated from economic trends and any ensuing volatility.

Swissmedic's autonomy is also limited by the Confederation's corporate governance policy, presenting, for instance, the following dichotomies:

- e-Government and the world of open data versus the protection of confidential information and official secrecy;
- procurement regulations versus the ability to respond quickly to operating infrastructure needs;
- autonomy and the elimination of conflicts of interest versus immediately accessible up-to-the-minute expertise.

In compliance with these provisions, Swissmedic has introduced various efficiency-enhancing measures, focusing primarily on the definition and informatisation of business processes.

Increasing efficiency and effectiveness with an eye on the outcome compels us to deploy our limited resources where they can deliver the greatest benefit in terms of fulfilling our operative mandate and meeting our strategic objectives. Under the banner of "effective resource management", we adopted an approach that was both systematic and comprehensive. At the same time, we realised that Swissmedic needs to carve out some leeway if it is to be able to respond to changes in its sphere of operation.

Steps were initiated in 2014 aimed at placing 5% of the current headcount on reserve by the end of 2015. As well as being on call to expedite process innovation and perform new tasks, this contingency of personnel will also serve as a financial reserve since revenue trends are difficult to predict from today's vantage point. The planning process for 2015 also involved testing effective resource management capability, including an investigation into how far efficiency can be increased further through consciously focusing on the mandate, through adopting a risk-based approach or through additional process optimisation – including the use of IT support.

Effective resource management is a challenge, it demands a willingness to rethink and to make changes. Organisational development, process innovation and leadership are hallmarks of a learning organisation. At the same time, we need to remain up-to-date with the latest developments in natural science if we are to be able to take competent decisions and action. Growing sensitivity on the part of the public and politicians' demands for greater transparency turn up the spotlight on Swissmedic too. For the Swiss Agency for Therapeutic Products and its employees, this represents a huge opportunity to showcase their commitment, capabilities and impact.

Jürg H. Schnetzer
Director of Swissmedic

Activities during the year

OMCL Annual Meeting 2014

The highlight among the events on Swissmedic's calendar in 2014 was the Official Medicines Control Laboratory (OMCL) Annual Meeting, co-organised with the European Directorate for the Quality of Medicines and Healthcare (EDQM). Over 200 attendees from accredited laboratories throughout Europe gathered in Interlaken to exchange ideas, discuss new standards and harmonise new procedures. Decisions were taken on the network's future direction. Besides illegal medicinal products, other key topics under discussion were medical devices and collaboration with other laboratories in the field of cosmetics.

Closer cooperation between Swissmedic and the BfArM

In January 2014, the German Federal Institute for Drugs and Medical Devices (BfArM) and Swissmedic signed a joint declaration of intent (JDI) to work more closely together. A similar agreement has been in place with the Paul-Ehrlich-Institut (PEI) in Germany since 2013. As co-signatory to the JDI with the BfArM, Swissmedic now has frameworks of cooperation established with both of Germany's federal bodies responsible for the regulation of therapeutic products. The objective is not only to share information, but also to promote an understanding of each other's regulatory structures, requirements and processes, as well as to launch specific collaborative actions.

Trials with experimental Ebola vaccines in Western Switzerland

Vaccinations offer hope in the fight against the Ebola epidemic. Promising vaccine candidates have already been administered to more than one hundred volunteers in Switzerland. In October, two applications to conduct clinical trials with different Ebola vaccines were filed with Swissmedic for review. As required by law in the case of submissions for genetically modified organisms, Swissmedic also consulted the Federal Office of Public Health (FOPH), the Federal Office for the Environment (FOEN) and the Swiss Expert Committee for Biosafety (SECB) before reaching a decision on the two vaccines. The applications were fast-tracked and approved within one month.

Trials at Lausanne University Hospital (CHUV) were given the go-ahead for the end of October, and at the beginning of November the Geneva University Hospitals (HUG) were granted permission to use the novel vaccine. These studies, as well as the licences issued by Swissmedic, attracted global attention. Numerous media reported on the start of the trials and requested details.

The tests, which are receiving substantial support from the World Health Organization (WHO), provide the basis for the optimal planning and safe conduct of subsequent trials with several thousand subjects in African countries affected by the outbreak.

Increased customer satisfaction

Swissmedic runs customer surveys to obtain information on how the Agency and the work it does are perceived and rated by the various stakeholders. The survey carried out at the end of 2014 is based on the same questionnaire as was used in 2012. Above all, this allowed Swissmedic to pinpoint changes in assessments between 2012 and 2014. The follow-on evaluation offers Swissmedic an opportunity to identify and tap into areas with potential for improvement.

Compared against the 2012 survey, shareholders' overall satisfaction with Swissmedic has risen by three points from 66 to 69 out of a possible 100 points.

After a detailed analysis of the findings, Swissmedic will define and instigate appropriate measures.

Initial experience with the new procedure with prior notification

Following the entry into force of the revised Therapeutic Products Fees Ordinance, applications for medicinal products containing a new active pharmaceutical ingredient or for an additional indication can, under certain conditions, be processed 20% faster subject to payment of double the fee. In consultation with the pharmaceutical industry, Swissmedic has defined the details of the procedure with prior notification and set them out in an information sheet.

Since 1 January 2013, Swissmedic has received a total of 15 enquiries regarding the performance of such a procedure. Eight applications in all were then actually submitted. As at end 2014, two of the ensuing procedures had been concluded on schedule with the issue of a decision. The experience gained during the pilot phase for the new procedure will be evaluated in conjunction with the pharmaceutical industry in 2015.

Further step towards digitalisation

Swissmedic is systematically implementing its plans in the direction of digital data processing and eGovernment. A number of major milestones were achieved in the authorisation process in 2014:

- The proportion of applications filed in electronic format (eCTD) is rising continually, reaching around 90% in the case of submissions for medicinal products containing new active substances (NAS).
- The new eDok format introduced in 2014 met with a high level of acceptance in its first year, accounting for approximately 20% of applications submitted.
- Since May 2014, paper applications have been automatically scanned in and delivered electronically to reviewers.
- Authorisation holders can call up information on milestone planning and application statuses directly online in the newly launched eGovernment portal. Information for healthcare professionals and patient information can now also be securely shared via portal. As at end 2014, more than 140 companies are using these portal functions.
- Swissmedic securely disposes of paper documents that are no longer required. Since the changeover to digitalisation, the volume of paper disposed of has fallen from 145 tonnes (2012) to 45 tonnes (2014) p.a. Existing and future measures will bring this figure down even further in the coming years.

Revision of the Therapeutic Products Licensing Requirements Ordinance (TPLRO)

Enforcement of the additional TPLRO requirements in respect of the information and texts on containers and packaging material will help to make medicines safer by further reducing the risk of mix-ups. Adjustments are being implemented in two stages according to risk-based criteria. The necessary applications for variations for injectables had to be submitted by the end of 2013 and were all processed during the year under review. The cut-off for applications for variations for all other medicinal products was end 2014.

Swissmedic authorisation times for human medicinal products in an international comparison

In a joint study with the industry associations scienceindustries, VIPS, Interpharma and Intergenerika, Swissmedic analysed the authorisation periods for key authorisation procedures (innovative and non-innovative first authorisations as well as major variations) for 2013. The aim of the study is to make Swissmedic processes even more transparent and also to compare assessment times and admission periods with the figures for the European (EMA) and US regulatory authorities (FDA). The analysis revealed that standard and fast-tracked first authorisation procedures for medicinal products containing new active substances in Switzerland are completed faster in terms of overall time compared with the EMA, but slower than the FDA; the EMA and FDA are faster when it comes to the other standard procedures. A detailed summary of the results can be found on the Swissmedic website at www.swissmedic.ch/pilotstudie2013.

Collaboration on this study was rated as efficient and good by all the parties involved and will continue in 2015 for the purposes of evaluating the data for the 2014 financial year.

Swissmedic hosts 34th meeting of the European Competent Authorities for Medical Devices

The meeting of the representatives of the Competent Authorities for Medical Devices (CAMD) was held in Zurich at the end of May 2014. At the request of the Greek authorities, Swissmedic hosted the meeting under Greece's Council Presidency. The CAMD is a central discussion platform for the competent authorities and the EU Commission designed to promote continuing improvements in the safety of medical devices in Europe. Attracting close on 70 participants, the well-attended CAMD meeting provided an opportunity to confer on further developments regarding the regulation of medical devices and future strategic issues.

Replacing the former Central Management Committee (CMC), a new seven-member Executive Group was also elected to oversee future collaboration among the authorities of the member states and the EU Commission.

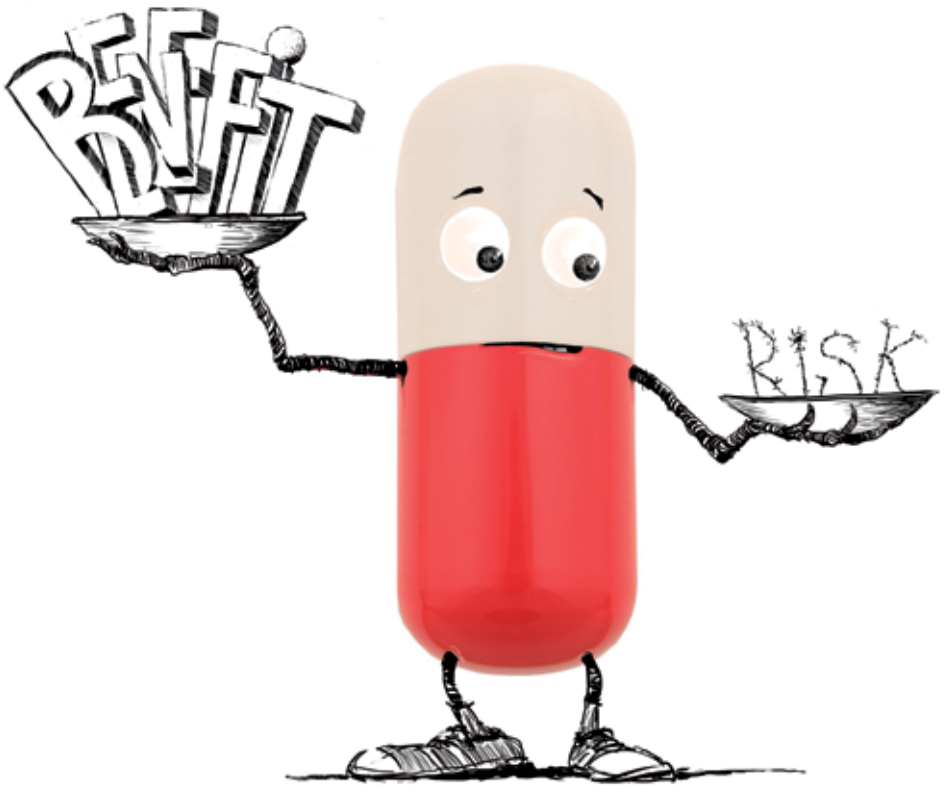
Every medicinal product comes with risks

No medicinal product is without risks and side effects. What may be common knowledge for specialists is often next to impossible to communicate in the day-to-day operations of a therapeutic products agency.

"Cancer prevention treatment suspected of causing severe side effects in girls". The editorial team of the Swiss TV documentary programme Rundschau chose a hard-hitting headline for their report. It featured two young women who contracted multiple sclerosis (MS) after being administered a vaccination against the pathogen that causes cervical cancer. The two are in no doubt that their illness is a result of the vaccination. For them and the reporting journalist this clearly means the vaccination is bad.

In her report, the journalist failed to mention that several epidemiological studies had established no connection between the vaccination and the contraction of MS. The TV report triggered an emotional debate on the Internet. Around half of the comments made are in favour of the vaccination, and the other half against. The majority of the vaccination's critics are clear in their minds that if a medicine produces severe side effects, it must not be authorised.

But the reality is quite different for any regulatory agency. Its most important tool is a risk-benefit analysis. If the expected benefit of a medicinal product outweighs the risks, authorisation is justified, albeit under one crucial condition: If the risk-benefit ratio proves unfavourable subsequent to authorisation, the medicinal product must be withdrawn from the market. It sounds simple, but is in fact highly complicated. Why?



Approximately 90 women die of cervical cancer in Switzerland each year. Saving some of these lives is the goal behind the vaccination. The vaccination protects against infection with carcinogenic viruses and reduces precursors. Only the future can tell how significant the decrease in the number of cancer cases will be. Years or even more than a decade can pass between the time of infection with the virus and the onset of the disease.

The side effects of a medicinal product can be catastrophic for sufferers. Rare and unexpected risks sometimes only become evident when the product is on the market. The main reason for this is that when a new medicinal product is authorised, it has usually only been tested in clinical trials on a limited number of persons.

The most recent example of this is the fourth generation of contraceptive pills. Only after they had been taken by thousands of women did it become evident that they presented a risk of embolism which, while very low, was twice as high as with the second-generation precursor products. However, compared to the risks and possible complications of an unwanted pregnancy and given that precautionary measures are specified in the product information and doctors should prescribe a suitable contraceptive pill for the patient in question, the risk-benefit profile is still positive.

It is no easy matter explaining this to the wider public and virtually impossible in the case of a patient who has suffered serious side effects. Anyone arguing in public that the benefits of a medicine balance out any severe side effects is immediately branded an insufferable cynic.

Be that as it may, anyone demanding risk-free medicinal products is asking for the impossible. It is a truism for any medical professional that there can be no effect without the risk of side effects. This is why it is essential to read the information provided with every medicinal product and to monitor any side effects as closely and systematically as possible. Known as pharmacovigilance, this is one of Swissmedic's core tasks.

It also means not covering up any uncomfortable findings. Adverse reactions to medicinal products are one of the most common causes of death in Europe. According to the EU Commission, some 200,000 people die each year in the European Union as a result of the side effects of medicines, making this the fifth most frequent cause of death in Europe.

For many critics, this is reason enough to write off the entire pharmaceutical industry. For Swissmedic, it is motivation to make authorisation and market surveillance even better and even more efficient and to prevent side effects as far as possible. Currently, around 8,000 medicinal products are authorised in Switzerland. Each one of them can produce side effects. But everybody who uses medicinal products can play a part by ensuring that any such side effects are reported. This is also in the best interests of the manufacturers as it is the only way to make medicinal products safer. But the bottom line is and remains that effective medicinal products will never be risk-free.

Swissmedic helps to strengthen African regulatory authorities

Effective, safe, high-quality medicinal products for southern Africa: Swissmedic is with the Bill & Melinda Gates Foundation to make this a reality. The objective is to transfer Swiss expertise in order to strengthen the African regulatory authorities.

Eight-year-old Asmaa's face is disfigured by an ugly growth. The little Tanzanian girl has leishmaniasis, also known as black fever. It is an infectious disease caused by parasites. Some two million people contract the infection every year, and for some of them it has a fatal outcome. The girl urgently needs medicines, but they are very difficult to obtain in her home country of Tanzania. There are many reasons for the poor availability of medicinal products in southern Africa. One of them is the delays that are caused by the often long, uncoordinated authorisation procedures in the individual countries. African states realised that faster market access for medicinal products is one of the key factors in ensuring the adequate provision of healthcare for the population, so the issue was taken up at cross-national level by the African Medicines Regulatory Harmonisation (AMRH) programme. One of the aims of this programme is to improve Africa's healthcare systems through a variety of activities in collaboration with the World Health Organization and other partners.

Participants at the Joint Planning Meeting between the East African Community, the Swiss Agency for Development and Cooperation and Swissmedic held in Kigali, Ruanda.

Swissmedic has also recently started to help expedite the provision of medicinal products in the countries of southern Africa. The foundation of this partnership was laid in January 2014 with the signing of a memorandum of understanding (MoU). This agreement, which is not legally binding, establishes a partnership between the Bill & Melinda Gates Foundation, the Federal Department of Home Affairs (DHA) and the Federal Department of Foreign Affairs (DFA). It will coordinate and consolidate resources with the aim of strengthening the regulatory systems in these countries and providing patients with high-quality, life-saving medicines as rapidly as possible. The Swiss Agency for Therapeutic Products and the Swiss Agency for Development and Cooperation (SDC) are taking the joint lead in implementing the measures. The intention is for the project to be funded not by Swissmedic but from special project budgets provided by the SDC and the Bill & Melinda Gates Foundation.

A specially formed working group has been developing specific project proposals since the memorandum of understanding was signed. These proposals, outlined during the past year, focus on various points in the authorisation process.

A project outline has been derived from an existing initiative of the AMRH programmes. It envisages support for the East African Community (EAC) in its efforts to harmonise the requirements for the authorisation of medicinal products in the five member states Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania. Experts from Swissmedic could provide assistance during the development and implementation of the harmonised guidelines and contribute their expertise should questions and problems arise. Furthermore, Swissmedic could provide targeted training coordinated by the WHO. This would help to build capacity within the East African authorities and establish a common level of knowledge.
Another project aims to make the Swissmedic authorisation procedure and the procedure for granting scientific advice meetings accessible to representatives of the African regulatory authorities and the WHO. This is intended to apply particularly to medicinal products designated not for Switzerland but for the African market. Insight into Swissmedic's scientific activities should generate confidence, which in turn could lead to faster market access and a transfer of expertise.

The project outlines are currently being discussed with the local partner authorities, the Bill & Melinda Gates Foundation and the World Health Organization. The aim is to pick up on existing initiatives and to generate added value through Swissmedic's involvement in areas where the African authorities have identified deficits.

These projects are still in the planning phase, but they are gradually taking shape. In the longer term, Swissmedic's involvement in Africa could help children suffering from black fever, like Asmaa in Tanzania, to gain rapid access to the medicines they need.

ElViS lives!

No, not the iconic singer with the famous quiff. ElViS is the abbreviation for Electronic Vigilance System, one of several online tools designed to deliver greater efficiency and less paperwork to Swissmedic and its partners.

A lorry drives up to the delivery ramp at Swissmedic. A muscular man unloads more than one hundred kilos of paper files from the Swissmedic archive in Zollikofen. The reason for this enormous effort is the need to review the marketing authorisation of a medicinal product. Scenes like this should soon be a thing of the past.

In future, it will be possible to submit all registration documents online. The tool behind this development is called Swissmedic Portal. It permits secure electronic data exchange between Swissmedic and the marketing authorisation holders. Now only electronic files are sent back and forth instead of mountains of paper, and applicants can check the progress of their application at any time. The name of the tool that increases transparency for everyone concerned is application tracking. But this is only the beginning. There are plans to expand online services gradually over the coming years.

Market monitoring is another area in which the paperwork can reach alarming proportions. The Therapeutic Products Act requires companies and healthcare professionals to report adverse effects associated with medicines. Yet any doctor who wants to submit a report of this kind must first get hold of a form, complete it and send it off. This always used to work well, and indeed it still does, but it is hardly compatible with our digital, networked world. It was high time for a modern online solution. This has been available on the Swissmedic Portal since last October as ElViS, or Electronic Vigilance System to give it its full name.

For a few months now, healthcare professionals and pharmaceutical companies have been able to report suspected adverse drug reactions (ADR) directly on the Internet without any need for paper, a printer or even a stamp. “Our aim is the right report at the right time in the right quality,” says Senior Expert Rudolf Stoller from the Safety of Medicines group at Swissmedic. He hopes that ElViS will help the people who are required to submit reports to gain a better understanding of the work done by Swissmedic, thus leading to better-quality reports.

Paper-and-ink reports can still be submitted for the time being. Nevertheless, Swissmedic and the six regional pharmacovigilance centres expect paper reports to peter out eventually.

ElViS can also be used to submit case-related documents, such as laboratory reports or X-ray images. Once their report has been successfully sent, users can save the report and acknowledgement of receipt on their computer’s hard drive for their own records. Data protection and security satisfy the most stringent requirements. Swissmedic hopes that this new, user-friendly option for reporting adverse drug reactions will make a further contribution to improving the safety of medicinal products. Those responsible also hope that it will enhance awareness of the obligation to report ADR.

In expanding its online services, Swissmedic is facilitating communication with its partners. As Friedemann Schulz von Thun, a communication expert, recently wrote: “Communicating well is a source of happiness.”

Outlook

Market monitoring of medical devices intensified at European level

Following the scandal surrounding harmful breast implants manufactured by the French company Poly Implant Prothèses (PIP), in 2012 the EU Commission ordered intensified monitoring activities for medical devices. The resulting PIP Action Plan is based on the existing and newly implemented Regulations and provides for specific measures.

The Notified Bodies play a central role in market access and monitoring of medical devices. In 2014, therefore, the competent authorities, Swissmedic among them, focused on intensified monitoring of the Notified Bodies on the basis of the new Commission Implementing Regulation (IR (EU) No. 920/2013). In addition, a European pilot project for joint market-monitoring actions was initiated and is scheduled for implementation in 2015. For the time being, Switzerland is an observer in this project.

Changes in vigilance for medicinal products

The pharmacovigilance network came into being in its present form on 1 January 2002, the date on which the Therapeutic Products Act (TPA) entered into force, making it mandatory to report adverse drug reactions (ADR). This replaced the previous structure, which had consisted of voluntary reporting to the National Drug Pharmacovigilance Centre (SANZ), the regional pharmacovigilance centres and to companies.

Since then, the six regional pharmacovigilance centres, which are attached to the Institutes of Clinical Pharmacology, have received and processed ADR reports from healthcare professionals and patients on behalf of Swissmedic as part of a contractually regulated service.

Processing comprises input into the national ADR database operated by Swissmedic, an initial professional evaluation and feedback to the reporter. The current provisions of procurement legislation, changed needs in terms of market monitoring at Swissmedic (greater emphasis on a high rate of signal identification) and the introduction of a new, electronic reporting system for ADR (ElViS) have resulted in existing contracts being terminated with effect from the end of 2015. The new framework necessitates a new contractual arrangement between Swissmedic and external regional vigilance centres. A call for tenders for this service will be published in the first six months of the year in line with the requirements of the public procurement legislation. This reassignment is likely to lead to major changes in the pharmacovigilance system in Switzerland.

Information exchange with the authorities in the ACSS Consortium

Since 2011, representatives of the authorities in the ACSS Consortium (Australia, Canada, Singapore and Switzerland) have been meeting at regular intervals to harmonise the regulatory requirements for the authorisation of medicinal products containing known pharmaceutical active ingredients. With the consent of the marketing authorisation holders, evaluation reports on applications for authorisation of medicinal products with known active pharmaceutical ingredients are now being exchanged more frequently with the authorities in the ACSS Consortium, and this collaboration is being extended to medicinal products with new active pharmaceutical ingredients. The main purpose of this is to establish mutual confidence in the assessment activities and thus to create conditions in which the partner authorities can make use of each others' evaluations. In the long term this will increase efficiency and make optimal use of the available expertise. The overall aim is to improve access to high-quality, safe and effective medicinal products.

Facts and figures

Business statistics as at end 2014

Firms with a Swissmedic licence

The licences below were attributed to a total of 1,092 firms.	
Manufacturing of medicinal products:	
Manufacturing of medicinal products (with a licence for wholesale distribution)	241
Manufacturing of medicinal products (without a licence for wholesale distribution)	99
Wholesale distribution of medicinal products:	
Import of medicinal products	552
Wholesale trade of medicinal products	826
Export of medicinal products	442
Foreign trade with medicinal products	366
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	38
Blood transfusion services or hospitals with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	32
Controlled substances	
Establishment licences for handling controlled substances	355
Laboratories with FOPH recognition	
Microbiological and serological laboratories inspected by Swissmedic	98

Number of authorisations by type of product as at end 2014

Human medicinal products (original, generic, co-marketing medicinal products)	5,012
Phytopharmaceuticals	667
Homeopathics	652
Anthroposophics	426
Ayurvedic medicinal products	1
Tibetan medicinal products	6
Bacterial and yeast products	28
Vaccines	73
Blood products	92
Radiopharmaceuticals	35
Biotechnologicals	298
Veterinary medicines	714
Allergens	367
Transplant products	1
Generators	4

Number of authorisations by dispensing category as at end 2014

Dispensing category/Authorised medicinal products	
A Dispensed once only on medical or veterinary prescription	1,696
B Dispensed on medical or veterinary prescription	3,844
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	44
C Dispensed after expert advice from medical personnel	609
C/D Dispensed after expert advice from medical personnel/Dispensed after expert advice	23
D Dispensed after expert advice	1,956
E Dispensed without expert advice	171
Total	**8,376**

Homeopathic and anthroposophic medicinal products without indication authorised by the notification procedure as at end 2014

Single products	11,533
Combined products	1,093

Swissmedic as an agency

Staff headcount at year end	428
Full-time positions at year end	356,1
Total women	55,8%
Total men	44,2%
Staff working part time (part time is defined as working up to 89% of a full-time post)	45,1%
Average age of staff	46,6 years
Women	44,8 years
Men	48,3 years
Language distribution:	
German	85,6%
French	12,2%
Italian	2,2%
Rhaeto-Romanic	0%
Fluctuation rate	4,4%

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.

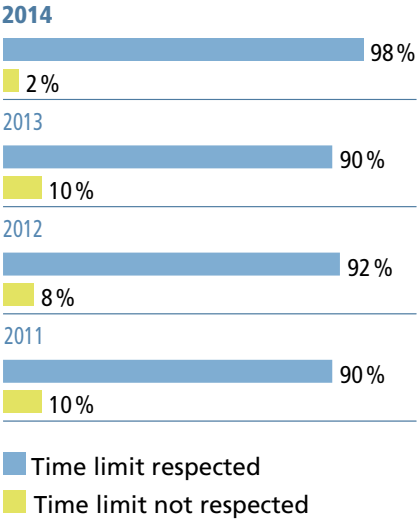
Activities

- A total of 14,673 applications was submitted in 2014, while 14,305 applications were finalised. The results for the last 6 months show that 98% of all applications were finalised on schedule. Time lines for applications for new innovative drugs were respected in an average of 90% of cases; the equivalent figure for new non-innovative products was 92%. The corresponding percentages for the various kinds of variations were close to 100% (see table on page 30).
- There were 26 scientific advice meetings, 20 pre-submission meetings and 19 clarification meetings in 2014. Roughly 75% of the questions were answered in writing, while face-to-face meetings took place in 25% of cases.
- In the course of cooperation with the Clinical Trials department (Licensing division), the Preclinical Review department undertook 14 assessments for the notification of clinical trials, while the Quality Review department undertook 35.

Time limits

For 2014, 98% of all applications were completed within the prescribed time limits. For innovative medicinal products, the time limits were respected in 90% of cases, and for non-innovative medicinal products, the figure reached 92%.

Percentages of time limits respected for **all** completed applications for human and veterinary medicines for the strategy period 2011-2014



Human medicinal products*

First authorisations

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

Activities

- In 2014, Swissmedic processed 253 applications for first authorisations of innovative medicinal products and major variations thereto, and 261 applications were completed.
- Of the 37 medicinal products with new active pharmaceutical ingredients that were authorised for the first time, seven were completed by means of the fast-track procedure.
- A total of 330 applications for non-innovative first authorisations were completed: 56 of them concerned co-marketing products.
- One request for the parallel importation of a medicinal product was submitted in 2014.
- 103 applications for processing under Article 13 of the Therapeutic Products Act (TPA) were completed. 83 of these were processed under Article 13 TPA, 77 of which were approved.

Human medicinal products with a new active pharmaceutical ingredient authorised in 2014

ATC	Active pharmaceutical ingredients	Product name	Application
Alimentary tract and metabolism	Dexlansoprazolum	Dexilant®, capsules with modified release of the active ingredient	Erosive oesophagitis
	Fidaxomicinum	Dificlir™, film-coated tablets	Clostridium difficile-associated diarrhoea CDAD
	Albiglutidum	Eperzan®, powder and solvent for solution for injection in pre-filled pen	Diabetes mellitus type 2
	Dapagliflozinum	Forxiga®, film-coated tablets	Diabetes mellitus type 2
	Canagliflozinum	Invokana™, film-coated tablets	Diabetes mellitus type 2
	Empagliflozinum	Jardiance®, film-coated tablets	Diabetes mellitus type 2
Anti-infectives for systemic use	Dasabuvirum	Exviera®, film-coated tablets	Chronic hepatitis C genotype 1
	Haemagglutininum influenzae A/H1N1 and A/H3N2, Haemagglutininum influenzae B/Victoria and B/Yamagata	Fluarix® Tetra, suspension for injection	Active immunisation against influenza
	Sofosbuvirum	Sovaldi®, film-coated tablets	Chronic hepatitis C
	Dolutegravirum	Tivicay®, film-coated tablets	HIV infections
	Ombitasvirum, Paritaprevirum	Viekirax®, film-coated tablets	Chronic hepatitis C genotype 1

* The performance indicators regarding marketing authorisations are shown on page 30.

	Sofosbuvirum, Ledipasvirum	Harvoni™, film-coated tablets	Chronische Hepatitis C Genotyp 1
Antineoplastic and immunomodulating agents	Obinutuzumabum	Gazyvaro®, concentrate for solution for infusion	Chronic lymphatic leukaemia
	Afatinibum	Giotrif®, film-coated tablets	Non-small-cell lung cancer (NSCLC)
	Ponatinibum	Iclusig®, film-coated tablets	Chronic myeloid leukaemia
	Ibrutinibum	Imbruvica®, capsules	Mantle cell lymphoma
	Pomalidomidum	Imnovid®, hard capsules	Multiple myeloma
	Plerixaforum	Mozobil®, solution for injection	Mobilisation of haematopoietic stem cells
	Dabrafenibum	Tafinlar®, hard capsules	Advanced melanoma
	Arsenic trioxide	Trisenox®, concentrate for solution for infusion	Acute promyelocytic leukaemia (APL)
	Siltuximabum	Sylvant®, powder for concentrate for solution for infusion	Castleman's disease
Blood and blood-forming organs	Turoctocogum alfa	NovoEight®, preparation for injection	Haemophilia A
	Nonacogum gamma	Rixubis, powder and solvent for injection	Haemophilia B
	Argatrobanum monohydricum	Argatra®, concentrate for solution for infusion	Anticoagulation in adult patients with HIT-II
Cardiovascular system	Macitentanum	Opsumit, film-coated tablets	Pulmonary arterial hypertension
Musculoskeletal system	Human articular chondrocytes	Novocart 3D®, transplant product	Reconstruction of articular cartilage defects in the knee by matrix-associated autologous chondrocyte transplantation (ACT)
Nervous system	Lisdexamphetamini dimesylas	Elvanse®, capsules	Attention deficit hyperactivity disorder (ADHD)
	Nalmefenum	Selincro®, film-coated tablets	Reduction of alcohol consumption in adult alcohol-dependent patients with a high-risk drinking habit.
	Dimethylis fumaras	Tecfidera®, gastrore-sistant capsules	Relapsing remitting multiple sclerosis
Respiratory tract	Umeclidinium, Vilanterolum	Anoro® Ellipta®, single-dose powder for inhalation	COPD
	Ivacaftorum	Kalydeco, film-coated tablets	Cystic fibrosis
	Vilanterolum	Relvar® Ellipta®, single-dose powder for inhalation	Asthma, COPD
	Olodaterolum	Striverdi® Respimat®, solution for inhalation	COPD
Sensory organs	Ocriplasminum	Jetrea®, concentrate for solution for injection	Vitreomacular traction, including when associated with a macular hole
Genitourinary system and sex hormones	Mirabegronum	Betmiga™, prolonged-release tablets	Symptomatic treatment of overactive bladder (OAB) syndrome.
Miscellaneous	Florbetapirum(18-F)	Amyvid®, solution for injection	Radiodiagnostic agent for the PET imaging of βamyloid neuritic plaque density in the brain
	Radium-223 dichloridum	Xofigo, solution for injection	Symptomatic bone metastases in castration-resist-ant prostate cancer

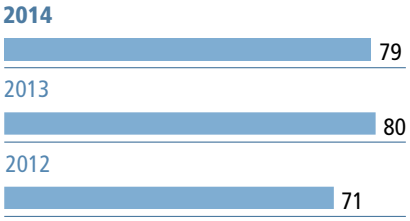
Human Medicines Expert Committee (HMEC)

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 eleven times during 2014 and issued 79 recommendations regarding marketing authorisation applications. The majority of them concerned new authorisations or additional indications for medicinal products.
- In addition, 30 expert reports for the purpose of full assessments and 52 reports on individual aspects were provided by the HMEC experts.
- An eighth ordinary HMEC member specialising in neurology joined the panel.
- An additional expert role was introduced for members of the Swissmedic Medicines Expert Committees (HMEC and VMEC). Ordinary and extraordinary members have now been supplemented by advisory members, who are subject to less stringent vested interest requirements. However, these advisory members may be employed functionally only for written expert reports on individual aspects and are subject to the same recusal rules as ordinary and extraordinary SMEC members.

Marketing authorisation applications
Number of HMEC recommendations



Extensions and discontinuations

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

Activities

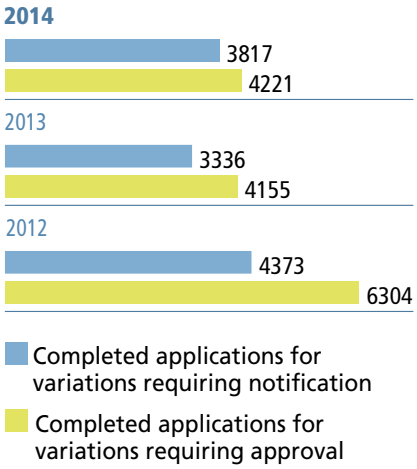
- In 2014, a total of 1,442 applications to extend the marketing authorisation were submitted, and 1,409 applications were completed.
- 270 applications for the discontinuation of a product and 19 applications for the discontinuation of a dosage strength of a product were received in 2014. 356 applications for the discontinuation of a product and 23 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 4,227 variations requiring notification were submitted in the year under review; 4,221 notifications were completed.
- Regarding modifications requiring approval, 3,692 applications were submitted and 3,817 were completed.

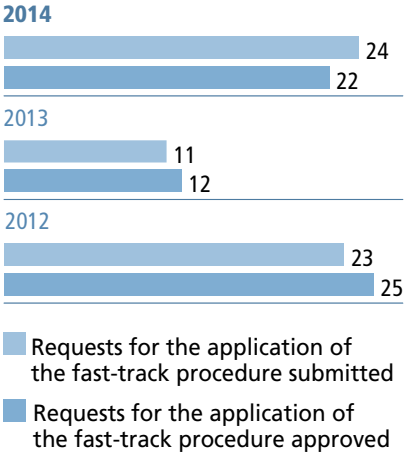


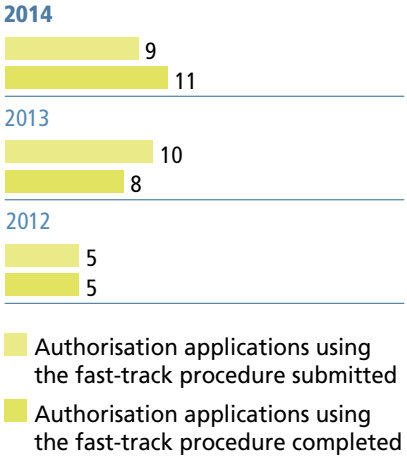
The fast-track authorisation procedure

Applicants may request that the fast-track procedure is applied for human medicinal products or major variations to them, 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 the application may be submitted accordingly. For Swissmedic, the time limit for processing the authorisation application is reduced from 330 days to 140 days.

Activities

- In 2014, a total of 24 requests for the fast-track procedure to be applied were submitted, and 22 fast-track requests were approved.
- A total of nine authorisation applications using the fast-track procedure were submitted, and eleven were completed.





The Procedure with Prior Notification (PPN)

Since 1 January 2013, Swissmedic has provided applicants with the possibility of having the assessment carried out 20% more rapidly, provided that they give prior notification of the submission date of their application (5 – 8 months in advance). For this to be accepted by Swissmedic, the following conditions must all be fulfilled:

– The authorisation application must concern a human medicinal product with a new active pharmaceutical ingredient (new API) or an additional indication for a human medicinal product.
– The clinical and preclinical studies must 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.

For Swissmedic, the processing period for the authorisation application is reduced by 20%, i.e. from 330 days to 264 days. For applicants, the fee is subject to a 100% surcharge.

Activities

- Of the five requests for the PPN to be applied, three were approved. No request was withdrawn, and two are currently being processed.
- In 2014, five authorisation applications using the PPN were submitted. Two have been completed, and three further submissions are already planned.

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 distinction is made between the recognition of orphan drug status and the – usually subsequent – authorisation of a medicinal product as an orphan drug. The authorisation procedure for orphan drugs is exempt from processing fees.

Activities

- A total of 20 applications were submitted in 2014 for the recognition of the orphan drug status, and the status was granted for 20 products.
- Five products were newly authorised as orphan drugs. Further orphan indications were approved for six previously authorised orphan drugs. Orphan drug status was not withdrawn for any product, while the status was discontinued for two others.

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 by children in accordance with these plans. The Swissmedic Paediatrics Working Group is responsible for the consistent handling of this specific group of medicinal products. The Ordinance on Fees, valid as of 1 January 2013, foresees a reduction of 90% in fees for the authorisation of medicinal products with exclusively paediatric indications and for corresponding major variations. This measure is intended to encourage developments in the area of paediatric medicines.

Activities

- Although mandatory in the EU, the submission of a paediatric investigation plan remains voluntary in Switzerland. A PIP was however submitted to Swissmedic 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. Notifications for a total of 21 paediatric trials were received in 2014.
- Inspections within the framework of paediatric clinical trials were considered important. Annual planning will continue to take account of inspections to assess compliance with Good Clinical Practice (GCP).

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

- Currently, three processes for pathogen inactivation in labile blood products have been authorised in Switzerland by Swissmedic. One of these processes is used in all blood transfusion services across Switzerland, while a second is used in just one blood transfusion service. The third authorised process is not currently employed in Switzerland.
- Several requests for authorisation conditions, variations or extensions relating to these process authorisations 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 in a risk-based approach.

Activities

- One transplant product was authorised by Swissmedic in 2014. Since the authorisation holders of the two transplant products authorised in 2012 and 2013 have meanwhile waived these authorisations, only one authorised transplant product is currently available in Switzerland.
- The sharp rise in requests for company meetings with Swissmedic indicates a growing interest on the part of the pharmaceutical industry in the further development of transplant products and gene therapy. In 2014, Swissmedic held 17 company meetings (scientific advice, pre-submission 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

- In 2013, Swissmedic completed eight applications for the first authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication.
- A total of 685 products without an indication were newly authorised by means of the notification procedure. This concerned 665 single products and 20 combined products.
- In 2014, 64 applications for simplified authorisation with a reduced dossier were completed. 57 of these products were authorised and seven were rejected or withdrawn.

Herbal medicinal products

Herbal medicinal products or preparations contain only herbal substances or preparations. Within the framework of the simplified authorisation procedure it is possible, 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

- No herbal medicinal products with a new active pharmaceutical ingredient were authorised.
- 29 applications for non-innovative first authorisation of herbal medicinal products were completed. 25 of these concerned co-marketing products.

Asian medicinal products

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

Activities

- The co-operation with the Swiss Centre for Applied Human Toxicology (SCAHT) was continued with the aim of broadening knowledge of the substances on the list of traditional Asian substances (TAS list) and modifying the list where appropriate.

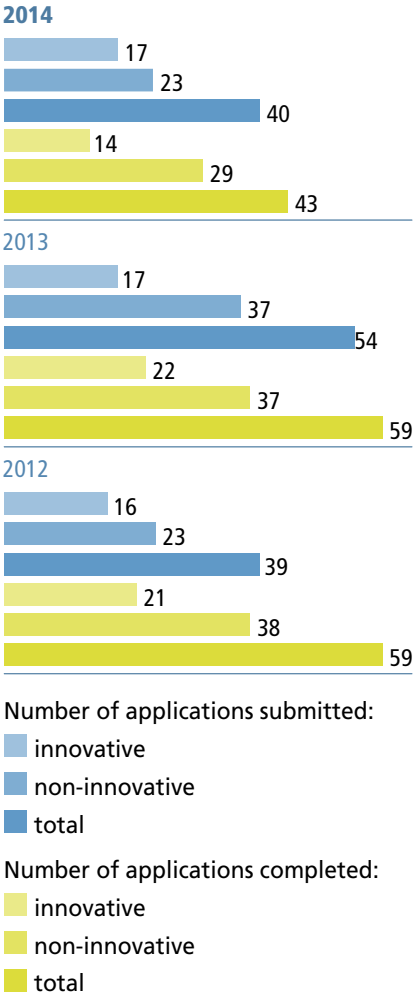
Veterinary medicinal products

First authorisations

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

Activities

- 17 applications for innovative first authorisation and major variations were submitted, and 14 applications were completed.
- Of these 14 applications, three concerned the first authorisation of a medicinal product with a new active pharmaceutical ingredient.
- All the applications were processed within the prescribed time limits.
- As regards new active pharmaceutical ingredients introduced into drug therapy in veterinary medicine over the past year, all the innovations concerned small animal medicine (dogs, cats).



Veterinary medicinal products with a new active pharmaceutical ingredient authorised in 2014

	Active pharmaceutical ingredients	Product name	Application
Dermatologicals	Oclacitinibum	Apoquel ad us. vet. film-coated tablets	Treatment of pruritus associated with allergic and atopic dermatitis in dogs
Metabolism	Human insulin	ProZinc® 40 IU/ml ad us. vet., oral solution	Treatment of diabetes mellitus in cats
Hormones	Carbimazolum	Vidalta® ad us. vet., film-coated tablets	Treatment of hyperthyroidism in cats

Veterinary Medicines Expert Committee (VMEC)

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

Activities

- At its five meetings in 2014, the VMEC assessed 13 applications for authorisation or additional indications.

Extensions and discontinuations

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

Activities

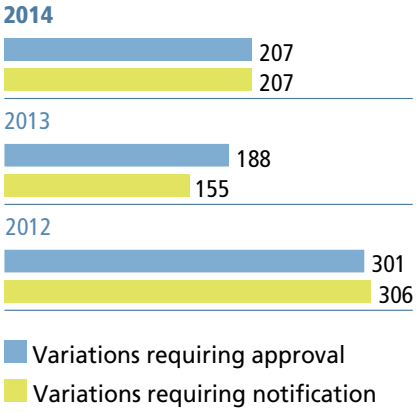
- In 2014, the authorisation was extended for 120 products.

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 2014, 207 variations requiring approval and 207 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

- No MUMS status was issued and no MUMS preparation was authorised in 2014.

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 2014, five appeals were lodged with the Federal Administrative Court against official decisions taken by the Agency in connection with product authorisations. The cases are still pending.
- Two decisions of the Federal Administrative Court were contested before the Federal Supreme Court, and both appeals were dismissed.
- Of the proceedings still pending before the Federal Administrative Court or the Federal Supreme Court, judgement has been passed on 13. Six appeals were rejected and six dismissed. The Federal Administrative Court upheld one appeal. This involved a question on the levying of fees in connection with the withdrawal of an application.

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		
	2014	First half year, cumulative	Second half year, cumulative	Total 2014
Marketing authorisation procedures (all application categories), proportion of procedures completed within the prescribed time limits	99%	97%	98%	98%
First marketing authorisations of innovative medicinal products (ZL1A); proportion of procedures completed within the prescribed time limits	95%	86%	95%	90%
First marketing authorisations of non-innovative medicinal products (ZL1B); proportion of procedures completed within the prescribed time limits	98%	93%	91%	92%
Extensions / discontinuations of marketing authorisations (ZL2); proportion of procedures completed within the prescribed time limits	99%	93%	99%	96%
Scientific variations (ZL3A); proportion completed within the prescribed time limits	99%	99%	99%	99%
Administrative variations (ZL3B); proportion completed within the prescribed time limits	99%	98%	98%	98%

In 2014, 98% of all applications were completed within the prescribed time limits. In category ZL1A the time limits were respected in 90% of cases, while this figure was as high as 92% in category ZL1B.

Special activities and events

- The new SAP-based data and resource management system was introduced in 2013, and various improvements were made in 2014 in order to reduce administrative work and simplify certain processes. In 2014, a project to handle all documentation in electronic form in a document management system (DMS) took shape. Companies have been asked to send all their documents electronically, and no longer as hardcopy. The electronic Common Technical Dossier (eCTD) is the most user-friendly format, with hyperlinks that are very helpful in the practical work of evaluating applications. Companies are encouraged to apply this format to as many applications as possible. The majority of applications for medicinal products with new active substances already arrive in eCTD format. A new electronic format for applications, the so-called eDok format, was created by the Submissions division as a way of offering applicants an alternative non-eCTD structured electronic format. The number of eDok applications has increased significantly since it was introduced. Taking all applications into consideration, however, the majority still arrive in paper format and need to be scanned in-house.
- A benchmarking study carried out in collaboration with industry stakeholders compared the overall times needed by Swissmedic, the FDA and the EU for various types of marketing authorisation process in 2013. The study showed that the official process time lines in Switzerland for new innovative products are longer than in the EU. In the fast-track procedure intended for new innovative drugs or additional indications of such products that deliver significant new benefits in comparison with products already on the market, Swissmedic is substantially faster than the EU. The aim is to carry out a benchmarking study of this kind annually in the future.
- Adaptations were made to several regulatory processes:
  - The criteria for the fast-track procedure were discussed with industry stakeholders and the interpretation of these criteria was clarified. Subsequently the fast-track procedure information leaflet was partly revised.
  - The Administrative Ordinance / Instructions on the Authorisation of similar biological medicinal products (biosimilars) was revised to reflect current scientific and technical knowledge and entered into force on 1 February 2014. It now also governs the requirements for the authorisation of biosimilars for monoclonal antibodies.
  - The Formal Requirements guide and the corresponding directory now summarise all the general formal requirements, the requirements for Module 1 and the accompanying letter in a simplified and centralised form. As a result, it was possible to remove redundant information from a large number of other instructions, information leaflets and administrative ordinances.

Licensing

Medicinal and transplant products

Establishment licences for medicinal and transplant products

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

Activities

- At the end of 2014, 1,092 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 2014, the number of licences issued for the first time, extended or amended was 659, which is once again slightly lower than for the previous year.

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

Special licences for medicinal and transplant products

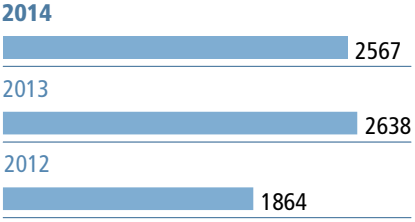
On application and within 24 hours, Swissmedic issues medical professionals with a special licence for importing small quantities of medicinal and transplant products that are not authorised in Switzerland but are essential for the treatment of specific patients. The import, use or dispensing of these products is the sole responsibility of the medical professional in question.

Activities

- The number of special licences showed a slight drop compared to the previous year.
- The proportion of special licences for radiopharmaceuticals increased to 36%, compared to the previous year's figure of around 30%.

Medicinal and transplant products

Number of special licences



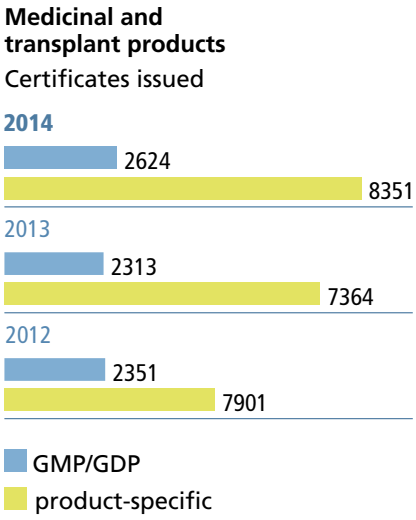
Performance indicator	Target	Result
Special licences; proportion of procedures that were completed within 24 hours	100%	99%

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

- In 2014, Swissmedic issued 2,624 Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) certificates.
- 8,351 product-specific certificates were issued.



Performance indicator	Target	Result
GMP/GDP certificates; proportion of procedures completed within 14 days	95%	98%

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

- The figures for 2014 remained roughly constant, with 355 companies in possession of an establishment licence for handling controlled substances and 180 processed applications for modifications, renewals or the start of operations.
- 7,804 import and export permits were issued for international trade.
- Since March 2013, all companies have been provided with the possibility of applying for import and export permits electronically, via the NDS-WEB (National Drug Control) system. In the fourth quarter of 2014, as much as 98% of all applications were submitted electronically.
- In 2014, Swissmedic analysed 34 individual substances and two substance groups and applied to the Federal Office of Home Affairs for their inclusion in the relevant Ordinance (BetmVV-EDI).

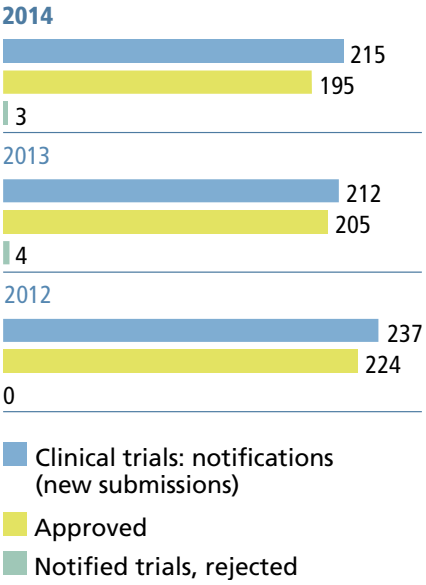
Performance indicator	Target	Result
Import and export permits for controlled substances; proportion of procedures completed within 10 working days	95%	98%

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

- The Human Research Act (HRA) and its three ordinances (KlinV, HFV, OV-HFG) entered into force on 1 January 2014 without any transitional period. From this date, Swissmedic has reviewed clinical trials dossiers in accordance with the distribution of tasks between Swissmedic and the Ethics Committees provided for by the new legislation.
- In 2014, Swissmedic received 228 applications for clinical trials with medicinal products, 195 of which were approved. The remaining trials were either rejected or withdrawn by the sponsor.
- A total of eleven applications for clinical trials involving transplant products and gene therapy were newly submitted in 2014. Seven of these applications concerned gene therapy, while the others related to first-in-man trials. Nine studies in all were approved in 2014. A further four studies are currently being processed. In addition, eleven Annual Safety Reports were reviewed (seven of which related to gene therapy) and 19 applications for protocol amendments were examined and approved.
- Swissmedic also continued to collaborate with the Federal Office of Public Health (FOPH) and Swissethics, the Association of Swiss Ethics Committees on research involving humans, with the aims of facilitating the implementation of the new law, supporting the ethics committees as they take on tasks for which Swissmedic used to be responsible, and co-ordinating and harmonising the interpretation of the new law in the three ordinances. In this connection, Swissmedic took part in six meetings organised by the FOPH agency responsible for coordinating research involving humans.
- Swissmedic organised two seminars for external participants, held a round-table meeting with the Swiss Clinical Trial organisation (SCTO) and the Swiss Group for Clinical Cancer Research (SAKK), and gave 32 presentations to various affected organisations (clinical trial units; SwAPP ExEx Meeting; MEGRA Module XI; ECPM), and at conferences (CLINAM) and symposiums (SCTO symposium). Furthermore, Swissmedic published new instructions for the submission of clinical drug trials, as well as a support document in the form of questions & answers.



Performance indicator	Target	Result
Approvals of clinical trials (first submissions); proportion of trials approved within 30 days	100%	97%

Inspections

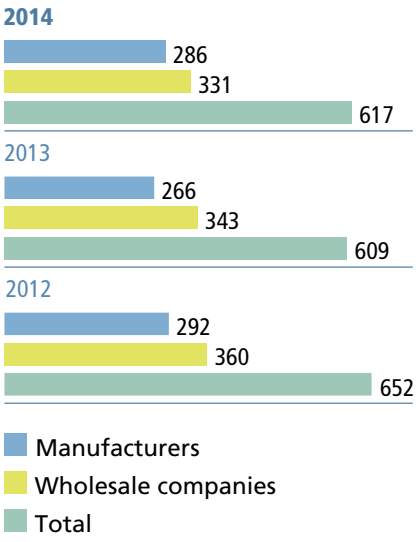
GMP and GDP inspections

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 2014, the Swissmedic inspectorate carried out 61 GMP / GDP inspections of manufacturers and wholesale companies, while the regional inspectorates carried out 556, i.e. a total of 617 inspections, which is comparable with the figures for the two previous years.
- The inspections carried out by the Swissmedic inspectorate concerned the following areas: transplant products 18%, blood transfusion services 36%, pre-approval inspections 8%, "for cause" inspections 10%, pharmaceutical sector inspections 28%.
- The Swissmedic inspectorate successfully passed the audit conducted by the Swiss Accreditation Service (SAS) and received extended accreditation under the new standard 17020:2012.
- Within the framework of the Mutual Recognition Agreement (MRA), Health Canada completed its annual review of the equivalence of the Swiss inspection system and reconfirmed its equivalence status.
- In 2014, Swissmedic again took part in several assessments of partner authorities within the framework of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and intensified its activities within the new structure of the PIC/S.

GMP/GDP inspections
(Swissmedic and regional inspectorates)



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

GCP inspections and pharmacovigilance

All clinical trials carried out in Switzerland by sponsors and research institutes, as well as trial locations, facilities and laboratories, have been inspected by Swissmedic 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

- Swissmedic carried out a total of 22 GCP and GVP inspections in 2014, and provided expert support for a further six foreign inspections in Switzerland organised by Europe and the USA.
- Swissmedic carried out a further three GCP inspections in the area of advanced therapies involving clinical trials with transplant products and gene therapy.
- In 2014, the GCP/GVP inspectors again participated in EMA inspectors training courses and the GCP inspectors working group.

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 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.

Activities

- In 2014, the Swissmedic GLP unit carried out ten routine inspections within the framework of its monitoring activities.
- An additional test facility was added to the GLP monitoring programme following a successful first inspection in 2014.
- In a pilot project conducted in collaboration with the GCP inspectorate between 2012 and 2014, a total of three test facilities were inspected to address the interface between bioanalytics and plasma samples from clinical trials. Further joint inspections are carried out on an ad hoc basis rather than routinely.
- 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 results are expected to be discussed during the meeting of the OECD GLP Working Group in April 2015. The last inspection of this type had been carried out in 2001.

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, genetic examinations on humans, and heroin-based treatments. Swissmedic also carries out some of the inspection activities in the therapeutic products sector for the Principality of Liechtenstein.

Activities

- In 2014, Swissmedic carried out 41 inspection procedures for the FOPH and one for the Principality of Liechtenstein.
- The module contracts with the FOPH that form the basis for these activities were extended as they came up for renewal.

Inspections by foreign authorities in Switzerland

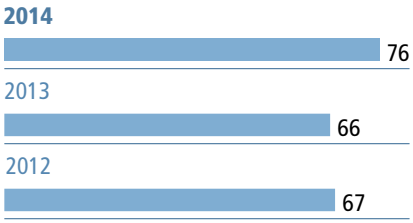
Swissmedic and the regional inspectorates operated by the Cantons will, if required, accompany inspections of companies in Switzerland by foreign authorities. In so doing, the Swiss inspectors assume the role of representatives of the Swiss inspections system.

Activities

- In 2014, foreign authorities carried out 70 inspections at pharmaceutical companies in Switzerland. The inspecting authorities were the USA with 45 inspections, Brazil with seven, Korea with five, China with three, Mexico, Turkey, Saudi Arabia and Kazakhstan with two each and Belarus and the Yemen with one each.
- Swissmedic also accompanied six GCP inspections by foreign monitoring authorities.

Inspections by foreign authorities in Switzerland

Number of inspections (GMP and GCP)



Monitoring of the blood transfusion service

Swissmedic monitors Swiss blood transfusion activities by means of inspections, licences, market monitoring of devices and standardisation. Blood 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 consultation with Swissmedic and the FOPH, the Swiss Red Cross transfusion service (SRK) has approved an action plan to be implemented in the event that (autochthonous) West Nile Virus (WNV) is discovered in blood donated in Switzerland. This plan defines various measures based on the prevailing risk threshold, in particular the stepwise introduction of nationwide WNV testing using modern, molecular detection methods. The procedure adopted in Switzerland has earned international recognition.
- In connection with the Ebola epidemic, the specific measures implemented by the Swiss Red Cross transfusion service for assessing blood donors who have visited high-risk regions, been in contact with Ebola patients or otherwise been exposed to the Ebola virus, were also evaluated.
- After antibodies were detected in individual donors tested for Chagas disease, Swissmedic instructed the blood transfusion services to report all infections discovered in donors and the measures taken in each case.

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

- The move to the new laboratory building in the previous year brought together the separate OMCL units at a single location in September 2013. As a result, it was also possible to combine the two existing accreditations into one. The routine monitoring visit by the Swiss Accreditation Service (SAS) took place in March 2014. Accreditation was confirmed.
- In the area of official batch release, the number of applications for analyses of plasma pools and the inspection of stable blood products showed a further increase over previous years in 2014.
- Since the number of vaccines manufactured in Switzerland has declined sharply, the number of applications for batch releases of vaccines also fell.
- A peptide and protein identification method was developed for non-authorised or counterfeit biotech preparations. This method uses the quadrupole mass spectrometer.
- The procurement of a pipetting robot has set the stage for greater automation and corresponding efficiency gains in the future.

Analysis conclusions for new marketing authorisations and market monitoring

	2012	2013	2014
Authorisation procedure: number of medicinal products examined	26	33	54
Market monitoring: number of medicinal products examined	1676	1763	1980
Other (pharmacopoeia, round robin tests)	–	–	375
Total	**1702**	**1796**	**2409**

Batch assessments and plasma pool analysis

	2012		2013		2014	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH and EU)	544	88	635	117	701	74
Notifications	310	160	319	149	312	169
Plasma pool analyses	1563	–	1950	–	2337	–
Product analyses as WHO reference laboratory	–	35	–	35	–	16

Performance indicator	Target	Result
Batch releases, notifications, plasma pool analyses: proportion of assessments completed within the prescribed time limit	100%	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. Judgements by that Court may in turn be contested before the Federal Supreme Court.

Activities

- Three appeals were lodged before the Federal Administrative Court against official decisions by the Agency in connection with establishment licences in 2014. The cases are still pending.
- One judgement, in which the appeal was rejected, was made on the appeal proceedings that were already pending before the Federal Administrative Court or the Federal Supreme court

Special activities and events

FOPH and Swissmedic campaign on cell therapy

In an action plan designed to control dubious applications and the production of fresh cells, the FOPH and Swissmedic have asked the Cantons to draw up an inventory of all providers (hospitals, practices, medical personnel) for whose activities the Cantons have been responsible to date. The replies received from the Cantons by the end of 2014 on possible offerings of cell therapy and similar treatments were reviewed by the FOPH and Swissmedic and, where necessary, corrective measures were initiated in consultation with the Cantons.

Approval of two Ebola vaccine trials in Switzerland

Swissmedic approved the implementation of two trials with vaccines against the Ebola virus in which safety aspects were tested in volunteers. Since the vaccines contain genetically modified organisms, these trials were approved within a short period, with input from the FOPH, FOEN and the Swiss Expert Committee for Biosafety (SECB).

Market surveillance

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

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

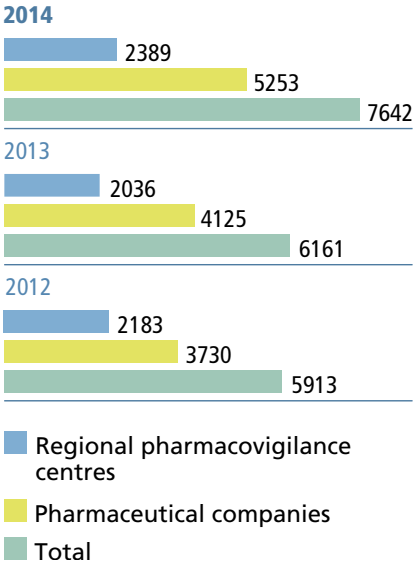
Within the framework of the pharmacovigilance network, the reports on adverse drug reactions are assessed in six regional pharmacovigilance centres (RPVC) on behalf of Swissmedic and recorded in the national database. The professionals who submit the reports receive appropriate feedback. Reports on adverse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

Activities

- In 2014, Swissmedic entered 7,642 reports of suspected adverse reactions to medicinal products in the database. These were sent by the six RPVC (2,398) and the industry (5,253). The marked increase compared with the previous year is primarily the result of a greater reporting volume both from companies and from the RPVC.
- Roughly 25% of the reports from companies were submitted to Swissmedic electronically, using the pharmacovigilance gateway launched in December 2012. In 2014, two more major companies started using the gateway, with two more about to join in the near future.
- After nearly two years of project activities, the online reporting portal ElViS (Electronic Vigilance System) became operational in early October. HCP who have hitherto been using reporting forms to notify the RPVC of suspected cases can now do so online, while pharmaceutical companies without gateway access to the Swissmedic database can also send their reports electronically to Swissmedic. By the end of the year, 16 companies had been given access after receiving the appropriate training.

Adverse drug reactions, human medicinal products

Number of reports



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

Haemovigilance

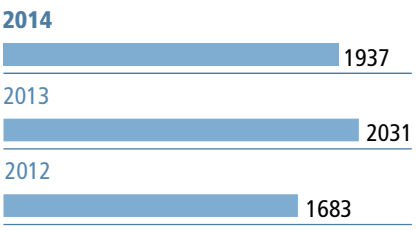
Haemovigilance requires all adverse events associated with the selection of blood donors and the collection, production and administration of blood transfusions to be reported. The aim of the haemovigilance system is to quantify transfusion risks, to identify emerging risks and to identify potential for improvements that will make blood products for transfusion or their use safer.

Activities

- In 2014, a total of 1,937 reports were received. About 56% of these related to transfusion reactions, 3% to the wrong product being transfused, and 41% to near-miss events in which the error was realised and corrected before the transfusion began.
- Two workshops were held and two working visits were made to hospitals with transfusion centres to train haemovigilance officers and HCP, while three presentations were given to specialist audiences in Switzerland.
- Signal verification to assess the safety profile of labile blood products concerned the safety of blood platelets after extended storage, the pulmonary side effects of pathogen-inactivated blood platelets and the relevance of hepatitis E transmission by labile blood products.

Adverse events involving blood products

Number of reports



- Swissmedic has intensified monitoring of confirmed infections in blood donors and of protective measures adopted by the manufacturers.
- In connection with the Memorandum of Understanding, Swissmedic held a telephone conference with the US regulatory agency FDA to explain Swiss haemovigilance data on platelet concentrates that have been treated in Switzerland since 2011 using the Intercept® pathogen inactivation process. The information aided the FDA in its decision to approve Intercept® in the USA from 2014 (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427500.htm).

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

Vigilance for veterinary medicinal products

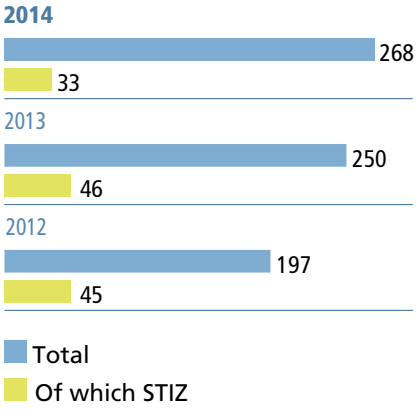
Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich for the collection and assessment of reports on adverse reactions to veterinary medicinal products. Reports on vaccines for animals are recorded by the Institute for Virology and Immunology (IVI) of the Federal Food Safety and Veterinary Office (FSVO).

Activities

- In 2014, the number of adverse reactions to veterinary medicinal products submitted to Swissmedic was 268, which constitutes an increase of almost 7% compared to the previous year. Of the reports, 33 were submitted by the Swiss Toxicological Information Centre (STIZ) in Zurich.
- The majority of the reports concerned domestic animals. Five signals were generated from the 268 reports.

Adverse drug reactions, veterinary medicinal products

Number of reports



Performance indicator	Target	Result
Report on new findings	1	1

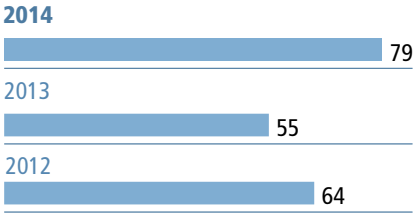
Risk management

Within the framework of the 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.

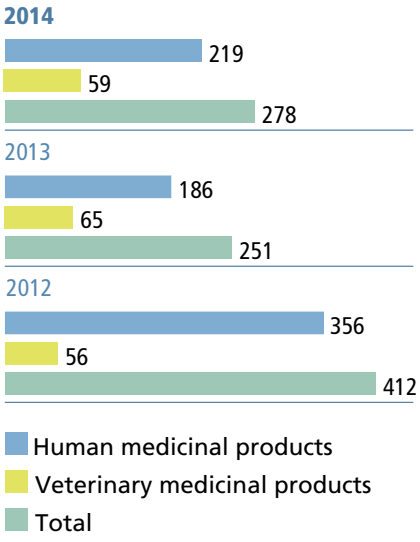
Activities

- One of the main activities in the Safety of Medicines group is the assessment of pharmacovigilance plans. A total of 79 first submissions or updates of pharmacovigilance plans were assessed, as were 27 answers from firms to the Lists of Questions (LoQ) sent to them by Swissmedic.
- Swissmedic assessed 219 periodic reports (PSUR/PBRER) on human medicinal products in 2014. The short assessment process with systematic prioritisation made it possible to reduce the time taken. Of the PSUR, 59 concerned veterinary medicines; PSUR are mandatory for most of these products.
- Swissmedic processed 118 safety signals concerning medicinal products, of which 56 came from Switzerland and 62 were identified from international sources.
- Six pharmacovigilance inspections were carried out jointly with the Licensing division and Swissmedic accompanied the same number of pharmacovigilance inspections carried out in Switzerland by foreign authorities.

Pharmacovigilance plans
Number of assessments



PSUR
Number of assessments



Performance indicator	Target	Result
Number of signals identified from the reports	120	118*

* 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 2014 Swissmedic concluded nine reviews. In several cases, risk mitigation measures could be taken without initiating a review procedure. In 14 cases, and either on their own initiative or as ordered by Swissmedic, authorisation holders sent a DHPC to healthcare professionals to inform them of new risks relating to medicinal products.
- The administration of solutions containing hydroxyethylene starch (HES) for fluid replacement was standard practice for many years. New information about the risks of mortality and renal failure, in particular, led Swissmedic to undertake a lengthy process in conjunction with the pharmaceutical manufacturers concerned to redefine the correct use of HES-containing solutions.
- The review of hypersensitivity reactions during parenteral iron administration was concluded with appropriate measures to mitigate risk.
- Review processes were started to harmonise and update the product information for combined hormonal contraceptives (CHC). All the firms involved were informed about the planned changes in a hearing.
- In consultation with Swissmedic, the Swiss Society for Gynaecology and Obstetrics provided healthcare professionals and users with information about the risk of thromboembolisms under CHC.

Performance indicator	Target	Result
Completed procedures including reviews: Number of official decisions	30	23

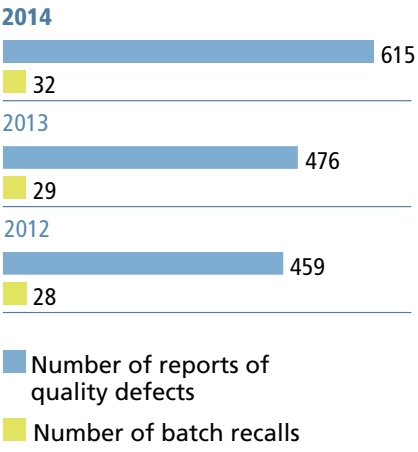
Quality defects and batch recalls

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 is the international exchange of information and the examination of foreign reports with regard to their significance for the Swiss market.

Activities

- The number of quality defects rose sharply in 2014. A total of 615 reports were submitted. In 407 cases Switzerland was affected and measures were initiated. Forty-one of them were classified as being highly urgent (life-threatening).
- Official decisions to carry out 32 batch recalls were taken.
- In 18 cases, applications were approved to place products produced for other countries on the market temporarily in order to overcome supply shortages.
- A quality defect from the previous year led to precarious supply shortages of adrenaline pens for the emergency self-treatment of allergic reactions. To overcome this situation, products produced for the American market were released temporarily for the Swiss market.
- Swissmedic and European regulatory authorities investigated deficiencies in the manufacture of pharmaceutically active substances produced by a major Indian pharmaceutical company. It was found that the use of active substances sourced from this manufacturing facility had no negative effects on the quality of the medicinal products authorised in Switzerland.
- This year there were again numerous examples illustrating the ease with which inadequate controls during the production of packaging materials and the packaging process itself can lead to major problems. Two recalls had to be carried out because cartons containing different dosages of the same product had been mixed up during the packaging process, and in another case units of the wrong product were packed. Furthermore, in one case an unnoticed printing error on a pack resulted in a report that a counterfeit product was on the market, which luckily proved to be untrue.

Quality defects



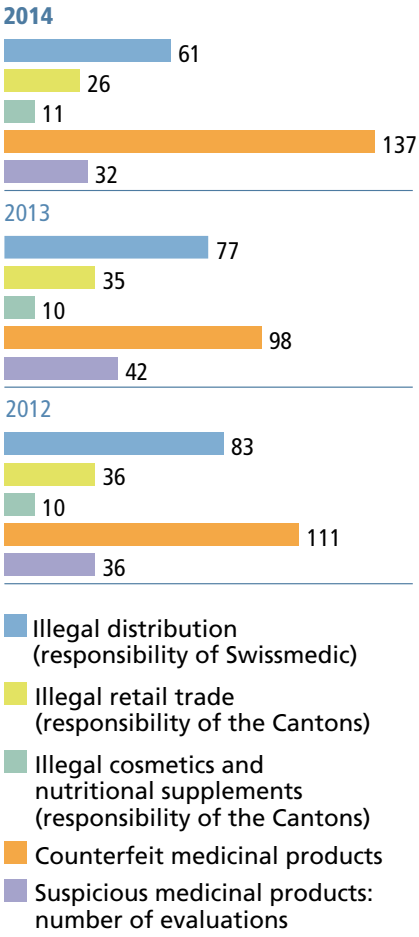
Measures against illegal medicinal products

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 2014, Swissmedic received 312 reports on illegal activities related to medicinal products. Of them, 61 concerned illegal distribution with a link to Switzerland.
- Some 37 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.

- Of the 137 reports on counterfeiting, 16 concerned Switzerland.
- Some 1,198 unauthorised imports of medicinal products led to administrative proceedings being initiated.
- A new database launched by the European Directorate for the Quality of Medicines (EDQM) and sponsored by Swissmedic enables precise information about counterfeit and illegal products to be captured and represents a further instrument in the international fight against counterfeit medicinal products.
- It had been discovered in the EU that medicinal products were being systematically stolen in Italy, relabelled and channelled into the European parallel import market. Swissmedic participated in work done by the international network to identify the supply chains and the roles played by the wholesalers involved.
- Objections were sent to the major mail-order pharmacies in Germany based near the border, informing them that it is not permitted to import ready-to-use medicinal products into Switzerland on a commercial basis without the appropriate authorisation. These pharmacies had transported medicinal products across the border into Switzerland and then sent them to customers through the Swiss postal service.



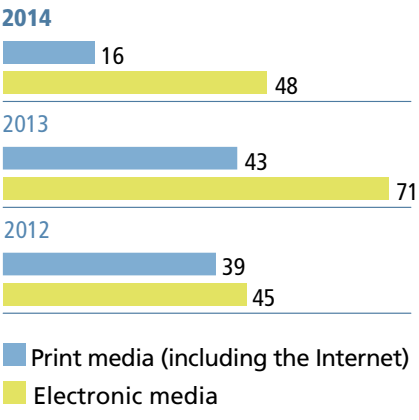
Control of advertising

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 64 applications submitted for prior control, 16 involved printed advertising, three of which were Internet sites, which are classified as printed media for regulatory purposes. The other 48 applications involved advertising in electronic media such as television commercials or e-boards.
- A total of 42 advertisements targeting the public or healthcare professionals were processed by Swissmedic. In 16 cases, administrative proceedings were initiated, and in seven cases an official objection was issued.
- As a result of a judgement issued by the Federal Administrative Court, the way the requirement for prior control is handled in practice was changed in June 2014, leading to a substantial decline in the number of applications. Now advertisements in printed media and those involving audiovisual media only need to be submitted to the Agency for approval if potential for dependence or abuse is mentioned in the product information of the medicinal product being advertised.

Advertising
Number of applications



- A publication was issued on the subject of the provision of free-of-charge initial supplies of medicinal products immediately after launch, as this constitutes an unauthorised advertising activity. The opinion expressed by Swissmedic that such activities violate the provisions of Article 10 of the Therapeutic Products Advertising Ordinance was confirmed by the Federal Administrative Court.

Performance indicator	Target	Result
Prior control of advertising: proportion of cases where a preliminary decision was taken within 4 weeks of receipt of	80%	100%

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%	98%
Number of presentations, publications and circulars to raise awareness among stakeholders	12	13

Appeals procedures regarding the market monitoring of medicinal products

Appeals against official decisions taken by Swissmedic may be lodged with the Federal Administrative Court within 30 days. That Court's judgement may in turn be contested before the Federal Supreme Court.

Activities

- In 2014, appeals were lodged with the Federal Administrative court against 14 official decisions by the Agency in connection with the market monitoring of medicinal products. Most of them concerned the illegal import of medicinal products. In four cases, the appeals were not admitted by the court. Two appeals were 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 four cases. The Federal Administrative Court did not admit three appeals and dismissed one.

Special activities and events

Campaign against illegal imports of narcotics

During Operation PANGEA, an international week of action targeting illegal sales of medicinal products, Swissmedic cooperated with the Swiss Customs Administration, the Antidoping Switzerland foundation and the National Pharmacy Office in Liechtenstein. The focus this year was on narcotic substances in response to an increase in imports of sleeping pills containing narcotics prior to the campaign. Within one week, 125 illegal imports were confiscated at Zurich airport and at the postal distribution centre in Zurich-Mülligen.

Involvement in improving the safety of blood transfusions

The haemovigilance experts at Swissmedic were involved in several international networks: they represented Switzerland in the International Haemovigilance Network, participated in the European Committee on Blood Transfusion CD-P-TS and chaired the WHO Blood Regulators Network with a representative from the Inspectorates department. The latter network published two documents on the subjects of „Convalescent plasma in management of Ebola“ and „Deferral of blood donation for risk behaviours“.

Switch to new coding system for ADR reports

In early February the Swissmedic database was successfully switched from the WHO-ART coding system and ICD 10 to MedDRA in close cooperation with the Uppsala Monitoring Centre operated by the WHO. The new system is also used by the industry and enables considerably more detailed coding and thus more accurate recording of adverse drug reactions that are reported.

Medical devices

Medical devices encompass an extremely large range of products, including implants such as hip prostheses and heart pacemakers, in vitro diagnostics such as HIV or pregnancy tests, or products for the general public such as contact lenses. Before these products can be placed on the market, 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 clinical trials of medical devices that are not yet authorised for the market.

Placing on the market

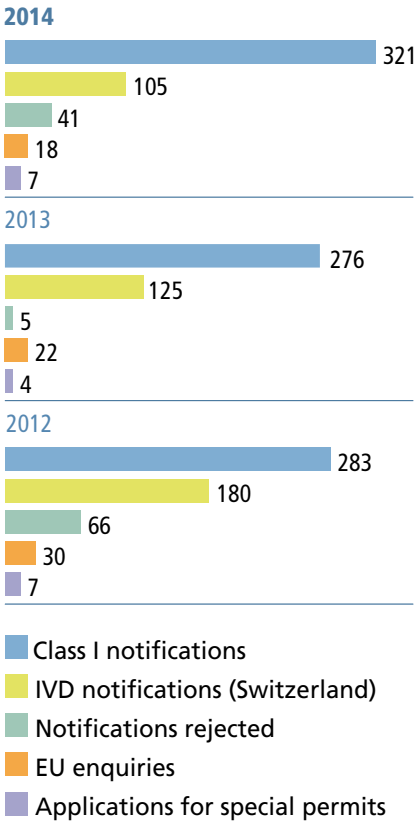
Manufacturers of medical devices associated with greater risks must bring in officially recognised notified bodies for the conformity assessment. Notification is mandatory for certain medical devices, and for these Swissmedic receives the notifications, carries out random checks on their classification, 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

- In 2014, 321 notifications for class I medical devices were received. This class covers devices such as reusable surgical instruments, adhesive plasters and rolling walkers.
- Swissmedic received 105 notifications for in vitro diagnostic medical devices (IVDs).
- In 41 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 2014, Swissmedic took part in 18 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 2014, seven applications for special permits were reviewed, five 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

- In 2014, Swissmedic received 49 requests for mutual assistance from its European partner authorities.
- Swissmedic issued seven requests for mutual assistance to its European partner authorities.
- The 2012 PIP Action Plan (developed as a result of the scandal surrounding harmful breast implants manufactured by the French company PIP) provides for intensified joint monitoring of the European market. More effectively harmonized and enhanced monitoring of the notified bodies was initiated in 2013. In 2014, Swissmedic participated in internationally monitored audits of these bodies which also included reviews of product documentation.
- In addition, a European pilot project for joint market monitoring actions was initiated in 2014 and is scheduled for implementation in 2015. For the time being, Switzerland is an observer in this project.

Materiovigilance

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

Activities

- A total of 2,405 cases of materiovigilance were processed, 1,124 of which were incidents that occurred in Switzerland. The number of notifications was thus slightly lower than 2013's record figure.
- In 770 cases, the implementation of corrective safety measures in Switzerland was monitored. A total of 126 reports on defective medical devices (National Competent Authority Reports, NCARs) were drawn up for the attention of foreign authorities, and Swissmedic received 807 NCARs from the European partner authorities
- In 697 cases, a public safety report was published on the Swissmedic website for the information of users.
- In addition, new cases of suspected incidents or concrete actions to be taken on pending cases are discussed during monthly telephone conferences with the other European monitoring authorities.
- In 2014 Swissmedic organised a meeting of hospital contacts, provisionally for the last time.

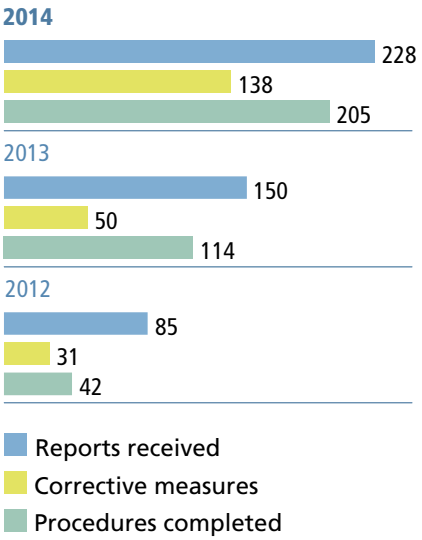
Performance indicator	Target	Result
Reports requiring immediate action; first measures taken within 10 days	100%	100%

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

- A total of 228 reports where an infringement of conformity was suspected were received by Swissmedic in 2014.
- In 138 of the cases opened as the result of the reports, corrective measures were imposed, for example modification of the product descriptions or halting distribution.
- A total of 205 reports were completed in 2014.
- The number of reports has increased sharply, and they therefore had to be 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 2014 it was consequently also possible to complete substantially more reports and take more corrective measures than the year before.



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 First activities for priority 3 cases initiated within 90 days	90%	100%

Clinical investigations

Swissmedic monitors clinical investigations of medical devices for human use if the products or the intended use in Switzerland are not yet CE certified. Notification to Swissmedic was mandatory for intended investigations of such products, and the notifications were reviewed. The investigations have required 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

- In 2014, 36 notifications for new investigations of medical devices not yet authorised for the market were assessed, representing a decrease of about 14% compared with the previous year.
- A total of 571 notifications relating to clinical trials that had already been approved were processed.
- More in-depth examinations were necessary for two ongoing clinical trials.
- The preparatory work for the implementation of the Human Research Act (HRA) was completed successfully. Training sessions were offered, for example, and interpretation aids and leaflets were provided.

Performance indicator	Target	Result
Notifications of clinical trials; proportion assessed within 30 days	100%	97%

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

- The monitoring of the CABs was one of the main focus areas of Swissmedic in 2014.
- Swissmedic carried monitoring audits in the area of medical devices at three of the CABs in Switzerland.
- In 2014, Swiss experts took part in three inspections of authorities in Europe that designate notified bodies.
- During the year, Swissmedic carried out an inspection in a hospital in the area of reprocessing and the reporting system.
- 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. No inspections of clinical trials or maintenance were performed.

	2012	2013	2014
CAB inspections (excluding ISO 13485)	1	4	3
Joint assessments	n/a	4	2
Inspections of clinical trials	0	2	0
Hospital audit: reprocessing	0	0	1
Hospital audit: maintenance			0
Hospital audit: reporting system	0	0	1
Inspections by foreign authorities*	39	30	54
Inspections of market controls	0	1	6

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

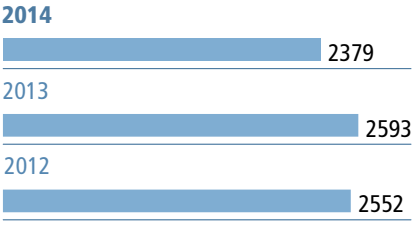
Export certificates

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 2,379 export certificates were issued in 2014. In 99% of cases this service was provided within 30 days.

Export certificates



Appeals procedure concerning the market monitoring of medical devices

Appeals against official decisions taken by Swissmedic may be lodged with the Federal Administrative Court within 30 days. That Court's judgement may in turn be contested before the Federal Supreme Court.

Activities

- In 2014, one appeal was lodged against an official decision of the Agency in connection with the market monitoring of medicinal devices. The appeal was dismissed.
- Of the appeals already pending before the Federal Administrative Court, one was dismissed.

Special activities and events

Enhanced monitoring of medical devices

Following the scandal surrounding harmful breast implants manufactured by the French company Poly Implant Prothèses (PiP), in 2012 the EU Commission ordered intensified monitoring activities for medical devices. The resulting PIP Action Plan is based on the existing Regulations and provides for specific measures. In 2014 the focus was on intensified monitoring of the notified bodies on the basis of the new Commission Implementing Regulation (IR (EU) No. 920/2013).

Adaptation of legislation

The introduction of the Human Research Act (HRA) led to a modification of the process approving clinical trials with medical products; the new process was implemented successfully.

In addition, new European Implementing Regulations made it necessary to adapt legislation and existing state agreements. These updates were initiated and in some cases have already been implemented.

Standards

Legal matters

Legislation

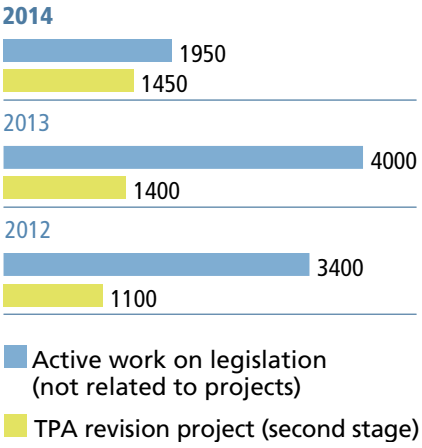
Swissmedic's legal mandate, its areas of competence and its enforcement role in the therapeutic products sector are laid down in binding laws and ordinances. In a rapidly developing environment, the area of legislation – meaning work in connection with enacting and maintaining the legal basis – is one 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; 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

- Activities in 2014 focused on the parliamentary consultation process for the ordinary revision of the Therapeutic Products Act (second stage). The proposal was discussed at several meetings of the Committees for Social Security and Health and during subsequent plenary sessions of the two Councils. Swissmedic attended these meetings with the FOPH, the lead entity responsible for preparing the legislation. With its resolution on 7 May 2014, the National Council approved the ordinary revision of the Therapeutic Products Act following the initial consultation process. On 10 December 2014, the Council of States decided to adopt its draft revision of the proposal submitted by the National Council. The parliamentary consultation process will continue in 2015 in a bid to resolve the differences between the two Councils.

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.

Activities

- In 2014, Swissmedic – together with Swiss experts from industry, universities, pharmacies and the authorities – devoted a total of 11 person years to specialised work in this area, with 57% being carried out by the Swiss Agency for Therapeutic Products. The Agency's Pharmacopoeia division is Switzerland's national pharmacopoeia authority. A total of 136 experts from Switzerland were mandated to work in the various national and European committees and groups working on the pharmacopoeia. This is a clear indication of the value placed on the pharmacopoeia on the one hand, and of the expertise that Switzerland can provide in the pharmaceutical sector on the other.
- The 8th edition of the Ph. Eur., as well as supplements 8.1 and 8.2, entered into force in 2014.
- Various text sections in the Ph. Helv. were updated to reflect the state of the art in science and technology.
- Also revised in connection with the new Swissmedic website was the information about the pharmacopoeia that is made available as a service to site users and which also describes the options for assisting with the work on the pharmacopoeia.

Technical standards for medical devices

If medical devices comply with the valid harmonised standards published in Europe, they are considered to be in conformity. Swissmedic publishes an annual list of these harmonised standards in the Federal Gazette, and is involved in various national standards committees and technical committees. 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 the harmonised standards for medical devices was updated in 2014 and published in the Federal Gazette. The annual update is necessary because standards are subject to an ongoing modification process. The list now consists of 293 standards.
- In 2014, Swissmedic was active in four national standards committees, whose purpose is to check proposals for international standards concerning medical devices.

Special activities and events

50 years of the European Pharmacopoeia (Ph. Eur.)

In 1964, Switzerland was one of the founder states of the Ph. Eur. and, as a signatory to the Convention on the Elaboration of a European Pharmacopoeia, undertook to assist with the elaboration of the Ph. Eur. and to incorporate the resulting quality specifications into Swiss law. An international conference was held in Strasbourg in October 2014 to mark the 50th anniversary of the Ph. Eur. Numerous Swiss experts participated in this event, and several actively contributed to the programme. Swissmedic highlighted this anniversary in various publications and reported on Switzerland's crucial contribution to the Ph. Eur.

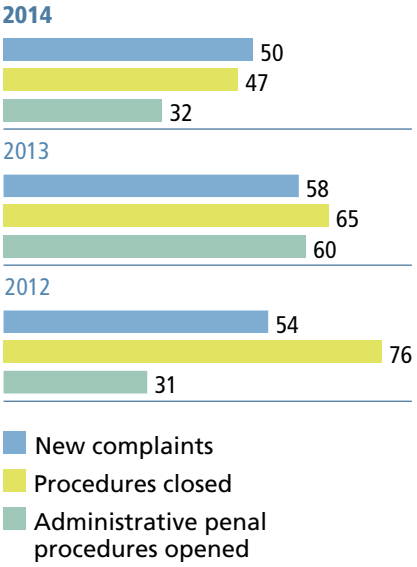
Penal law

General developments

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

Activities

- The Penal division received 50 new complaints and closed 47 cases. It opened 32 administrative penal proceedings. The marked fall in the number of proceedings opened compared to the previous year is primarily attributable to one case in 2013, which on its own involved 16 defendants.
- The resulting proceedings required considerable resources in terms of investigations and workload. This is why the number of searches and hearings remained stable in relation to the previous year. The investigative measures themselves and the scenarios in question were extremely complex. In one case for example, seven searches and three examination hearings occurred on the same day in Switzerland, simultaneously with one search and two hearings in France. This development also affects the complexity of pending proceedings. In the aforementioned case, by way of example, one hearing conducted some time after the searches involved no fewer than 15 participants.
- Since 2013, the Penal division has repeatedly demonstrated that it possesses the resources and experience needed to respond quickly, especially to cases requiring urgent action. This is a crucial factor for the quality of the penal proceedings.
- As regards international cooperation in criminal matters, the skills and experience acquired over the past few years enable Swissmedic to respond promptly to incoming requests.
- Work with a view to ratifying the Medicrime Convention continued with the evaluation of the results of the consultation procedure.

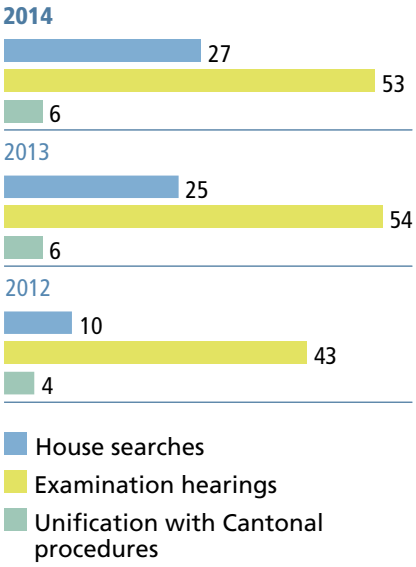


Investigative measures

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 2014, Swissmedic carried out 27 house searches and 53 hearings.
- Two appeals against coercive measures were lodged with the Federal Criminal Court. The Court refused to admit either appeal. It also rejected an appeal lodged in 2013 against a refusal to release seized objects and documents.
- A ruling issued against a credit card provider was also the subject of an appeal. The decision to reject this appeal was not contested before the Federal Criminal Court.
- Furthermore, the Federal Criminal Court admitted two requests from Swissmedic, one submitted in 2013 and one in 2014, to remove the seals affixed to documents seized during a search.
- As regards international cooperation in criminal matters, Swissmedic handled three requests, two from Germany and one from Israel. These concerned the collection and forwarding of evidence. In the opposite direction, five requests were addressed to France, Germany, Austria, Italy and the United States with the aim of obtaining evidence and blocking a bank account. Excellent collaboration with the French authorities enabled searches and examination hearings to be planned and conducted rapidly and in a co-ordinated manner in both countries.
- Six 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).

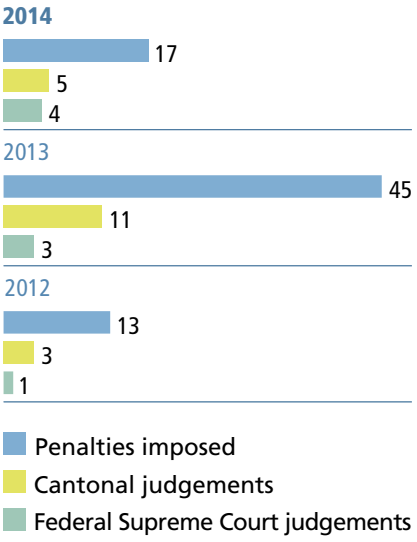


Decisions/judgements by Swissmedic and by courts

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

- A total of 17 penalties were imposed, of which eight concerned the illegal import of medicines, six illegal trading, one illegal advertising for a product based on botulinum toxin and two a violation of the ban on promising and accepting material benefits. The marked fall in the number of penalties imposed compared to the previous year is primarily attributable to one case in 2013, which on its own resulted in 16 convictions in a simplified procedure. The Agency also dismissed three cases. The first was dismissed due to insufficient evidence, the two others because the offences were committed in Germany. The latter were forwarded to the relevant German public prosecutor.
- The Cantonal courts issued decisions in five cases, with two acquittals and three convictions. The first two cases concerned the same situation mentioned above concerning the promise and acceptance of material benefits. The other three resulted in convictions for illegal trading in medicines.
- In one of these three cases, erectile stimulants that had been advertised as entirely plant-based nutritional supplements (in capsule form and as an energy drink) were classified by the courts as a medicinal product. As a consequence, their import into Switzerland for subsequent mail order sale without the corresponding authorisations and licences violated the TPA.
- In another case, Swissmedic instituted proceedings against the responsible person in a company that had exported and re-imported medicinal products for years, despite only possessed a licence to trade in medicinal products abroad. Swissmedic fined this person and imposed a financial penalty, and the company had to pay a six-figure sum in damages based on the illegally obtained earnings. The accused individual then demanded a judicial review, during which the Cantonal court of first instance reduced the fine to just a financial penalty. Following an appeal by Swissmedic, the financial penalty was increased by the court of second instance. No further appeal can be heard and these damages are legally enforceable.
- The Federal Supreme Court refused to admit four appeals submitted by the Office of the Attorney General of Switzerland on behalf of Swissmedic concerning cases involving doctors who participated in the above-mentioned illegal trading in medicines for arthritis. This decision was prompted by the fact that the appeals had not been signed by an authorised signatory. This was a surprising outcome because these decisions marked a deviation from the practice of the Federal Supreme Court up to that point.



Stakeholder management

Information

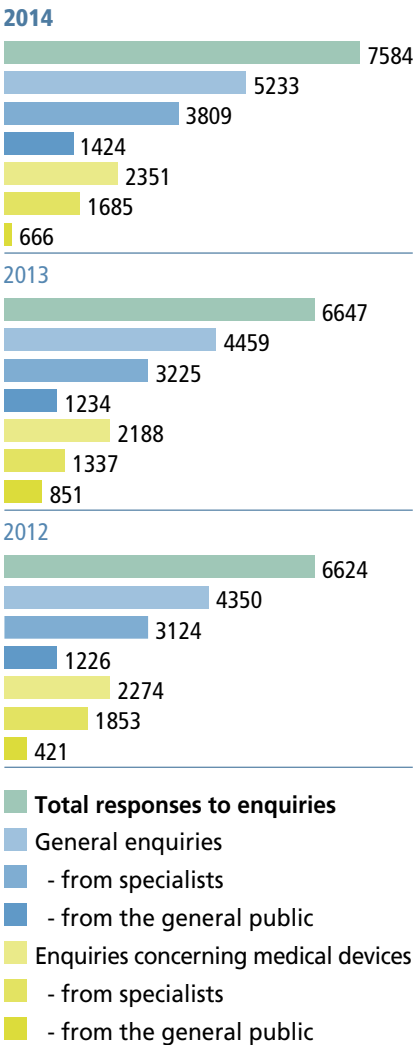
Swissmedic provides fast, targeted information on new findings concerning therapeutic products that could constitute health hazards. In addition to safety-relevant information, new authorisation decisions or major changes to medicinal product information are of considerable interest.

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 2014, Swissmedic responded to 7,584 enquiries, which represents a significant increase compared with previous years. A large number of enquiries concerned the entry into force of the new Human Research Act (HRA).
- A total of 95% of all enquiries were answered within ten calendar days.



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

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

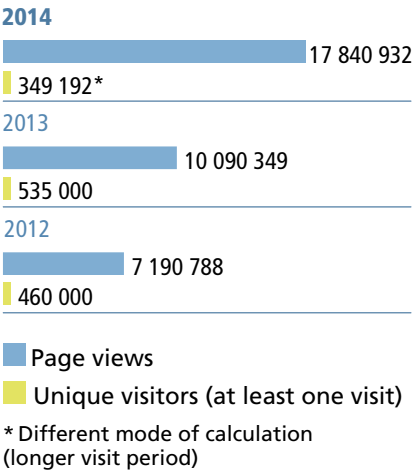
- In the year under review, Swissmedic answered 934 (i.e. an average of around four a day) enquiries from journalists.
- Swissmedic issued seven press releases in 2014, on measures for improved patient safety in cardiac surgery (in collaboration with the FOPH), warnings against illegal drug imports, the approval of two Ebola vaccine trials in Switzerland and on international cooperation.
- Reporting was dominated by doubts about the efficacy of influenza medicines, in particular Tamiflu. Swissmedic referenced the scientific basis for authorisation and the detailed and transparent information provided for healthcare professionals.
- The criminal proceedings pursued by Swissmedic against importers of illegal doping agents attracted frequent press enquiries, as did the question of medicinal safety (focusing on the latest generation of anticoagulants, on hormonal contraceptives and vaccines against cervical cancer).

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 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

- In addition to its annual report, Swissmedic also published communications on the safety of medicines (Vigilance News) in a new layout.
- Swissmedic's haemovigilance annual report provided interested readers with the latest findings on the monitoring of labile blood products.
- Following a technical overhaul in the previous year, further enhancements were made to the website, which primarily entailed optimising and adjusting the search function and the newsletter tool.
- In the year under review, Swissmedic published 22 safety-related notices on medicinal products (mainly Direct Healthcare Professional Communications, DHPCs) on its website.
- The weekly publications on safety measures for medicinal products contained 697 user information circulars.
- In 13 cases, Swissmedic cited current risks in connection with the use of certain medicinal products.
- With over 4,000 visitors a day to the website, demand for information on the authorisation of two Ebola vaccine trials in Switzerland was especially high.



* Different mode of calculation (longer visit period)

Events

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

Activities

- The highlight among the events on Swissmedic's calendar in 2014 was the OMCL Annual Meeting, co-organised with the European Directorate for the Quality of Medicines and Healthcare (EDQM). Over 200 attendees from accredited laboratories throughout Europe gathered in Interlaken to exchange ideas, discuss new standards and harmonise new procedures.
- The meeting of the representatives of the Competent Authorities for Medical Devices (CAMD) was held in Zurich at the end of May 2014. At the request of the Greek authorities, Swissmedic hosted the meeting under Greece's Council Presidency.
- Swissmedic organized a total of 16 events in 2014, down slightly on 18 in the previous year. However, in terms of the number of participants, more external stakeholders attended a Swissmedic event. Thanks to their interconnectedness, high informational content and exacting quality standards, the Swissmedic information events are a firm fixture in external stakeholders' diaries.
- The Haemovigilance unit also organised its two workshops in 2014 once again. The up-to-the-minute first-hand information and direct contact between the authorities and users are very much appreciated.
- Electronic document management and the associated formal requirements have brought numerous changes. These formal requirements were presented and discussed at an eDM workshop attended by 230 visitors, who used and valued the opportunity to put questions directly to Swissmedic.
- The Narcotics division also organised various workshops, the Clinical Trials division staged an information event on GCP/GVP inspections, and a committee of experts on counterfeit medicines held a conference under the auspices of the EDQM.
- Swissmedic completed the year's calendar of events with another information session on changes in the area of authorisation as well as the last conference for materiovigilance contact persons from hospitals to be held in this form.

Presentations and addresses

Swissmedic staff members give presentations and addresses on current topics both in Switzerland and abroad. These are essentially external events organised by third parties that provide the framework for the presentations. The range of subjects encompasses the entire spectrum of the Agency's service mandate.

Activities

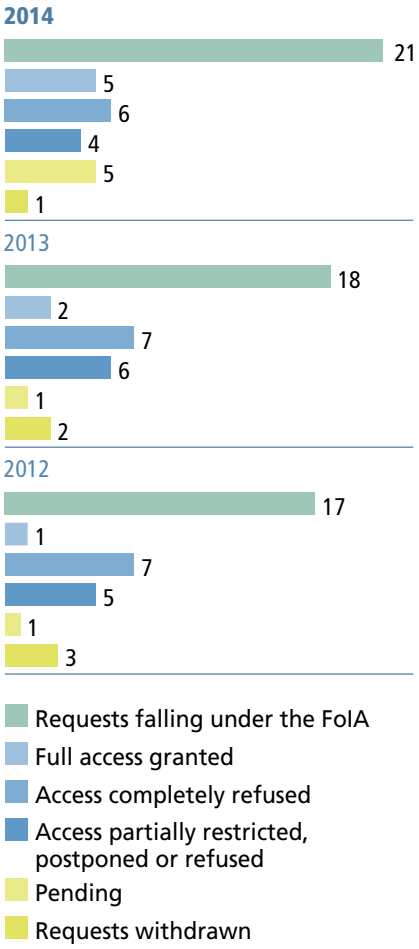
- Swissmedic staff gave 138 presentations and addresses at external events in 2014. These events comprised congresses, seminars and conferences intended for a specialised public from the pharmaceutical and regulatory sectors.
- Following the introduction of the new Human Research Act, Swissmedic's mandate to conduct inspections in all areas of good clinical practice (GSP) has been expanded. One of the main aims of this year's presentations and addresses was to inform the relevant stakeholder groups of these changes.

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

- In the year under review, Swissmedic received 21 requests that fall under the FoIA. Their number remains roughly constant compared with previous years.



Collaboration

Collaboration between Swissmedic and its various stakeholders is defined in the concept for national and international collaboration. The concept states that the inclusion of external stakeholders, with their often diverging interests, in Swissmedic's various fields of activity is a fundamental principle. The collaboration is based on a relationship that creates trust, and that preserves 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
– The therapeutic products industry and its associations/organisations
– Service providers from the therapeutic products industry
– Cantonal and federal authorities and parliament

Activities

- On 20 January 2014, Swissmedic briefed patient and consumer organisations on the new direction that collaboration is to take, based on the two cornerstones of actively providing information to these organisations and actively involving them in Swissmedic's defined fields of activity. The new direction was well received by representatives of the patient and consumer organisations, who signalled a willingness to serve on the working group.
- On 19 February and 22 October 2014, two Regulatory Affairs round table meetings were held with industry association representatives. Among other matters, Swissmedic updated them on developments in the areas of authorisation and licensing, on the projects roadmap, the newly launched Electronic Vigilance System (ElViS) and international collaboration with partner authorities.
- 5 May 2014 saw the first round table discussion on current issues in market surveillance with industry association representatives.
- Six meetings were held with representatives of the Swiss Association of Cantonal Pharmacists to discuss standardising implementation.
- A working group made up of representatives of the cantonal medical officers and cantonal pharmacists, haemovigilance contact persons from the hospitals and Swissmedic experts initiated steps to draw up guidelines for the improvement of quality assurance in the transfusion chain.

Participation of Swissmedic in external further training initiatives

Swissmedic is becoming increasingly involved in the area of initial and further training in the therapeutic products sector.

Activities

- In 2014, Swissmedic once again took an active part in the Middle European Organisation for Regulatory Affairs (MEGRA) further training course "StartUp Schweiz", and provided speakers for each module.
- Within the framework of the Certificate of Advanced Studies (CAS) course on health systems and health policy held in 2014 at the Zurich University of Applied Sciences, Swissmedic presented the Agency's work and its various sectors.
- Swissmedic experts also gave customised presentations as part of the University of Neuchâtel's Health Law CAS programme and ETH Zurich's Master's degree course in Medicinal and Industrial Pharmaceutical Sciences (MIPS).

International collaboration

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

International network

In recent years, Swissmedic has consistently continued its strategy of networking with partner authorities and has now concluded information exchange agreements with virtually all internationally recognised therapeutic products authorities of a comparable standard. Using and intensifying the existing collaboration and working towards further forms of co-operation, with clear goals, constitutes an important strategic objective. 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

- In 2014, Swissmedic expanded its network for collaboration with partner authorities by signing legally non-binding joint declarations of intent with the following institutions: the German Federal Institute for Drugs and Medical Devices (BfArM), the Ministry of Food and Drug Safety of the Republic of Korea, the Ministry of Health of the State of Israel and the Medicines Control Council of South Africa.
- In March, the Japanese Pharmaceutical and Medical Device Agency (PMDA) seconded a liaison officer to Swissmedic. Dr. Jun Kitahara, Director Division of Regulatory Cooperation, Office of International Programs, was stationed in Switzerland for one year. The purpose of his assignment was to help strengthen cooperation between the two authorities in the area of pharmacovigilance.
- Swissmedic received representatives from various international authorisation agencies in 2014, including from Uganda and Tanzania, the Gulf States, and China. The visits were aimed at sharing information in a wide range of areas of therapeutic products regulation and had various priorities. Conversely, experts from Swissmedic visited the two German bodies Paul-Ehrlich-Institut (PEI) and BfArM, the Health Sciences Authority (HSA) in Singapore, and the Australian Therapeutic Goods Administration (TGA). The objective of these visits too was to intensify collaboration and the exchange of information.
- The International Pharmaceutical Regulators Forum (IPRF) established in 2013 convened twice during the period under review. Swissmedic has agreed to serve as IPRF chair and secretariat for a second year. Marking the successful completion of its remit, the IPRF working group "General Principles for the Education and Training of GCP Inspectors" published its findings in the October 2014 issue of the DIA Journal "Therapeutic Innovation and Regulatory Science" (see www.i-p-r-f.org). A new working group is to be set up to address questions revolving around the topic of nanomedicines.
- Work under the International Generic Drug Regulators Pilot (IGDRP) was actively continued in 2014 as well. Swissmedic is participating in two information-sharing pilots, one of which involves the EU's decentralised procedure (DCP), and the other the centralised procedure of the European Medicines Agency (EMA). Upon simultaneous submission of an application for authorisation of a medicinal product with a known active substance without innovation (generic product) to a national authority of the EU or to the EMA and an authority taking part in the pilot, the national authority of the EU or the EMA will share the assessments in real time with the collaborating authorities.

Special activities and events

Swissmedic admitted as ICH member

During the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) held in Minneapolis, USA, from 30 May to 5 June 2014, the ICH Steering Committee decided – with immediate effect – to include Swissmedic and the Canadian Health Authority (Health Canada) as ICH members in recognition of their many years of collaboration. Under its previous observer status, Swissmedic represented the EFTA states and contributed actively to the various expert working groups.

Concrete measures taken to implement collaboration with representatives of patient and consumer organisations

The need to transform patients from passive recipients of therapeutic products into active, well-informed users of these products is indisputable. Swissmedic is endeavouring to foster this development and, at the beginning of 2014, redefined the way in which it collaborates with this group of stakeholders. It provided direct access via its website to information tailored to this target group and also briefed interested patient and consumer groups on the new direction of collaboration and the establishment of a working group for patient/consumer organisations. Initially set up as a two-year pilot and serving as a platform for the exchange of information and experiences, the working group met three times in 2014. This gives Swissmedic a direct line to the opinions and experiences of patients and consumers and – where feasible – allows the Agency to integrate their input into its processes. The working group also provides a channel for Swissmedic to give patients and consumers a better insight into its tasks and competences. The rules and minutes of working group meetings are available to the public on the Swissmedic website.

Telematik/Informatik

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

- Swissmedic continued to pursue its strategic IT plan throughout 2014. The IT organisation, including IT tasks delegated to outside suppliers, was further reinforced, but still requires additional optimisations in the direction of more efficiency and effectiveness.
- The new IT architecture launched in 2011 was completed on schedule. Its core components have been implemented, and the technical targets for the IT strategy period have been reached. By mid-2015, the IT strategy will be reviewed and aligned with business strategy, which was revised effective end 2014.
- In connection with the negative headlines on the Federal Administration's public procurement of IT products and services, Swissmedic voluntarily invited the Federal Finance Committee to audit its procurement practices. The unqualified audit report validated and reinforced the procedures that Swissmedic has been consistently applying over many years.

Solution development

Swissmedic's attainment of its strategic objectives depends to a very large degree on implementation of the projects road map. Swissmedic needs to tap into the potential offered by IT tools if it is to remain efficient in the face of continually growing business volumes while relying on static personnel and financial resources. In addition to increasing the level of internal automation, investments continue to be focused on expanding eGovernment services as a paperless, interactive method of communicating with Swissmedic.

Activities

- The initial services available since 2014 under the new eGovernment portal infrastructure allow authorisation holders to share information with healthcare professionals and patients and track the status of authorisation procedures.
- Thanks to the new Internet-based electronic vigilance system (ElViS), doctors, pharmacists and pharmaceutical companies can now submit adverse drug reaction reports online. This solution complements the B2B gateway already in place for the automated exchange of reports with companies.
- Swissmedic has started systematically digitising incoming letter post. The Agency has also begun digitising business correspondence dossiers on medicinal products, having previously filed them in paper form. The new document management system is scheduled to go fully functional in 2015.
- Effective January, the previous staff information system was migrated to the current SAP platform (SAP HCM). The old system was deactivated.

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 Federal Office of Information Technology, Systems and Telecommunication (FOITT), and other service and software suppliers are brought in for the maintenance and further development of IT resources.

Activities

- Valuable lessons were learned during the first full year of operation of the new SAP ERP/CRM platforms. Technical performance bottlenecks were relieved with the help of manufacturer SAP AG. Further optimisations are planned for 2015.
- The workplace office automation software was upgraded to the latest release as part of the general overhaul carried out by the FOITT.
- The launch of the eGovernment portal solutions marked the start of full operations by the Swissmedic IT Service Center, which is also increasing its support capabilities for Swissmedic's external stakeholders.
- Over forty small projects were run to update IT resources to the latest product releases and further enhance business functionalities.

Organisation

Swissmedic Agency Council

Current as at Dezember 2014

Chairwoman: Beerli Christine, barrister

Conti Carlo, Dr. iur.
Dürr Markus, Dr. med. vet.
Fontannaz Anne-Sylvie, pharmacist
Obrist Reto, Prof. Dr. med.
Suter Peter M., Prof. Dr. med

Members of the Swissmedic Human Medicines Expert Committee (HMEC)

Current as at December 2014

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

Ordinary members

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Cerny Andreas, Prof. Dr. med.
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Advisory members

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Members of the Swissmedic Veterinary Medicines Expert Committee (VMEC)

Current as at December 2014

Chairman: Wüthrich Andreas, Dr. med. vet.

Ordinary members

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

Auditors

Swiss Federal Audit Office

Our staff – our capital

status December 2014

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Income statement

(in KCHF)

	2014	2013
Procedural fees and income further to art. 69 TPA	38,708	35,900
Levies on sales	41,315	41,095
Other income	52	48
Federal contribution	13,900	14,700
Other operating income	171	173
Loss of revenues from procedural fees	-6,614	-6,335
Net income	**87,531**	**85,581**
Services for third parties	-1,521	-1,625
Personnel	-63,679	-63,259
Rental, maintenance, energy, transport and insurance	-2,572	-3,022
Administration	-5,631	-4,894
IT	-8,898	-11,570
Other expenditure	-764	-445
Amortisation	-5,477	-3,447
Total operating expenditure	**-88,541**	**-88,262**
Operating income	**-1,010**	**-2,681**
Financial income	10	8
Financial expenditure	-231	-273
Financial result	**-221**	**-265**
Loss for the financial year	**-1,231**	**-2,946**

Statement of comprehensive income

(in KCHF)

	2014	2013
Loss for the financial year	**-1,231**	**-2,946**
Other income Actuarial losses (gains)	-33,513	-12,022
Total comprehensive income	-34,744	9,076

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

Balance sheet

(in KCHF)

	as at 31.12.2014	as at 31.12.2013
Cash and cash equivalents	1,082	3,447
Receivables from sales and services	17,488	19,334
Other receivables	0	1
Prepaid expenses	22	69
Current assets	**18,592**	**22,851**
Fixed assets	3,681	3,581
Immovable property	75,396	73,048
Intangible assets	9,833	10,473
Capital assets	**88,910**	**87,102**
Total assets	**107,502**	**109,953**
Commitments on sales and services	5,380	5,433
Other commitments	29,049	31,649
Deferred income and short-term provisions	3,547	3,646
Short-term commitments	**37,976**	**40,728**
Firm advances	10,000	10,000
Provisions for loyalty bonuses	2,590	2,364
Provision for pension fund commitments (net)	70,824	36,005
Long-term commitments	**83,414**	**48,369**
Loss	-1,231	-2,946
Reserves	1,241	4,187
Endowment capital	14,500	14,500
Accumulated actuarial losses	-28,398	5,115
Own capital	**-13,888**	**20,856**
Total liabilities	**107,502**	**109,953**

Product accounting

(in KCHF)

Products Product groups	Principal funding of products based on 2011-2015	Expenditure	Procedural fees income	Results
Legal foundations	Federal contributions	-5,508	0	-5,508
Technical standards	Fees	-3,855	0	-3,855
Total Standards products group		**-9,363**	**0**	**-9,363**
Information for the general public	Federal contributions	-5,029	8	-5021
Information for the therapeutic products sector	Fees	-2,253	277	-1,976
Total Information products group		**-7,282**	**285**	**-6,997**
Marketing authorisation	Fees	-33,486	20,113	-13,373
Licences	Fees	-12,054	9,909	-2,145
Total Market Access products group		**-45,540**	**30,022**	**-15,518**
Medicinal products vigilance	Fees	-8,530	308	-8,222
Medical devices vigilance	Federal contributions	-2,905	0	-2,905
Market monitoring of medicinal products	Fees	-7,500	785	-6,715
Market monitoring of medical devices	Federal contributions	-2,625	0	-2,625
Total Market Surveillance products group		**-21,560**	**1,093**	**-20,467**
Penal law	Federal contributions	-3,360	95	-3,265
Total Penal Law products group		**-3,360**	**95**	**-3,265**
Services for third parties	Fees	-1,434	601	-833
Total Services for Third Parties products group		**-1,434**	**601**	**-833**
Total products		**-88,539**	**32,096**	**-56,443**
Levies on sales				41,315
Federal contributions				13,900
Other income				221
Other operating expenditure		-3		-3
Financial result				-221
Loss				-1,231

Products funded mainly by the Confederation

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result-based product accounting
Legal foundations	-5,508	0	-5,508
Information for the general public	-5,029	8	-5,021
Medical devices vigilance	-2,905	0	-2,905
Market monitoring of medical devices	-2,625	0	-2,625
Penal law	-3,360	95	-3,265
Total products funded mainly by the Confederation	**-19,427**	**103**	**-19,324**
Total Federal contributions			**13,900**
Expenditure surplus			**-5,424**

Annual Report 2014

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swissmedic

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