swissmedic

Annual Report 2013

ANNUAL REPORT
2013

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The year 2013 was not marked by a single major event but by many developments that – taken separately – are not particularly striking.
On 1 January, the revised Ordinance on Fees entered into force. In the preceding months, Swissmedic had made every attempt to complete as many applications as possible. Our aim was to avoid giving the impression that delays on our part would contribute towards causing higher costs for the firms.
The development of our revenues nevertheless remained somewhat below expectations: it meant that Swissmedic closed the year with a loss of nearly CHF 3 million. The Agency has sufficient reserves to cover this shortfall, however. A deficit is again expected in 2014. After the entry into force of the second phase of the Ordinance on Fees at the beginning of 2015, Swissmedic will once more return to positive figures.

The implementation of the IT roadmap is on track in terms of costs and timing. In July 2013, the key PRIME project was completed. Operating under SAP systems, it ensures that important functions such as business and project management, resource management, order processing and the medicinal product database are now computerised.
These innovations above all benefit the Authorisation sector. The cost of the project, at CHF 13.1 million, were lower than the CHF 15.3 million budgeted, and the project duration of 2.6 years was only marginally above the planned 2.5 years.
With regard to respect for time limits, the Authorisation sector had achieved a record level of 97% for all applications submitted by mid-2013.

As a result of the temporarily higher workload caused by the implementation of the new IT systems, the level of completion within time limits dropped somewhat during the second half year, meaning that the annual average was only 90%. Respect for time limits regarding first applications for authorisation, which are a substantial aspect within market access, nevertheless improved in comparison with 2012, from 74% to 90%.

In September 2013, Swissmedic's service mandate was extended by the Federal Council for one year, until the end of 2015. If the revised Therapeutic Products Acts does not enter into force as planned on 1 January 2016, the service mandate will again be extended for a maximum of one year. The new Therapeutic Products Act foresees new management mechanisms for the Agency. In future, it is to be driven by means of strategic objectives that are proposed by the Agency council and approved by the Federal Council. The Agency Council is already in the process of revising and reworking the strategy for the coming years.
The Federal Council has moreover expanded Swissmedic's service mandate to include working jointly with the Swiss Agency for Development and Cooperation (SDC) or other non-profit organisations on development projects.
This new activity is only possible if the full costs of such work are financed, and if the Agency's independence and its full operational capacity are not affected. During 2013, negotiations took place with the Bill and Melinda Gates Foundation, which led to the signature on 22 January 2014, and as a first milestone, of a Memorandum of Understanding in the area of strengthening regulatory systems in Sub-Saharan countries.

The Therapeutic Products Act constitutes the basis for the activities of the Agency. The central aspects are the legal requirements relating to medicinal products that are placed on the Swiss market. After the constant increase to the requirements for the authorisation of medicinal products that took place during the second half of the last century, and which are now reflected in the currently applicable legislation, there has been a tendency over recent years to reduce the criteria for authorisation and to facilitate access to the market for medicinal products. This above all concerns the area of complementary medicine and medicinal products with known active pharmaceutical ingredients. In contrast, discussions are taking place on an international level regarding whether the requirements should be made more stringent for medical devices.
This development is the result of prominent cases where defective products (e.g. breast implants and artificial hip joints) have in some cases led to severe damage to health. It is the difficult task of legislators to identify the appropriate degree of regulation in all areas.
For the Agency, it is essential that the requirements are clear-cut. This is the prerequisite if the selected solution is to be applied effectively and efficiently. It is also important that the necessary attention is paid to developments on an international level. Even though medicinal products authorisations are still (mainly) issued on a national basis and medical devices are placed on the market in accordance with regional regulations, the therapeutic products industry is nevertheless global and needs regulations that are harmonised to the maximum

possible extent. Such harmonisation not only permits costs to be reduced, but also, and above all, means that products whose safety and efficacy have been positively assessed are made available to patients rapidly.

The four-year period in office for the Agency council, as defined by the regulations, ended in 2013. With the exception of Prof. Gerhard Schmid, the other six members stood for re-election. During a Session of the Federal Council on 13 December 2013, they were re-elected. Over the next four years, a gradual renewal of the Agency Council will take place. The successor to Gerhard Schmid will be elected in early summer 2014, and will of course take into consideration the guidelines with regard to female representation and to members from the different language regions.

In order to take into account the justified need for transparency, a list of the current vested interests of members of the Agency Council was published on the Swissmedic website in December 2013. Particular thanks are due to the outgoing member of the Agency Council, Prof. Gerhard Schmid, whose extraordinarily competent, equitable and refined conduct was of considerable value to the work of the Council.

Christine Beerli
Chairwoman of the Swissmedic Agency Council

In a globalised environment of competition, effective, good governance has become a factor for the choice of location, as the political and economic sectors are well aware. Swissmedic is an authority that has oversight in the areas of safety and the economy. Political directives that are formulated in the form of laws and ordinances and tat are applied consistently are at times criticised as being bureaucratic and disproportionate, and simplified approaches – less costly and more rapid – are being called for. Scientists, interest groups and the media are nevertheless creating increasing awareness among the public about the risks arising from global procurement and manufacturing chains as a result of pricing pressure or supply bottlenecks, the risks of nanotechnology, the risks related to antibiotics in foods, risks regarding medicines obtained from the Internet, false claims to healing properties, and doubts about the quality of clinical trials, etc. Swissmedic is successful or effective if it can guarantee that only high-quality, safe and effective therapeutic products are placed on the market. Swissmedic is efficient if it is able to maintain this situation on a daily basis with the resources it has available – meaning via a business process model with measurable objectives. In this challenging environment, a therapeutic products authority cannot seek praise from its stakeholders; one the one hand, it must assess the impact of policies and on the other, it must earn respect when working with the actors involved. Thanks to transparency, a willingness to enter into discussions, and the political independence granted to the Agency, this is possible.

The pharmaceutical industry association has stressed the "pay for performance" principle during the discussions on an increase to fees. In this connection, Swissmedic offered a new option for authorisation: if prior notification is given of an application for a new active pharmaceutical ingredient, Swissmedic can plan and manage its teams of experts in a way that permits the internal processing time to be reduced by 20 percent. The requirements regarding studies and the extent of the assessment remain unchanged. This possibility has not been used as widely as Swissmedic had expected based on the discussions with the firms: in 2013, eleven requests for this procedure to be applied were received.

The Federal Administrative Court took a somewhat surprising decision in 2011, stating that Swissmedic could no longer make it mandatory for the firms to public their medicinal product information in a privately managed directory. This judgement led to fears of a scattering of the information, which is an essential factor for the correct, safe use of medicinal products. Swissmedic therefore decided to create its own publication platform for information related to all authorised medicinal products, and for both healthcare professionals and patients. The platform was made available to the general public and to healthcare professionals on 1 January 2013, and was completed by the middle of the year. It means that for the first time, all the texts approved by Swissmedic are available to the public in German and French (and the patient information also in Italian) for the first time. The data can be obtained free of charge by data refiners and completed with further data such as prices, codes, speciality list details, etc. and further processed or integrated within software tools. Since this further processing requires a relatively considerable amount of resources, various stakeholders expressed the wish that Swissmedic should also carry out the data refinement.

Swissmedic nevertheless deliberately restricts itself to its own areas of responsibility, and thus to providing a platform for publishing information on authorised medicinal products. As a result of parliamentary motions, Swissmedic carried out a partial revision of the Medicinal Products Authorisation Ordinance (AMZV) and the Ordinance on the simplified authorisation of medicinal products and the authorisation of medicinal products by the notification procedure (VAZV) in 2011 and 2012, and the revised versions came into force on 1 January 2013. The main objective of the revision was to avoid, to the greatest extent possible, the risk of confusion related to dispensing and use by imposing various measures in the area of product names and with regard to the texts and the design of packaging for medicinal products. During a process that was intensive for both parties, Swissmedic and the stakeholders concerned tackled the implementation of the new provisions at several workshops.On the part of Swissmedic, the issue was to fully respect the political will behind the revision, to provide detailed information to the authorisation holders on the related consequences of the revisions to the ordinances, and to use the Agency's discretionary powers in a way that ensured that the authorisation holders were not faced with an unnecessary burden. Adjusting the corresponding Administrative Ordinances and the publication of a Frequently Asked Questions document has provided clarity for all concerned regarding the implementation of these changes.

More clear, more networked and more mobile: this describes the new Swissmedic website after this year's overhaul. The objectives included making the considerable amount of information easier to find, enhanced user-friendliness thanks to functions that are in keeping with today's user habits, and a more modern design. Before launching the project, user needs were identified, the site navigation was changed to a dropdown menu, and a new search function was integrated. The site can now be accessed using any type of mobile device. With this update, Swissmedic is laying the foundations for continual improvement to its Internet services, and targeting the content more appropriately to the various types of user.

The laboratory on Erlachstrasse was no longer in compliance with zoning regulations, and the intended modernisation work included bringing together the two existing laboratory locations. Discussions with the University and authorities with laboratory facilities resulted in no potential synergies. A building project was initiated and developed in terms of timeline and budget framework. The authorisation sector moved into the new laboratory and office building on Freiburgstrasse in September, and the laboratory was able to function without interruption during the move. For the interior fixtures and fittings, and in addition to the requirements specific to the laboratory, the principles of transparency, teamwork, maximum IT support, and flexibility for future developments were all given considerable emphasis during the planning and building.

Dr Petra Dörr, Head of Communication and Networking, was appointed as the Deputy Director to replace Dr Hans-Beat Jenny as of 1 January 2013. In addition to continuing as the head of the Licensing Sector, Dr Jenny will continue to handle special topics designated by the Director, such as the further development of the quality management system and questions relating to the interface between Swissmedic, the Federal Office of Public Health and the Federal Food Safety and Veterinary Office.

Jürg H. Schnetzer
Director of Swissmedic

THE CENTRAL WEB PLATFORM CONTAINING MEDICINAL PRODUCT INFORMATION FOR HEALTHCARE PROFESSIONALS: OPERATIONAL SINCE JANUARY 2013

THE PRODUCT INFORMATION FOR HEALTHCARE PROFESSIONALS AND FOR PATIENTS IS A CENTRAL ELEMENT FOR THE AUTHORISATION OF A MEDICINAL PRODUCT. IT PROVIDES BOTH HEALTHCARE PROFESSIONALS AND PATIENTS WITH THE INFORMATION REQUIRED IN ORDER TO USE A MEDICINAL PRODUCT CORRECTLY AND SAFELY.

A complete, up-to-date list of the product information for all authorised human medicinal products in Switzerland, which can be used by both professionals and the public, is essential in order to guarantee the safety of medicines.

As the result of an appeal on the part of a pharmaceutical company, the Federal Administrative Court decided on 17 June 2011 that Swissmedic could no longer make it mandatory for firms to have the information for healthcare professionals and patient information published via a private provider, at their own cost. It soon became evident that this judgement would lead to the dispersal of the product information over various platforms. Some authorisation holders no longer published their texts in a directory aimed at completeness, such as the Medicines Compendium of Switzerland, but in those of various providers. A few of them even published the texts on their own website alone.

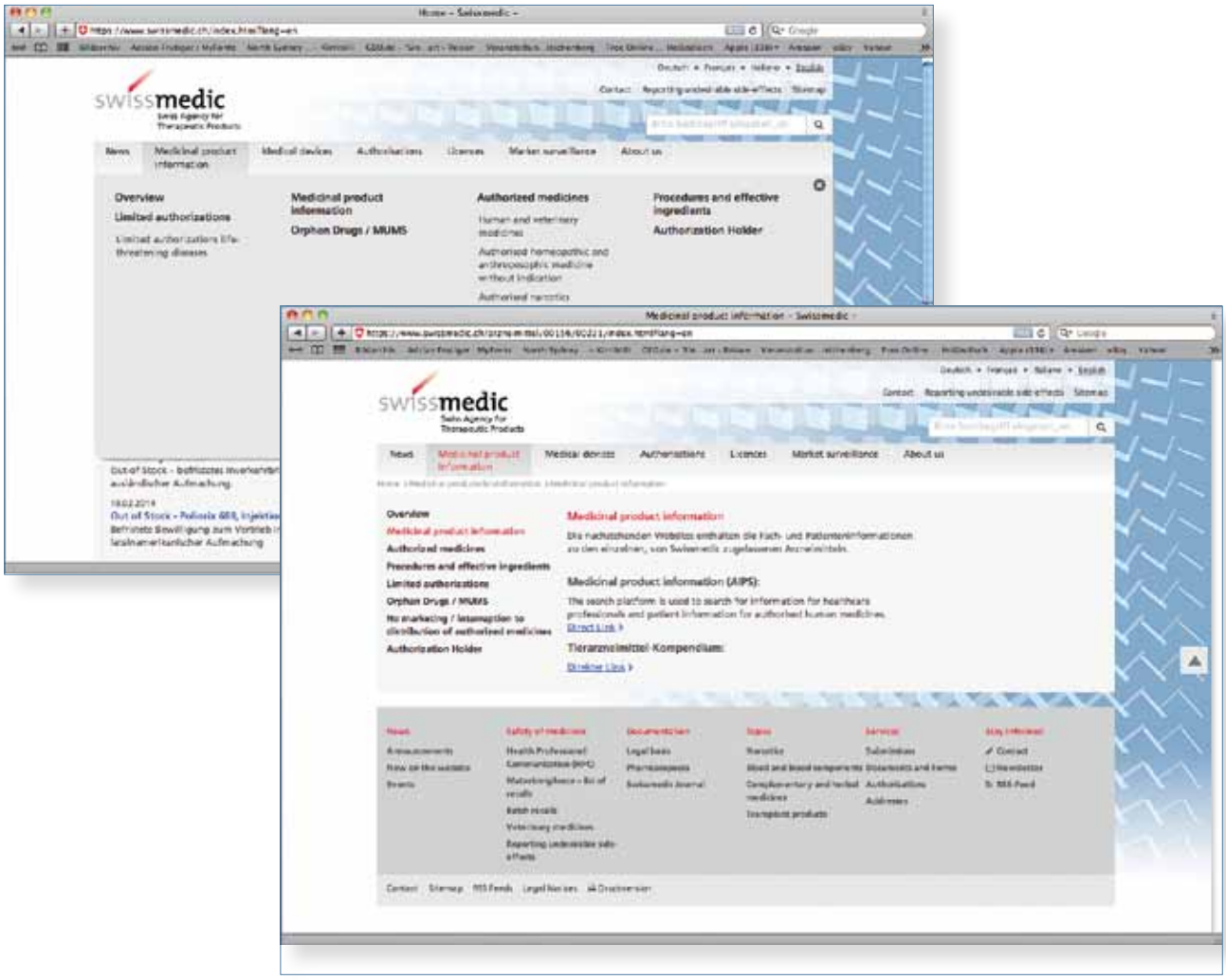
At the end of 2011, and for reasons of the safety of medicines, Swissmedic therefore decided to make available an appropriate, electronic directory of its own.

The task of creating this Swissmedic product information platform (AIPS) was attributed to a provider within the framework of a GATT / WTO call for tender. The new platform was launched, as planned, on 1 January 2013.

The AIPS platform consists of a freely accessible search platform (information system) and a secure area for registered, authorised authorisation holders to upload and release the texts (publication system). In addition, the basic data is available to third party providers of electronic compendiums of therapeutic products for download, in a standard, widely used machine-readable data format (xml). This means that the data can be used without technical obstacles for other purposes (e-books, apps, print versions, inclusion in internal information systems) and can be enriched by additional technical data such as codes, prices or details of whether a product is covered by health insurance.

All three applications can be accessed via the Swissmedic website. The AIPS platform can also be reached directly at www.swissmedicinfo.ch. Searches can be made by product names, active pharmaceutical ingredients, authorisation holders or ATC code; a full text search is also possible. The content of the directory is limited to information texts for healthcare professionals and patients relating to medicinal products currently approved by Swissmedic.

In order for healthcare professionals to be better informed of safety-relevant findings, medicinal products that have been the subject of a Healthcare Professional Communi-



cation (HPC) in the last twelve months are flagged, and linked to the corresponding page of the Swissmedic website. It is also possible to select texts that have been newly uploaded during the last three months and those that have been modified during the last four weeks, using the "New texts" and "Modified texts" buttons respectively.

Fulfilling the legal requirement to publish medicinal product information and ensuring that the latest texts are always uploaded and the translations are correct are aspects that remain the responsibility of the authorisation holders.

The authorisation holders were therefore urged to check that the latest versions were uploaded and to provide any missing product information without delay. They were also required to provide, in future, Italian versions of the patient information. Since January 2013, the authorisation holders have been required to publish all new and modified product information texts via the AIPS platform. Publication on the platform is a prerequisite for the first authorisation of a medicinal product.

By the end of May 2013, around 80% of the texts for all authorised medicinal products for which publication is mandatory had been uploaded to the AIPS publication platform, and by the end of November 2013, the platform was over 99% complete.

Thanks to the AIPS platform, Swissmedic is making available, for the first time and for both healthcare professionals and patients, a complete directory of the information texts for all authorised medicinal products. The texts are available in German, French, and also – for patient information only – in Italian.

BIOSIMILARS – SIMILAR BUT NOT IDENTICAL

BIOSIMILARS ARE MEDICINAL PRODUCTS MANUFACTURED USING BIOTECHNOLOGY WITH RECOMBINANT PROTEINS AS THEIR ACTIVE PHARMACEUTICAL INGREDIENT, AND WHICH HAVE A SUFFICIENT DEGREE OF SIMILARITY WITH A REFERENCE PRODUCT THAT HAS ALREADY BEEN AUTHORISED. THEIR OWN DOCUMENTATION CITES THE REFERENCE PRODUCTS, AND THE PRODUCT MAY – IF THE FIRST APPLICANT PROTECTION (DOCUMENT PROTECTION) FOR THE REFERENCE PRODUCT HAS EXPIRED – BE SUBMITTED TO SWISSMEDIC WITH A VIEW TO AUTHORISATION.

Swissmedic published its first instructions for the authorisation of similar biological medicinal products (biosimilars) in 2008, and the Agency has authorised a total of eight products with the three recombinant proteins erythropoietin, somatropin and filgrastim in accordance with them.

After five years, an adjustment of the instructions in line with the current status of science and technology was called for. In doing so, it was also necessary to include findings with regard to new categories of similar biological medicinal products such as those with monoclonal antibodies as their active pharmaceutical ingredients. Early in the summer of 2013, an internal working group had drawn up a first draft. At a consultation meeting that included representatives from industry, the stances of manufacturers of originator products and biosimilars were duly noted. After the management of Swissmedic approved the Administrative Ordinance / Instructions, Authorisation of similar biological medicinal products (Biosimilars) in December 2013, it came into force on 1 February 2014.

As is the case for Swissmedic's other Administrative Ordinances, the instructions relating to biosimilars are primarily intended for employees of the Agency, and serve to assist them in applying – in a uniform and equitable way – the legal provisions for the authorisation of similar biological medicinal products in accordance with Article 12, paragraph 4, letter d) in connection with Article 12, paragraph 5 of the Ordinance on the simplified authorisation of medicinal products and the authorisation of medicinal products by means of the authorisation procedure (VAZV; 812.212.23). Publishing the instructions is intended to provide transparency towards applicants regarding the requirements to be met in accordance with Swissmedic's practices.

Providing scientific proof of a sufficient degree of similarity encompasses the entire physico-chemical and biological characterisation of the candidate biosimilar and of the reference product; comparative, targeted preclinical and clinical data; and a critical assessment of the results. The possibility of submitting reduced mandatory documentation with regard to the pharmacological and toxicological tests (Preclinical, CTD Module 4) and clinical tests (Clinical, CTD Module 5) may be granted if the quality documentation (CTD Module 3) demonstrates sufficient similarity to the reference product.

The comprehensive comparability studies on the candidate biosimilar's quality, biological activity, safety and efficacy must be carried out using a reference product obtained from the Swiss market or a comparator product with the same active pharmaceutical ingredient obtained from the European market and that has been authorised there. In the latter case, the equivalence (sufficient similarity) between the European comparator product and the Swiss reference product must be demonstrated.

The fundamental principles of the current guidelines by the European Medicines Agency (EMA) are again used and implemented to the greatest possible extent. Adaptations specific to Switzerland are nevertheless necessary as a result of the different legal basis. For example, and unlike in the EU, low molecular weight heparins – which are not manufactured by means of recombinant technology – cannot be authorised in Switzerland on the basis of reduced documentation. In addition, Swissmedic requires the equivalence of the European comparator product and the Swiss reference product to be proved if the candidate biosimilar is compared with a product that is authorised in the European Union.

The naming of biosimilars in Switzerland is regulated in the same way as in the EU. Applicants may choose between a fantasy name and the name of the active pharmaceutical ingredient linked to the company name.

The active pharmaceutical ingredient of a biosimilar and its reference product is essentially the same biological substance. The authorisation of a biosimilar confirms that the difference between the biosimilar and its reference product has no effect on safety or efficacy. The authorisation by Swissmedic does not, however, make any statement regarding whether a biosimilar can be used interchangeably with the reference product. Such a decision is taken by the doctors in charge of the case.

ENHANCED MONITORING OF MEDICAL DEVICES

BACKGROUND

The so-called "PIP scandal" was discovered by the French authorities in March 2010. The French manufacturer Poly Implant Prothèse (PIP) had been placing non-compliant breast implants on the market for some years. In concrete terms, the firm had been using inexpensive industrial silicone to fill the implants. Over 100,000 women worldwide were concerned, of which 300 were in Switzerland. Even though this case was one of deliberately deceiving the conformity assessment bodies (CABs) and supervisory authorities and thus constituted a criminal act (in the meantime, the head of the firm concerned has been sentenced by a court), it also revealed weaknesses in the regulation and surveillance mechanisms of the medical device market that were valid at the time.

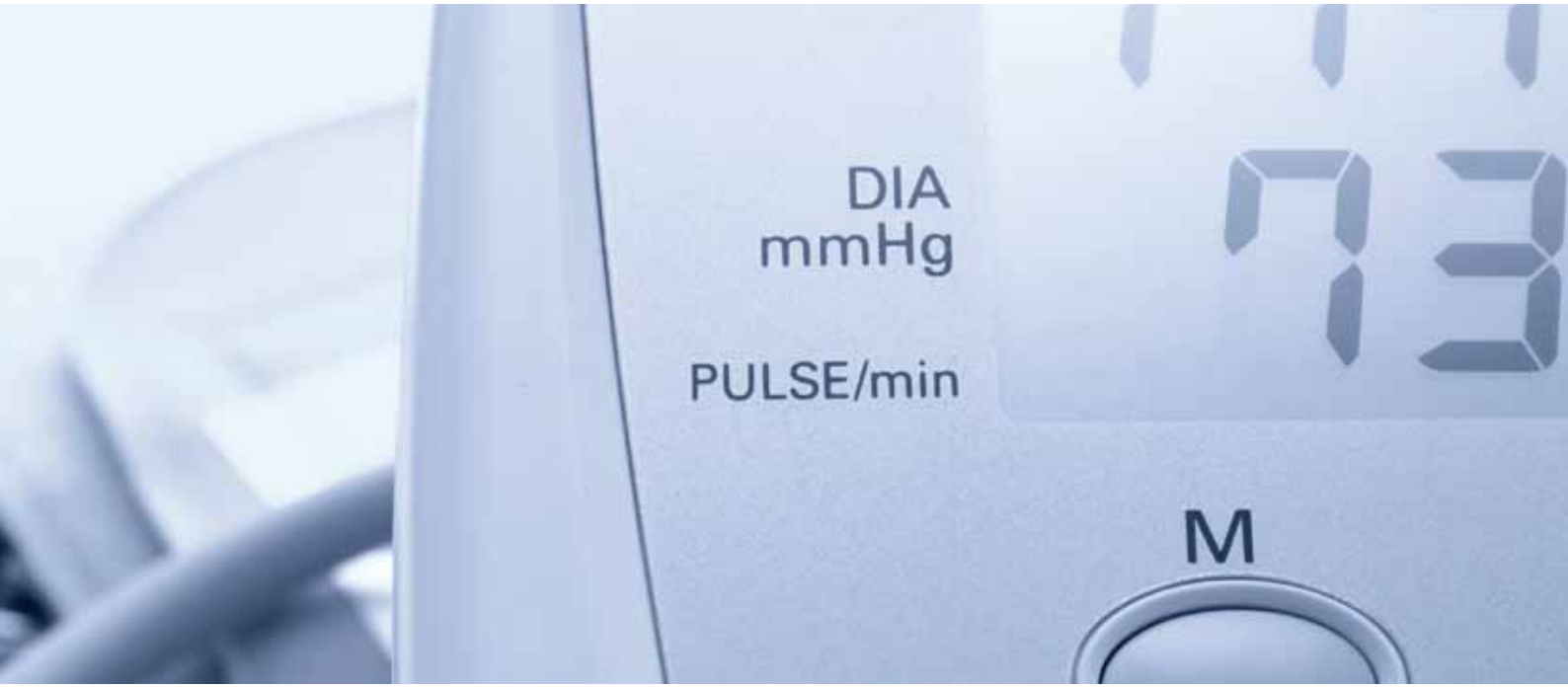
Switzerland is integrated in the European market in the area of medical devices. The range of devices available – around 500,000 different products – is huge and includes virtually all resources other than medicinal products that are used in medicine. The spectrum includes products for the general public such as blood pressure manometers or fever thermometers, diagnostic devices, medical apparatus and software, but also a large number of implants such as artificial joints or heart pacemakers.

For a medical device to be placed on the market, and unlike the procedure for medicinal products, conformity must be proved without this being assessed by the authorities. Conformity testing is basically carried out by the manufacturer, which brings in a CAB for the purpose. In concrete terms, this means that fundamental requirements and technical standards that are valid throughout Europe must be fulfilled. The CABs are accredited, appointed and assessed by national authorities (in Switzerland by Swissmedic and the Swiss Accreditation Service).

INCREASED SURVEILLANCE OF THE CABS

The surveillance of the CABs on the part of the authorities has been intensified throughout Europe since 2012. Before this began, assessment criteria to be applied uniformly were established in order to achieve improved harmonisation of the requirements. As a result, assessments of the CABs were carried out in every EU Member State and all Contracting States concerned, meaning also in Switzerland which is included in the European market as a result of the bilateral contracts.

In 2013, and together with the Swiss Accreditation Service (SAS), Swissmedic inspected the CABs operating in Switzerland and also took part in international joint assessments. During these missions, international teams of inspectors assessed the performance of the national supervisory authorities in Europe. These more stringent inspections



have already led to several of the around 70 European CABs being required to cease their activities or to take measures to improve their quality assurance.

NATIONAL AWARENESS CAMPAIGN REGARDING PRODUCTS FOR THE GENERAL PUBLIC

With the increase of commerce via the Internet, an increasing number of medical devices are also marketed electronically. In September 2013, Swissmedic wrote to over 100 providers of such products, informing them of the valid legal basis for the distribution and dispensing of medical devices to the general public. In particular, the attention of those responsible was drawn to the fact that products such as pregnancy tests, fever thermometers, blood pressure manometers or blood glucose meters were not normal consumer goods but medical devices and thus subject to an additional duty to provide information and to surveillance measures. The availability of specialised advice must therefore be guaranteed so that if needed, the customer can obtain information on the characteristics of the product, on its correct use, and if appropriate on whether specific products are appropriate for the treatment or the diagnosis of the individual concerned.

Providers must moreover ensure that only those products with the required conformity assessment and CE marking are made available, and they must be in a position to withdraw the products from the market in the case of safety-relevant problems. This awareness campaign has proved effectie, since many of the recipients of Swissmedic's communication will cease to distribute medical devices or will improve their quality assurance system and the expert advice provided.

AN INCREASE TO DELIMITATION ISSUES WITH REGARD TO PRODUCTS FOR THE GENERAL PUBLIC

Medical devices also include substances used in medicine whose main effect in or on humans is not pharmacological but physical. This includes, for instance, bulking agents in slimming products, laxatives containing macrogol, products for flatulence containing simeticone, or warming poultices.

Substances that have a pharmacological action may be contained in medical devices if they have only a supporting effect, such as medication-coated implants. As a result of the more stringent regulation of advertising for medicinal products, among other measures, an increasing number of products that are on the borderline with medicinal products are being placed on the market as medical devices.

Unlike the distribution channel for non-prescription medicinal products, the dispensing of non-prescription medical devices is not restricted to pharmacies and druggists. If the corresponding requirements are met – above all regarding advice and traceability – the devices may also be marketed by wholesale distributors or via the Internet. This leads to enquiries, complaints and clarifications that require considerable resources, including international mutual assistance procedures.

FACTS AND FIGURES

BUSINESS STATISTICS AS AT END 2013

Firms with a Swissmedic licence

The licences below were attributed to a total of 1,098 firms.	
Manufacturing of medicinal products: Manufacturing of medicinal products (with a licence for wholesale distribution)	245
Manufacturing of medicinal products (without a licence for wholesale distribution)	101
Wholesale distribution of medicinal products: Import of medicinal products	548
Wholesale trade of medicinal products	827
Export of medicinal products	436
Foreign trade with medicinal products	352
Laboratories with a Swissmedic licence to carry out microbiological or serological tests on blood, blood products or transplants for the identification of transmissible diseases, with a view to transfusion, transplant or processing	39
Blood transfusion services or hospitals with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	34
Controlled substance Establishment licences for handling controlled substances	351
Laboratories with FOPH recognition Microbiological and serological laboratories inspected by Swissmedic	94

NUMBER OF AUTHORISATIONS BY TYPE OF PRODUCT AS AT END 2013

Human medicinal products (original, generic, co-marketing medicinal products)	4,991
Phytopharmaceuticals	655
Homeopathics	668
Anthroposophics	370
Ayurvedic medicinal products	1
Tibetan medicinal products	6
Bacterial and yeast products	27
Vaccines	74
Blood products	93
Radiopharmaceuticals	33
Biotechnologicals	326
Veterinary medicines	698
Allergens	477
Transplant products	1
Generators	4

NUMBER OF AUTHORISATIONS BY DISPENSING CATEGORY AS AT END 2013

Dispensing category / Authorised medicinal products		
A	Dispensed once only on medical or veterinary prescription	1,792
B	Dispensed on medical or veterinary prescription	3,803
B/C	Dispensed on medical or veterinary prescription / after expert advice from medical personnel	34
B/D	Dispensed on medical or veterinary prescription / after expert advice	43
C	Dispensed after expert advice from medical personnel	604
C/D	Dispensed after expert advice from medical personnel / Dispensed after expert advice	23
D	Dispensed after expert advice	1,961
E	Dispensed without expert advice	164
Total		**8,424**

HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINAL PRODUCTS WITHOUT INDICATION AUTHORISED BY THE NOTIFICATION PROCEDURE AS AT END 2013

Single products	11,327
Combined products	1,124

SWISSMEDIC AS AN AGENCY

Staff headcount at year end	435
Full-time positions at year end	358.6
Total women	56.3%
Total men	43.7%
Staff working part time (part time is defined as working up to 89% of a full-time post)	43.2%
Average age of staff members	46 years
Women	44.5 years
Men	48 years
Language distribution:	
German	87.0%
French	11.2%
Italian	1.8%
Rhaeto-Romanic	0.0%
Staff turnover rate	4.5%

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.

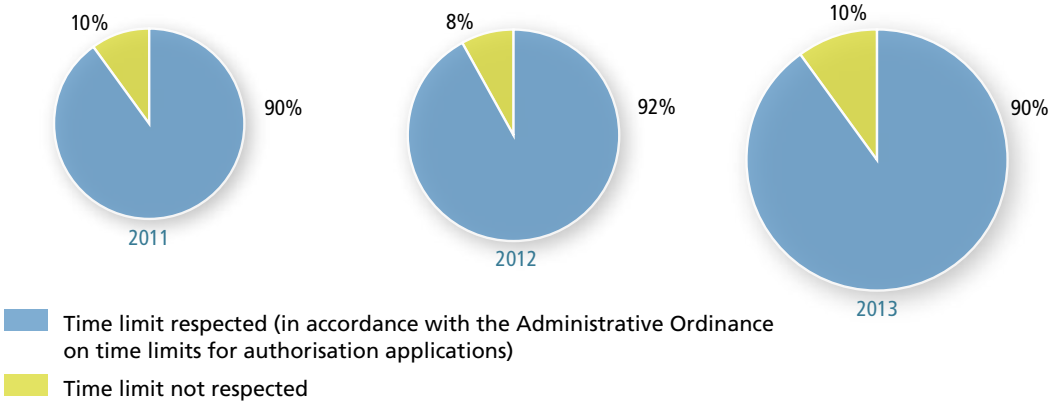
Activities

- The year 2013 was marked by the implementation of a new software system in June. This new SAP-based IT system replaced the old data management system Merlin and also the main resource management tool for the Marketing Authorisation sector. Besides the project work, all the employees had to be trained to use the new system. Overall, this caused delays in the processing times, especially in the transition period. For that reason, respect for the time limits was better during the first half year than the second half year, following the implementation of the new IT system. Overall, the time limits for all completed applications (for human or veterinary use) were respected in 90% of cases, which was lower than the 92% achieved during the previous year. In contrast, respect for time limits concerning first applications for innovative products (ZL1A) was considerably better (at 88% compared with 73% the previous year), as was the case for first applications for non-innovative products (ZL1 B – 93% compared with 75%).
- There were also several revisions of important regulatory processes:
  - Simplification of the process of Art 13, TPA: less documentation need be sent by applicants, faster processing at Swissmedic.
  - Implementation of the provisions of the revised Ordinance on the marketing authorisation of medicinal products (AMZV). The aim is to provide clearer texts on the outer packaging of medicinal products in order to reduce the risk of confusion or duplicated medication.
  - Revision of the instructions for biosimilars. This has been adapted to reflect the current status of science and technology: the particular characteristics of monoclonal antibody biosimilars were taken into consideration.
  - Revision of the instructions relating to the development of known active pharmaceutical ingredients: Swissmedic no longer takes a decision regarding generic status. This adaptation was related to the fact that the Therapeutic Products Act does not provide Swissmedic with a legal basis for taking a decision on whether a particular product fulfils the criteria of a generic product as laid down in the Health Insurance Act. The former instructions relating to the development of generic products has become obsolete and are thus replaced by those relating to known active pharmaceutical ingredients. Several meetings with industry stakeholders were held during the process of these revisions
- The development of the new publication platform for medicinal product information was highly successful; at the end of the year over 99% information texts for products authorised for the Swiss market had been published via this platform.
- The first applications using the new marketing authorisation procedure with prior notification were received. The procedure is 20% faster than the normal first authorisation procedure.
- 25 Scientific Advice Meetings, 20 Presubmission Meetings und 24 Clarification Meetings were held in 2013. In addition, eight Regulatory Round Table meetings or specific workshops were carried out with the relevant stakeholders.
- The assessment of nonclinical and quality documentation of clinical trial applications was carried out for 14 first-in-man studies.

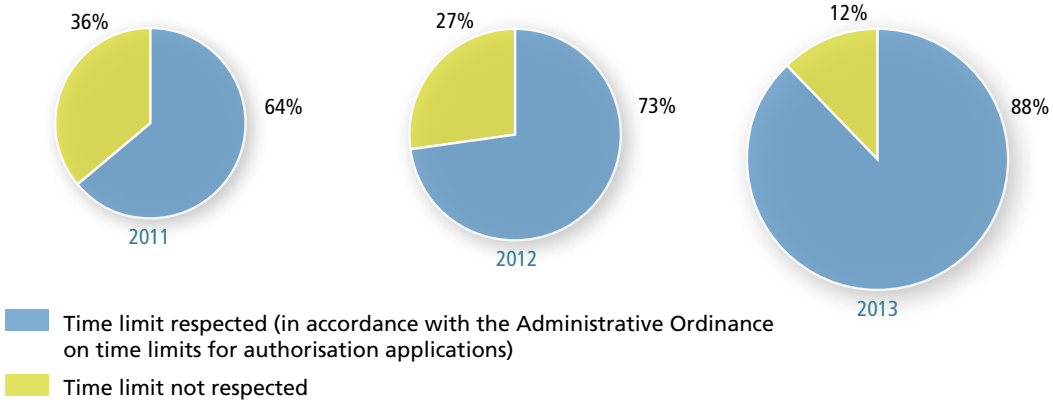
TIME LIMITS

For 2013, 90% of all applications were completed within the prescribed time limits. For innovative medicinal products, the time limits were respected in 88% of cases, and for non-innovative medicinal products, the figure reached 93%. The launch of the new IT system in June impacted the time limits for completing certain administrative applications in particular (primarily variations requiring notification).

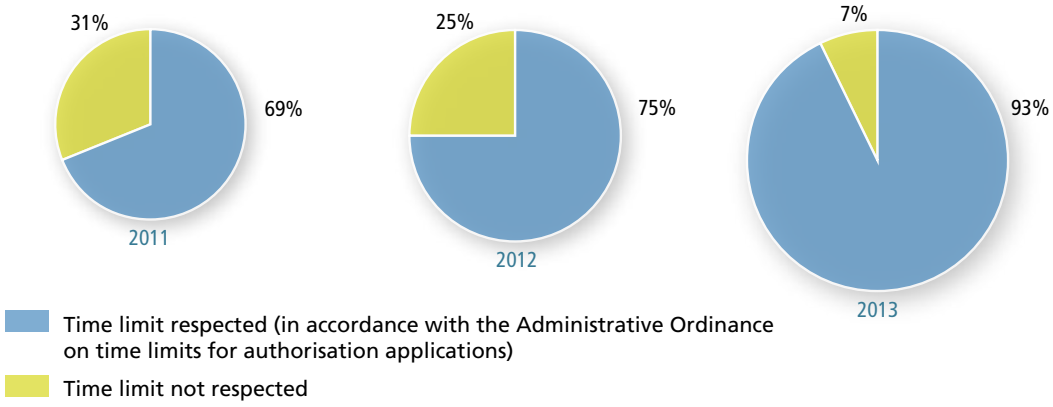
Time limits respected for **all** completed applications for human and veterinary medicines



Time limits respected for first authorisations of **innovative** human and veterinary medicinal products (ZL1A)



Time limits respected for first authorisations of **non-innovative** human and veterinary medicinal products (ZL1B)



AUTHORISATION OF HUMAN MEDICINAL PRODUCTS*

FIRST MARKETING 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 2013, Swissmedic received 260 applications for first authorisations of innovative medicinal products and major variations thereto, and it was possible to complete 215 of them.
- Of the 26 medicinal products with new active pharmaceutical ingredients that were authorised for the first time, it was possible to complete 4 by means of the fast-track procedure.
- A total of 313 applications for non-innovative first authorisations were completed: 49 of them concerned co-marketing products.
- In 2013, 77 applications to take Article 13 of the Therapeutic Products Act (TPA) into account were received. Of them, 63 were processed under Article 13, TPA and 60 were approved.

HUMAN MEDICINAL PRODUCTS WITH A NEW ACTIVE PHARMACEUTICAL INGREDIENT AUTHORISED IN 2013

	ACTIVE PHARMACEUTICAL INGREDIENTS	PRODUCT NAME	APPLICATION
Alimentary tract	Alogliptinum	Vipidia®, Film-coated tablets	Diabetes mellitus type 2
	Insulin Degludec	Tresiba Penfill®, solution for injection	Diabetes mellitus in adults
	Insulin Degludec	Tresiba FlexTouch®, solution for injection	Diabetes mellitus in adults
	Linaclotidum	Constella®, capsules	Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation
Anti-infectives	Ceftarolinum fosamilum	Zinforo™, powder for concentrate for solution for infusion	- Complicated skin and soft tissue infections - Community-acquired pneumonia
	Elvitegravirum, Cobicistatum, Emtricitabinum, Tenofovirum, Disoproxilum	Stribild®, film-coated tablets	Treatment regimen for antiretroviral-naïve adults with HIV-1 infection
	Rilpivirinum	Edurant®, film-coated tablets	In combination with other antiretroviral medicinal products to treat an HIV-1 infection
Eyes	Bromfenacum	Yellox®, eye drops	Post-operative eye inflammation following cataract removal in adults
Dermatologicals	Ingenolmebutate	Picato®, gel	Actinic keratosis

* The performance indicators regarding marketing authorisations are shown on page 31.

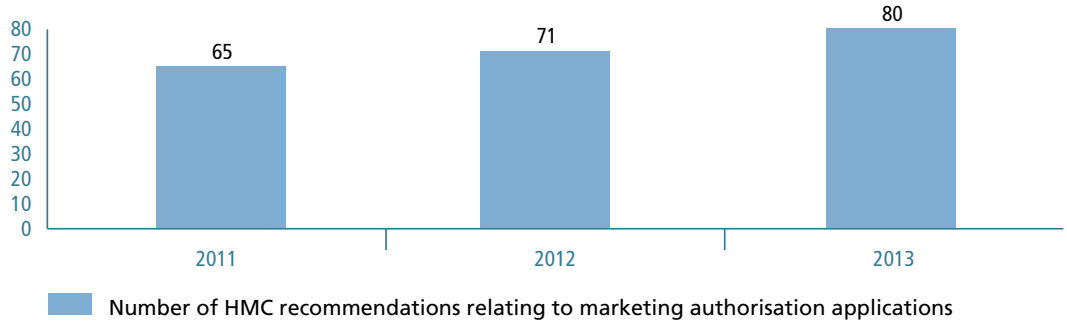
Heart and circulation	Levosimendanum	Simdax®, concentrate for solution for infusion	Acute decompensated severe chronic heart failure, if intravenous diuretics are not sufficient and inotropics are indicated
	Riociguat	Adempas®, film-coated tablets	Inoperable chronic thromboembolic pulmonary hypertonia
Immune system	Teriflunomidum	Aubagio®, film-coated tablets	Relapsing / remitting multiple sclerosis
	Tofacitinibcitrate	Xeljanz®, film-coated tablets	As monotherapy or combination therapy in adult patients with moderate to severe active rheumatoid arthritis who were non-responsive to a previous treatment with methotrexate or who did not tolerate methotrexate
Malignant tumours	5-aminolaevuline acid	Alacare®, plasters	Actinic keratosis of the face and scalp
	Bosutinibum	Bosulif®, film-coated tablets	Chronic myeloid leukaemia
	Brentuximabum Vedotinum	Adcetris®, powder for solution for infusion	- Relapsed or refractory CD30+ Hodgkin lymphoma - Relapsed or refractory systemic anaplastic large-cell lymphoma
	Enzalutamidum	Xtandi™, soft capsules	Prostate carcinoma
	Pralatrexatum	Folotyn®, solution for infusion	Peripheral T-cell lymphoma, after at least one previous therapy
	Regorafenibum	Stivarga®, film-coated tablets	Second-line therapy for metastised colorectal carcinoma
	Trastuzumabum Emtansinum	Kadcyla®, powder for concentration for solution for infusion	HER2-positive, inoperable, locally advanced or metastised breast cancer
	Vismodegibum	Erivedge®, capsules	Advanced basal cell carcinoma
Musculoskeletal system	Toxinum botulinicum typum A	Xeomin®, powder for solution for injection	- Blepharospasm - Torticollis spasmodicus - Spasticity of the upper extremities following stroke in adults
Herbal medicine	Cannabis sativae folii cum flore extractum spissum	Sativex®, spray for use in the buccal cavity	Symptomatic improvement in patients with moderate to severe spasticity as a result of multiple sclerosis
Psychiatry	Lurasidonum	Latuda®, film-coated tablets	Schizophrenia
Respiratory tract	Aclidinium bromidum	Eklira® Genuair®, powder for inhalation	Chronic obstructive lung disease
Transplants	Keratinocytes	EpiDex®, epidermal equivalent autologous	Persistent venous or arteriovenous leg ulcer, in adults

SWISSMEDIC 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

- In 2013, the HMEC advisory panel met 12 times and issued 80 recommendations regarding marketing authorisation applications. The majority of them concerned new authorisations or additional indications for medicinal products.
- In addition, 31 expert reports for the purpose of full assessments and 55 reports on individual aspects were provided by the HMEC experts.



EXTENSIONS AND DISCONTINUATIONS

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

Activities

- A total of 1,414 applications to extend the marketing authorisation were submitted, and 1,301 applications were completed.
- In addition, 356 applications for the discontinuation of a product and 26 applications for the discontinuation of a dosage strength of a product were received in 2013; 292 applications for the discontinuation of a product and 23 for the discontinuation of a dosage strength were completed.

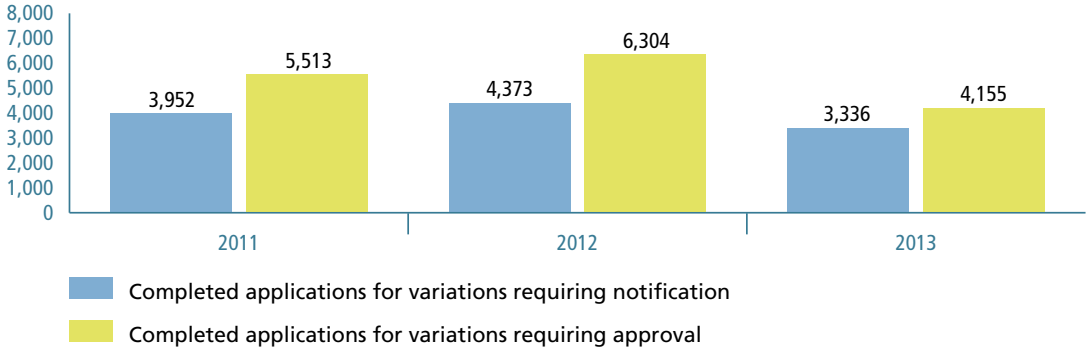
VARIATIONS REQUIRING APPROVAL AND VARIATIONS REQUIRING NOTIFICATION

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

(As a result of the entry into force of the new Ordinance on Fees and the new IT system, a comparison with the figures for the previous year would not be meaningful.)

- A total of 4,198 variations requiring notification were submitted in 2013; 4,155 notifications were completed.
- Regarding modifications requiring approval, 3,732 applications were submitted and 3,336 were completed.

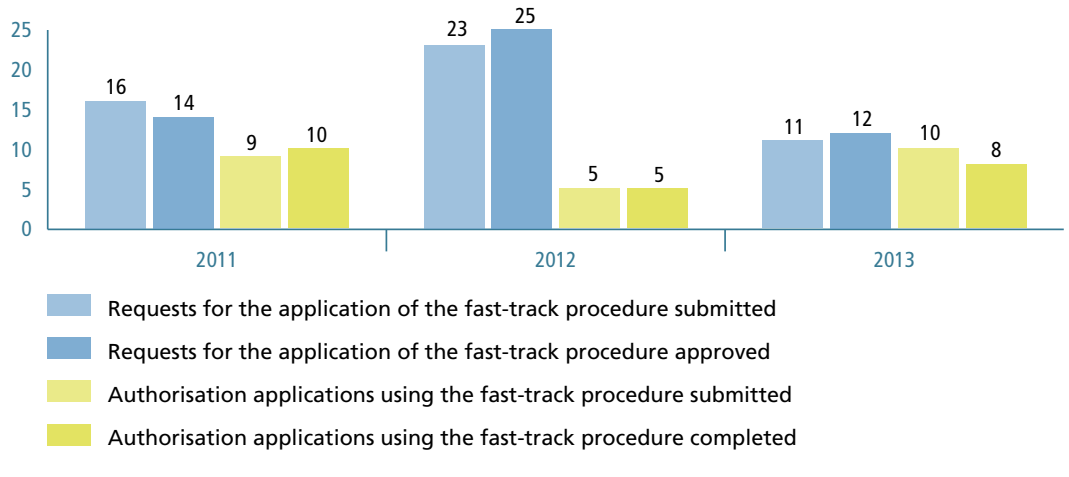


THE FAST-TRACK AUTHORISATION PROCEDURE

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 2013, a total of 11 requests for the fast-track procedure to be applied were submitted, and 12 fast-track requests were approved.
- A total of 10 authorisation applications using the fast-track procedure were submitted, and 8 were completed.



THE PROCEDURE WITH PRIOR NOTIFICATION (PPN)

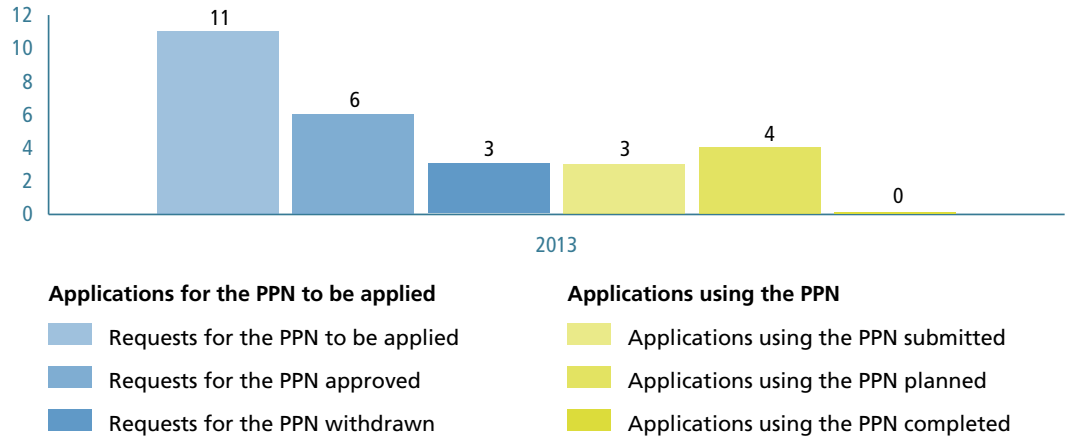
Since 1 January 2013, Swissmedic has provided applicants with the possibility of having the assessment carried out 20% more rapidly, provided that they give prior notification of the submission date of their application (5 – 8 months in advance). For this to be accepted by Swissmedic, the following conditions 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 eleven requests for the PPN to be applied, six were approved. Three requests were withdrawn, and two are currently being processed.
- In 2013, three authorisation applications using the PPN were submitted. No application has been completed as yet. Four 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 41 applications were submitted for the recognition of the orphan drug status, and the status was granted for 32 products.
- Five products were newly authorised as orphan drugs. Further orphan indications were approved for two previously authorised orphan drugs. Orphan drug status was withdrawn for one product, and for two others, the status was discontinued.

PAEDIATRIC MEDICINAL PRODUCTS

Since the entry into force of the 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 relevant 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.

Activities

- The Ordinance on Fees, valid as of 1 January 2013, foresees a reduction of 90% for the authorisation of medicinal products with exclusively paediatric indications and for major variations therefore. Major variations include, for example, an additional indication, dosage recommendation or dosage strength. This measure is intended to encourage developments in the area of paediatric medicines.
- The submission of a paediatric investigation plan remains voluntary in Switzerland. A PIP was however submitted with many applications for innovative products in 2013.
- The submission of PIPs proved helpful with regard to the notification of paediatric clinical trials. Notifications for eleven paediatric trials were received in 2013.
- Inspections within the framework of paediatric clinical trials were considered important. Inspections to assess compliance with Good Clinical Practice (GCP) are planned for 2014.
- Fewer than 6% of all adverse drug reactions (ADRs) reported to Swissmedic in 2013 concerned children and adolescents. An expansion of paediatric pharmacovigilance, beyond the existing vaccine vigilance, appears important. The concrete implementation of this issue is still under discussion.

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

- A simplified authorisation was granted to a blood transfusion service for the first time: it concerned an inactivation procedure for the processing of plasma for transfusion. A similar process for the processing of platelet concentrates was already introduced throughout Switzerland in 2011.

TRANSPLANT PRODUCTS

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

Activities

- Since the entry into force of the Transplantation Act in 2007, a total of 16 applications for the authorisation of transplant products have been submitted. At the end of 2013, two of these applications were still being processed.
- One transplant product was authorised conditionally in 2013, and a new application for a transplant product was submitted.
- In 2013, a total of 8 meetings with firms (Scientific Advice, Presubmission or Clarification Meetings) on transplant products were held with the applicants.

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. Quality, safety and tolerability must be guaranteed in each case.

Activities

- In 2013, Swissmedic completed 12 applications for the first authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication.
- A total of 232 products without an indication were newly authorised by means of the notification procedure. This concerned 127 single products and 105 combined products.
- In 2013, 163 applications for simplified authorisation with a reduced dossier were completed. Of them, 157 products were authorised and 6 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 own 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 the category E.

Activities

- One herbal medicinal product with a new active pharmaceutical ingredient was authorised.
- Six applications for non-innovative first authorisation of herbal medicinal products were completed. Two of them concerned applications for co-marketing products.
- In 2013, one application was submitted whereby the applicant requested that Art. 13, TPA was taken into consideration. The request was approved

ASIAN MEDICINAL PRODUCTS

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

Activities

- Co-operation with the Institute for Complementary Medicine (IKOM) was launched and intensified by means of presentations at Swissmedic on this specific field.
- Within the framework of the co-operation with the Swiss Centre for Applied Human Toxicology (SCAHT) in Basel, eight plants from the list of traditional Asian substances (TAS list) were assessed. The objective of the assessments is to broaden knowledge of these substances and where appropriate to adjust the list.

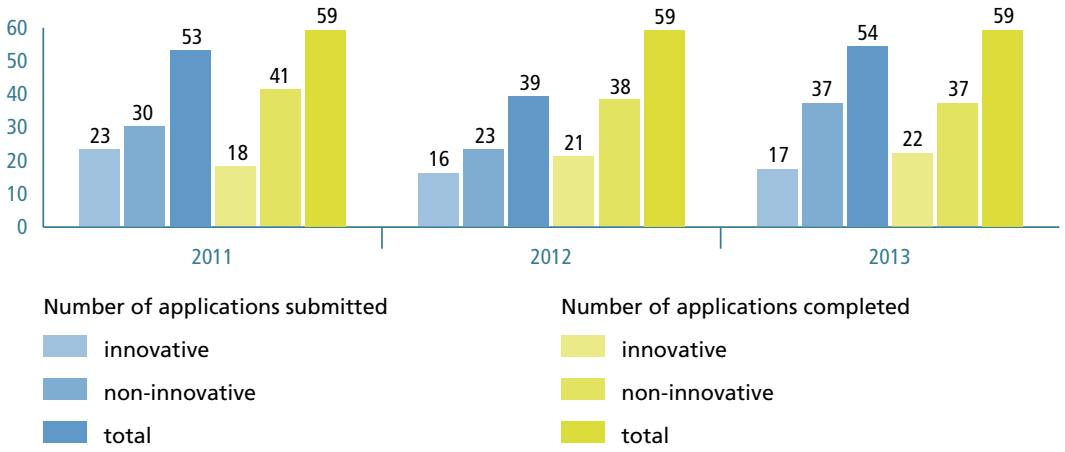
AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS)

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 differentiates between innovative medicinal products (medicinal products with new active pharmaceutical ingredients or major variations) and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients and co-marketing products). Major variations to a medicinal product require a new authorisation process. 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

- In 2013, 17 applications for innovative first authorisation and major variations were submitted, and 22 applications were completed.
- Of these 22 applications, 7 concerned the first authorisation of a medicinal product with a new active pharmaceutical ingredient, and 6 of them were granted their first marketing authorisation. One application was withdrawn by the authorisation holder



VETERINARY MEDICINAL PRODUCTS WITH A NEW ACTIVE PHARMACEUTICAL INGREDIENT AUTHORISED IN 2013

	ACTIVE PHARMACEUTICAL INGREDIENTS	PRODUCT NAME	APPLICATION
Antiinfective	Tildipirosin	Zuprevo® ad us.vet., solution for injection	Macrolide antibiotic for cattle
Antiparasitic	Closantelum, Ivermectinum	Closamectin ad us.vet., solution for injection	Antiparasitic for cattle
	Acidum formicum	Formivar ad us.vet., solution	Antiparasitic for bees
Heart and circulatory system	Telmisartanum	Semintra® ad us.vet., oral solution	Angiotensin II antagonist for cats
Nervous system	Imepitoinum	Pexion ad us.vet., tablets	Antiepileptic for dogs
	Buprenorphinum	Bupaq® ad us.vet., solution for injection	Analgesic for dogs and cats

SWISSMEDIC VETERINARY MEDICINES EXPERT COMMITTEE (VMEC)

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

Activities

- At its four meetings in 2014, the VMEC assessed eleven applications for authorisation or additional indications.
- The VMEC provided a stance on the EMA Draft Reflection paper on the risk of antimicrobial resistance transfer from companion animals.

EXTENSIONS AND DISCONTINUATIONS

Authorisations for a veterinary medicinal product are issued for five years. The authorisation holder must apply for an extension of an 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 2013, the authorisation was extended for 143 products.

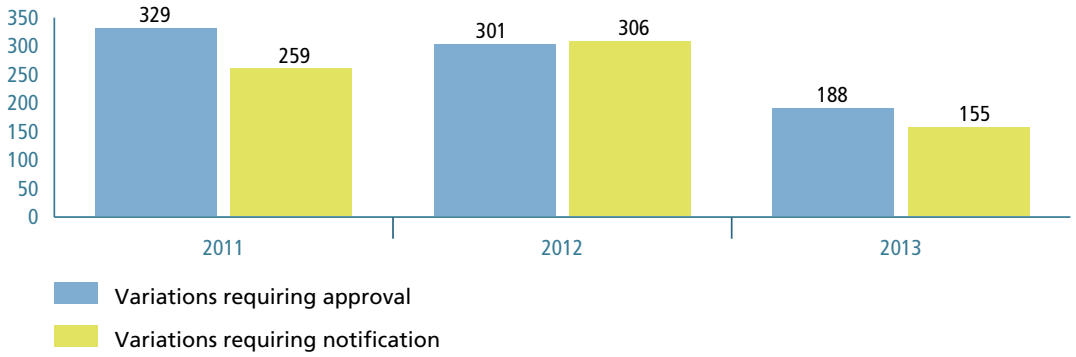
VARIATIONS REQUIRING APPROVAL AND VARIATIONS REQUIRING NOTIFICATION

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

(As a result of the entry into force of the new Ordinance on Fees and the new IT system, a comparison with the figures for the previous year would not be meaningful.)

- In 2013, 188 variations requiring approval and 155 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

- With the MUMS authorisation of the medicinal product Formivar ad us. vet. for bees, a regularly authorised veterinary medicinal product is now available to beekeepers to fight varroa by means of formic acid control.

APPEALS PROCEDURE REGARDING THE AUTHORISATION OF MEDICINAL PRODUCTS (HUMAN AND VETERINARY)

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 2013, 25 appeals were lodged with the Federal Administrative Court against official decisions taken by the Agency in connection with product authorisations. In one case, the appeal was not processed. One appeal was upheld because the authorisation holder had already been requested by the Agency to submit revised product information texts within the framework of the due process hearing: the revised texts should only be required once the final official decision is taken. The judgment is still outstanding for all of the other proceedings.
- Of the proceedings still pending before the Federal Administrative Court or the Federal Supreme Court, judgement has been passed on three. In one case, the appeal was partially upheld (reduction of the fees). One appeal was rejected and another was dismissed. The Federal Supreme Court did not process one appeal against a differing judgement by the Federal Administrative Court and dismissed a further appeal.

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		
	2013	First half year, cumulative	Second half year, cumulative	Total 2013
Marketing authorisation procedures (all application categories), proportion of procedures completed within the prescribed time limits	91%	97%	84%	90%
First marketing authorisations of innovative medicinal products (ZL1A); proportion of procedures completed within the prescribed time limits	85%	83%	92%	88%
First marketing authorisations of non-innovative medicinal products (ZL1B); proportion of procedures completed within the prescribed time limits	90%	89%	96%	93%
Extensions / discontinuations of marketing authorisations (ZL2); proportion of procedures completed within the prescribed time limits	95%	100%	94%	97%
Scientific variations (ZL3A); proportion completed within the prescribed time limits	95%	97%	94%	96%
Administrative variations (ZL3B); proportion completed within the prescribed time limit	95%	98%	72%	85%

SPECIAL ACTIVITIES AND EVENTS: AUTHORISATION OF HUMAN AND VETERINARY MEDICINAL PRODUCTS

Revision of administrative ordinances

There were several important changes to major sets of instructions. The revision of instructions relating to the application of Art 13, TPA was finalised: changes were made that reduced the amount of documentation required and that simplified the in-house process. Various meetings with stakeholders were held regarding the implementation of the new provisions in the context of the revision of the AMZV, which included requirements for clearer texts on the outer packaging of medicines. The ordinance on biosimilars was updated to take the special features of the more complex molecules into consideration, and especially those of monoclonal antibodies. The ordinance on generics was abolished since it was established that there is no legal basis for Swissmedic to take a decision regarding the generic status of a product. Instead, Swissmedic will in future take such decisions within the framework of provisions regarding medicinal products with known active pharmaceutical ingredients.

Procedure with prior notification

The new procedure for marketing authorisation applications with prior notification was implemented. In this procedure, the applicant informs Swissmedic of the submission plans 5–8 months in advance. The assessment carried out by Swissmedic takes 20% less time than that required for the usual marketing procedure. Eleven applications for applying this procedure were received in 2013.

LICENSING

LICENSING OF MEDICINAL AND TRANSPLANT PRODUCT

ESTABLISHMENT LICENCES FOR MEDICINAL PRODUCTS

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

Activities

- At the end of 2013, 1,098 companies held an establishment licence for the manufacture, wholesale, import, export and trade in foreign countries of medicinal and transplant products. Some of these companies carry out several of the activities mentioned.
- In 2013, the number of licences issued for the first time, extended or amended was 705, which is slightly lower than for the previous year.

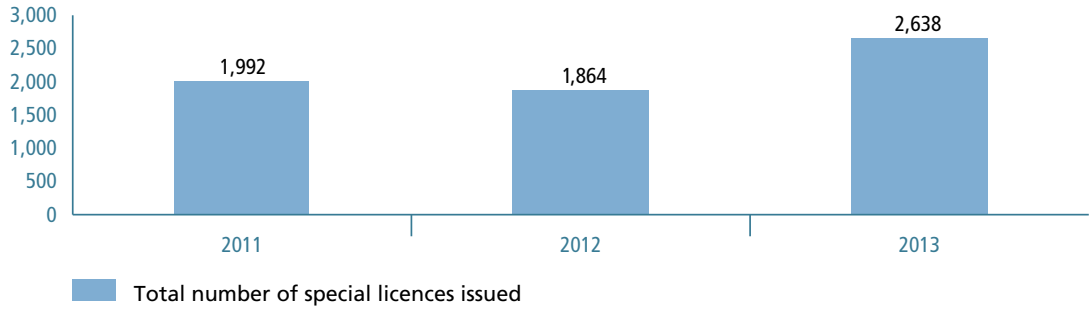
Performance indicator	Target	Result
Establishment licences; proportion of procedures that were completed within six months	95%	96%

SPECIAL LICENCES FOR MEDICINAL AND TRANSPLANT PRODUCTS

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

Activities

- In 2013, the number of special licences increased significantly, from 1,864 to 2,638.
- As of 1 January 2013, it is no longer possible to order allergen products that are not authorised and do not fulfil the requirements for a formula magistralis from the distribution company. Swissmedic has now created new special licences in order for patients that are already under treatment with these allergen products to continue their treatment with them. This new category accounts for approximately 30% of the special licences issued in 2013 and explains the increase mentioned.
- The number of special licences for radiopharmaceuticals has remained at a constant level or around 30%.



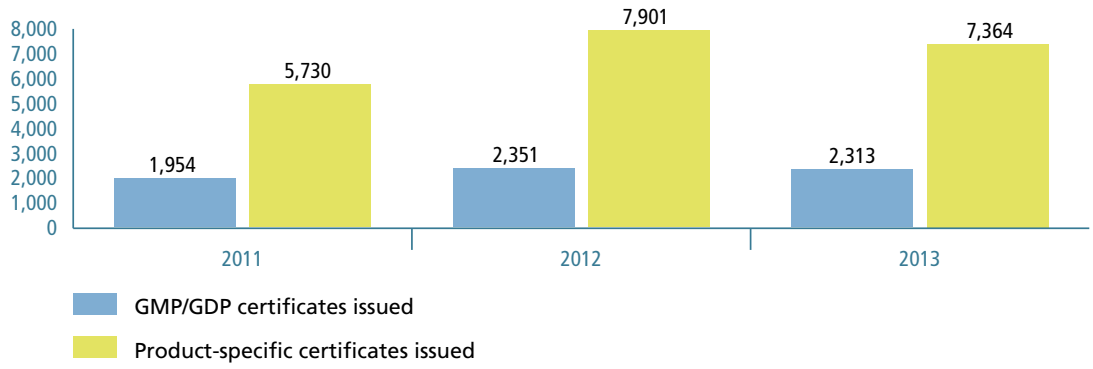
Performance indicator	Target	Result
Special licences; proportion of procedures that were completed within 24 hours	95%	98%

CERTIFICATES FOR MEDICINAL AND TRANSPLANT PRODUCTS

Companies with establishment licences may request copies (certificates) of their licences in German, French, English or Spanish. These certificates are confirmations for foreign countries 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 2013, Swissmedic issued 2,313 Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).
- Following the implementation of Directive 2011/62/EU (Falsified Medicines Directive) in the European Union on 2 July 2013, Swiss manufacturers of active pharmaceutical ingredients should have been required to attach a written confirmation of their GMP compliance to their exports to EU Member States. This would have led to an increase in the number of GMP certificates issued by Swissmedic. On 22 November 2012, and thanks to the mutual recognition agreement between the Swiss Confederation and the EU, Switzerland was the first country to be included on the list of third countries whose regulatory framework for active pharmaceutical ingredients intended for human medicinal products and the corresponding control and implementation measures guarantee a level of protection for public health that is equivalent to that provided by the EU.
- In 2013, 7,364 product-specific certificates were issued.



Performance indicator	Target	Result
GMP/GDP certificates; proportion of procedures completed within 14 days	98%	97%

CONTROL OF THE FLOW OF NARCOTICS

Swissmedic issues establishment licences to companies and individuals that handle controlled substances. Accounting is mandatory for controlled substances. Swissmedic examines the annual accounts of all companies holding an establishment licence and draws up the International Narcotics Control Board (INCB) report in accordance with the international agreement. The import and export of controlled substances must be licenced 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).

Activities

- In 2013, 351 companies were in possession of an establishment licence for handling controlled substances. A total of 179 applications for modifications, renewals or for the start of operations were professed. The figures have remained at the same level compared to 2012.
- Around 7,500 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, 85% of all applications were already submitted electronically.
- In 2013, Swissmedic analysed 24 substances and applied to the Federal Office of Home Affairs for their inclusion in the relevant Ordinance (BetmVV-EDI).

Performance indicator	Target	Result
Import and export permits for controlled substances; proportion of procedures completed within 10 working days	95%	97%

CLINICAL TRIALS WITH MEDICINAL PRODUCTS AND TRANSPLANT PRODUCTS

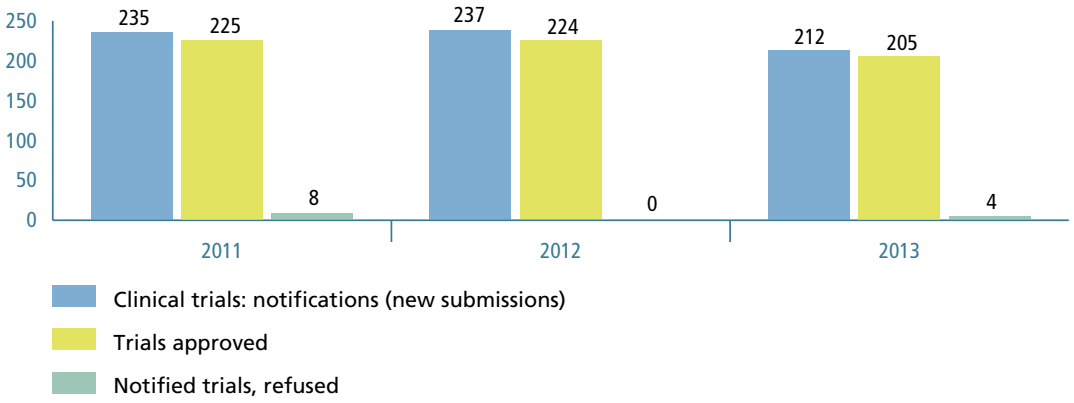
Clinical trials are used for the systematic gathering of information on medicinal products when used on humans. Swissmedic carries out controls to determine whether appropriate measures are taken to preserve the health and the personal rights of the participants and patients, the quality and safety of the test product, and the correctness of data and results. Clinical trials may only be carried out in Switzerland if they have been approved by a Cantonal Ethics Committee, upon which Swissmedic is notified and is required to state any objections within 30 days (notification procedure). During the trials, adverse reactions and amendments must always be reported to the Ethics Committees and/or to Swissmedic.

Activities

- In 2013, Swissmedic received 212 applications for clinical trials with medicinal products, and 205 were approved. Four applications were refused because of shortcomings to their form and / or content. Three applications were still being processed at the end of the year, within the applicable 30-day time limit.
- With regard to transplant products and gene therapy, twelve applications for clinical trials were submitted and all of them concerned first-in-man trials. In addition, 16 applications for amendments to trial protocols were submitted. Four of the applications for new clinical trials and five of the applications for amendments concerned gene therapy.
- In 2013, Swissmedic continued its collaboration with the Federal Office of Public Health (FOPH) and the Swiss Association of Ethics Committees for Clinical Trials (AGEK), with the aim of facilitating the transition to the new Human Research Act (HRA) and the related ordinances (KlinV, HFV, OV-HFG) at the beginning of 2014. Several working meetings with the FOPH and the AGEK took place. In addition, the Clinical Trials

division organised three workshops for external participants and two workshops for the scientific secretariat of the Ethics Committees.

- Swissmedic provided information on the new Human Research Act (HRA) and the related ordinances to a wide range of stakeholders by means of 22 presentations.



Performance indicator	Target	Result
Notifications of clinical trials (first submissions); proportion of trials assessed within 30 days	100%	100%

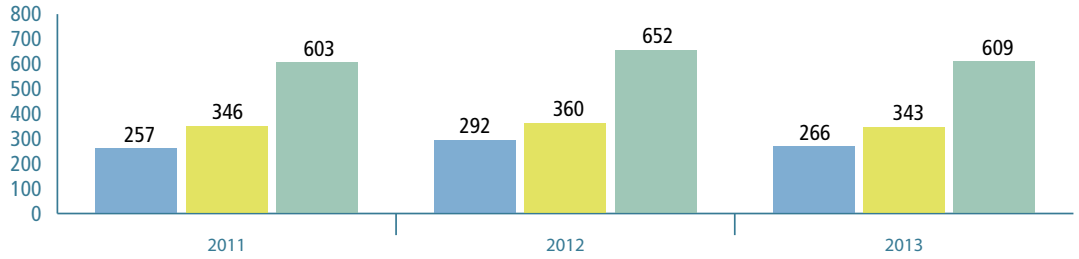
INSPECTIONS

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 examine respect for 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 2013, the Swissmedic inspectorate carried out 62 GMP / GDP inspections of manufacturers and wholesale companies and the regional inspectorates carried out 547, i.e. a total of 609 inspections, which is somewhat lower than in 2012 but comparable with the figures for 2011.
- The inspections carried out by the Swissmedic inspectorate concerned the following areas: transplant products 21%, blood transfusion services 36%, pre-approval inspections 11%, "for cause" inspections 3%, pharmaceutical sector inspections 29%.
- Swissmedic took part in the qualification of new inspectors for the Regional Medicines Inspectorate of Western Switzerland (ISOPTh), meaning that this inspectorate was once more in a position to function.
- International recognition of Swiss inspection practices within the framework of the Mutual Recognition Agreements (MRA) was again confirmed by Health Canada.
- Swissmedic and the regional inspectorates also took part in the inspection programmes of partner authorities abroad in 2013. This included an inspection of a manufacturer of active pharmaceutical ingredients in Japan with the European Directorate for the Quality of Medicines & HealthCare (EDQM). Swissmedic also took part in several assessments of partner authorities within the frame of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and intensified its activities within the framework of this important initiative.



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

Manufacturers

Wholesale companies

Total

Performance indicator	Target	Result
Licensing inspections; degree to which the annual plan was achieved	90%	100%

INSPECTIONS ON COMPLIANCE WITH GOOD CLINICAL PRACTICE (GCP) AND PHARMACOVIGILANCE (PV)

All clinical trials carried out in Switzerland by sponsors and research institutes, as well as trial locations, facilities and laboratories, may be inspected by Swissmedic with regard to compliance with Good Clinical Practice (GCP). In doing so, random checks are used to examine whether the safety and the personal rights of the participants and patients are guaranteed. Checks are also carried out to establish whether the results of the trials satisfy the scientific criteria for correctness and traceability. Pharmacovigilance inspections are above all to examine compliance with the legally prescribed mandatory reporting of adverse drug reactions.

Activities

- Swissmedic carried out a total of 18 GCP and pharmacovigilance inspections in 2013, and accompanied other eight foreign inspections in Switzerland organised by Europe, the USA and Japan. One GCP inspection was carried out in Switzerland within the framework of a PIC/S Joint Visit group.
- Swissmedic carried out one GCP inspection in the area of advanced therapies, concerning a clinical trial with a transplant product.

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

GLP INSPECTIONS

With the exception of pharmacodynamics for notification or authorisation procedures, nonclinical 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 2013, the Swissmedic GLP unit carried out 7 routine inspections within the framework of its monitoring activities.

- An additional test facility was added to the monitoring programme following a successful first inspection in 2013. An application for GLP certification in the area of medical devices has been submitted.
- Within the framework of collaboration with the GCP inspectorate from the Clinical Trials division, a joint two-day GCP / GLP inspection was carried out to address the interface between bioanalytics and plasma samples from clinical trials.

Performance indicator	Target	Result
GLP inspections; number carried out	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

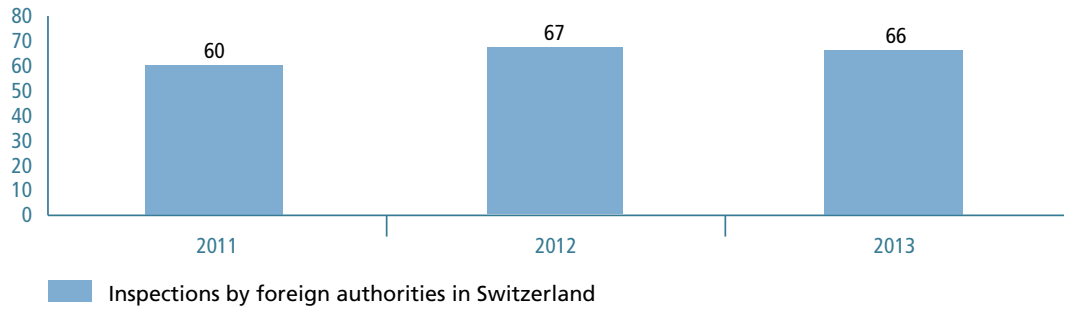
- In 2013, Swissmedic carried out 43 inspection procedures for the FOPH and 2 for the Principality of Liechtenstein.

INSPECTIONS BY FOREIGN AUTHORITIES IN SWITZERLAND

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

Activities

- In 2013, foreign authorities carried out 58 inspections at pharmaceutical companies in Switzerland. The inspecting authorities were the USA with 22 inspections, Turkey with 9, Korea with 8, Kenya with 5, Kazakhstan with 3, Brazil and Taiwan each with 2, and Saudi Arabia, Russia, Tunisia, China, Mexico, Libya and Uganda each with one inspection. In comparison with the previous year, a shift was observed with regard to the authorities carrying out the inspections: the USA and Brazil carried out significantly fewer inspections while Turkey, Korea and some African countries carried out more.
- Swissmedic also organised and accompanied 8 GCP and PV inspections by foreign monitoring authorities: the European, US and Japanese authorities for GCP inspections and the German authorities for the pharmacovigilance inspection.



MONITORING OF THE BLOOD TRANSFUSION SERVICE

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

Activities

- Within the framework of a market monitoring campaign, Swissmedic has begun a Swiss-wide investigation of amotosalen content in platelet concentrates that have undergone a pathogen inactivation process. Amotosalen is a dye that once activated by means of ultraviolet light, inactivates pathogens by the formation of clumps. The results will be available in 2014.
- Following political initiatives, the Federal Office of Public Health (FOPH) is examining a possible change to donor eligibility criteria in connection with MSM (men who have sex with men). Taking into account the epidemiological data available, Swissmedic has drawn up a stance on the issue for the Swiss Red Cross transfusion service (SRK) and the FOPH. As a result, the current practice of non-eligibility is to be continued.
- Following an outbreak of the West Nile virus (WNV) in neighbouring countries, the management of the SRK has regularly adapted the donor eligibility criteria in order to ensure that possible blood donors who have visited the affected countries will not be permitted to give blood. The revision of a WNV preparedness plan was continued.
- A further decrease in own blood donations was observed. Many hospitals have discontinued the manufacturing of these products.

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 premises at Freiburgstrasse 139 has created an excellent infrastructure for the Laboratory division (OMCL). By bringing the two laboratory units together (OMCL Biologicals and OMBL Pharmaceuticals) at a single location, it is possible to benefit from synergies, to optimise logistics processes and to keep the QM system, with its ISO 17025 accreditation, streamlined and efficient.
- In the area of forensics, the gas and liquid chromatography screening techniques with mass spectrometry detection have been further optimised. These techniques can, among other areas of use, rapidly and reliably reveal the presence of synthetic active pharmaceutical ingredients in slimming products and erectile stimulants declared as "herbal".
- Since an increase in the number of counterfeit or illegal biological medicinal products can be expected, the methods for analysing peptides and proteins by mass spectrometry and chromatography were further developed.
- Cases of haemolysis as a result of intravenous immunoglobulins, which have been observed worldwide, led to a broad market monitoring study to define the anti-A / anti-B isoagglutinine content in several hundred batches of various immunoglobulin products. These investigations attracted considerable attention on an international level. The comparisons of various methods for anti-A / anti-B identification in connection with the cases of haemolysis were published in the specialised journal "Biologicals".
- In the area of official batch release, the OMCL was faced with a further increase in applications for batch inspections of blood products and plasma pools.

Analysis conclusions for new marketing authorisations and market monitoring

	2011	2012	2013
Authorisation procedure: number of medicinal products examined	4	26	33
Market monitoring: number of medicinal products examined	1,304	1,676	1,763
Total	**1,308**	**1,702**	**1,796**

Batch assessments and plasma pool analysis

	2011		2012		2013	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU and WHO)	484	162	544	88	635	117
Notifications	290	176	310	160	319	149
Plasma pool analysis	1,642	–	1,563	–	1,950	–
Product analysis as WHO reference laboratory	–	28	–	35	–	35

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

APPEALS PROCEDURES REGARDING LICENCES

Appeals against decisions in connection with the licencing 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

- No appeals were lodged before the Federal Administrative Court against official decisions by the Agency in connection with establishment licences in 2013.
- No judgements were made on the appeal proceedings that were already pending before the Federal Administrative Court or the Federal Supreme court.

SPECIAL ACTIVITIES AND EVENTS: LICENSING FOR MEDICINAL PRODUCTS

The Licensing sector moves to Freiburgstrasse 139

Following the move of the laboratory (OMCL) in August 2013, the other five divisions of the Licensing sector relocated to the new laboratory and office building in September 2013, according to plan. This means that the entire Licensing sector has been united in a single location. During the move, the divisions were able to continue their work with virtually no interruption. The remote lending system for dossiers in paper form was launched seamlessly, and in the meantime has become well established.

Reporting system for controlling the flow of narcotics (MESA)

MESA, the new reporting system for controlling the flow of narcotics and psychotropic substances, has been operational since 1 January 2013. This web-based application permits authorised individuals and companies to enter their data directly in the system. Retailers, hospitals and medical professionals are no longer required to report on returns. The data from the discontinued, former reporting system has been transferred to the Cantonal control authorities, who have been given access to MESA. This ensures that the Cantonal authorities have access to all data.

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.

MEDICINES

MARKET MONITORING OF MEDICINES

MEDICINAL PRODUCT VIGILANCE

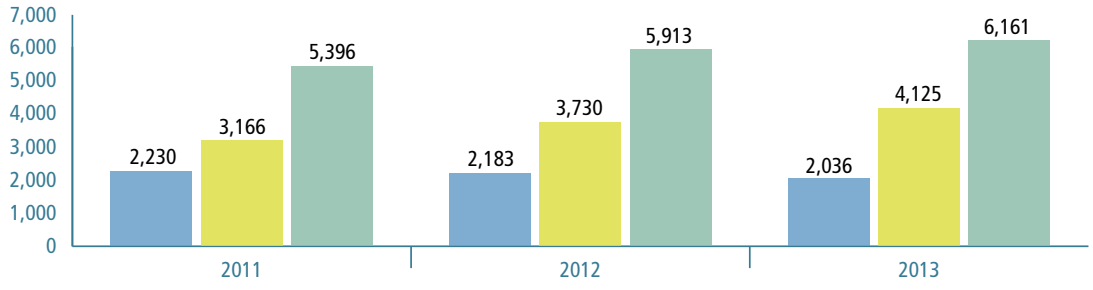
Swissmedic records safety signals associated with medicinal products, vaccines, labile blood products and veterinary medicines based on reports of adverse drug reactions (ADRs) from within Switzerland. If the investigations confirm a new risk, Swissmedic initiates the necessary measures.

PHARMACOVIGILANCE

Within the framework of the pharmacovigilance network, the reports on adverse drug reactions are assessed in six regional pharmacovigilance centres (RPVCs) 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 2013, Swissmedic received and assessed 6,161 reports on suspected adverse drug reactions from the 6 RPVCs and industry. The increase of 4.2% compared with the previous year is the result of the increasing number of reports from companies, whereas those submitted by the regional centres continues to decrease.
- Over 10% of the reports from companies were submitted to Swissmedic electronically, using the pharmacovigilance gateway launched the previous year.
- Dr Martina Schäublin replaced Dr Pia Caduff as the head of the Pharmacovigilance division at the beginning of the year.
- The key issues within the division's work included addressing the safety signals that were identified via spontaneous reporting and the FPE II project. The said project permits the electronic reporting of adverse reactions by professionals (and smaller companies), and is being developed in close collaboration with representatives of those submitting the reports.



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

Regional pharmacovigilance centres

Pharmaceutical companies

Total

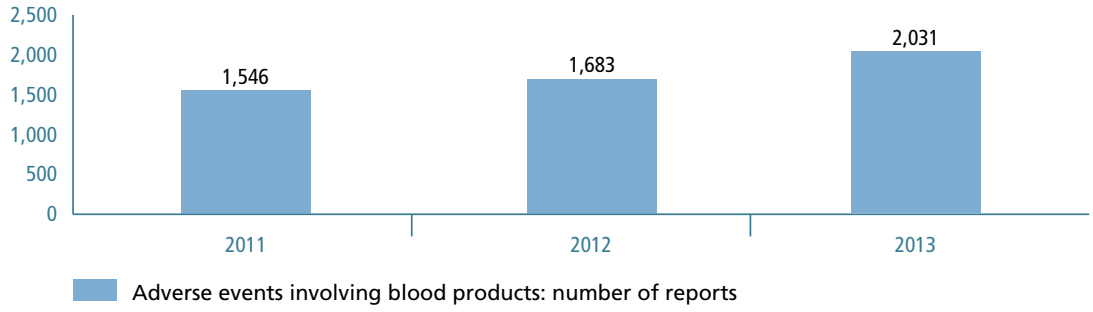
Performance indicator	Target	Result
Serious adverse reactions: proportion of assessments carried out and transmitted to the companies within 15 calendar days	95%	99%

HAEMOVIGILANCE

The system is based on the reporting of all incidents and transfusion reactions occurring in the course of the transfusion process, from the donor selection to the administration of blood products to patients. Emphasis is placed on identifying errors in the system. For that reason, so-called "near miss" events are also recorded, during which an error is detected and corrected prior to the transfusion. The assessment of haemovigilance reports provides a picture of the current risks related to transfusion, can indicate the cause of preventable transfusion incidents, and can reveal areas where corrective measures are necessary and possible. The objective of haemovigilance at Swissmedic is to improve the safety of transfusion therapy.

Activities

- In 2013, a total of 2,031 reports were received. The considerable increase of 21% compared with the previous year concerned – to an equal extent – reports on transfusion reactions and near misses. The increase can be imputed to more willingness to submit reports and the fact that the system is now well established.
- Two workshops were organised to provide training for haemovigilance officers.
- A report on experience with the pathogen inactivation procedure was published in the "Swiss Medical Forum", a specialised journal for medical training. The team also contributed to a safety pamphlet published by the Foundation for Patient Safety in Anaesthesia: "Blood is a special kind of juice – handling blood transfusions calls for great care".
- For the second time, the haemovigilance team organised the "Swisstransfusion" congress together with the Swiss Transfusion Centre and the Swiss Association for Transfusion Medicine.
- In 2013, the results and findings from reports received over the previous year were again published in the "2012 Annual Haemovigilance Report": www.swissmedic.ch/haemo



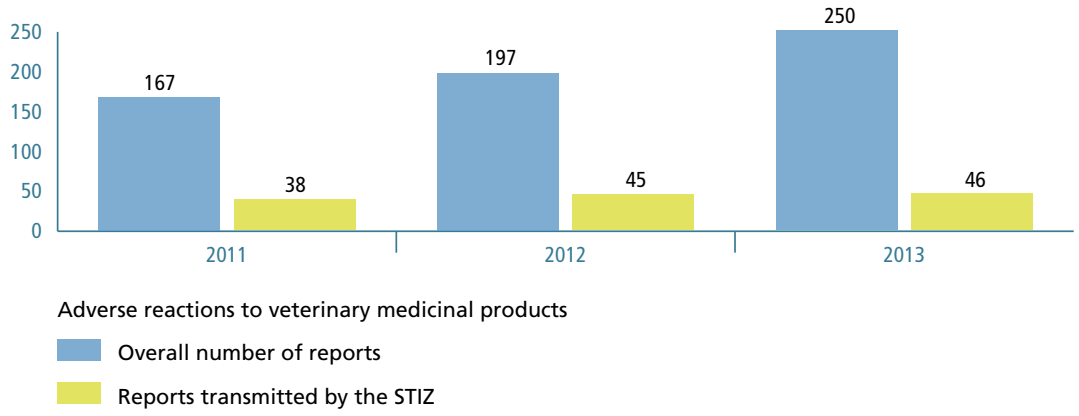
Performance indicator	Target	Result
Report on new findings	1	1
Training courses for haemovigilance officers	2	2

VETERINARY MEDICINAL PRODUCT VIGILANCE

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 do not fall within Swissmedic's mandate, and are recorded by the Institute for Virology and Immunology (IVI) of the Federal Food Safety and Veterinary Office (FSVO).

Activities

- In 2013, the number of adverse reactions to veterinary medicinal products submitted as 250, which constitutes an increase of almost 27% compared to the previous year. Of the reports, 46 were submitted by the Swiss Toxicological Information Centre (STIZ) in Zurich.
- The majority of the reports concerned domestic animals. Three signals were generated from the 250 reports.



Performance indicator	Target	Result
Report on new findings	1	1

RISK MANAGEMENT

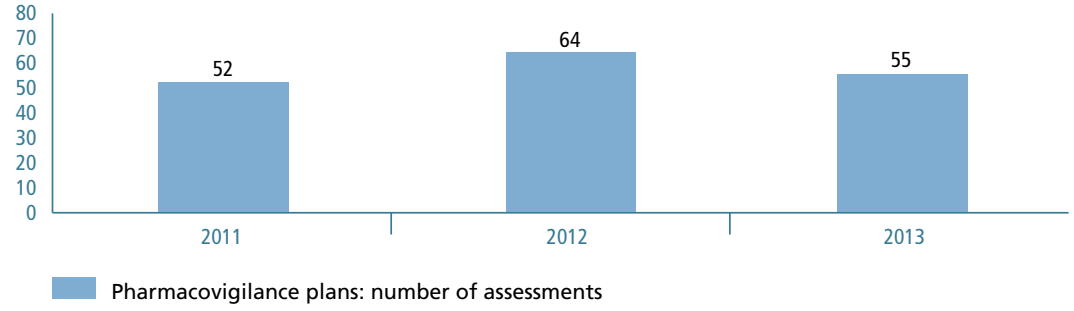
Swissmedic's tasks also include the assessment of international data on the safety of medicines. Within the framework of the authorisation of new medicinal products, firms must provide, for assessment, a pharmacovigilance plan in accordance with the guidelines by the International Conference on Harmonisation (ICH). This plan must be kept up to date by the firms and submitted, for example, within the framework of regular 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, now entitled Periodic Benefit Risk Evaluation Reports (PBRERs) rather than Periodic Safety Update Reports (PSURs). A further important element is the identification and assessment of safety signals from national and international sources.

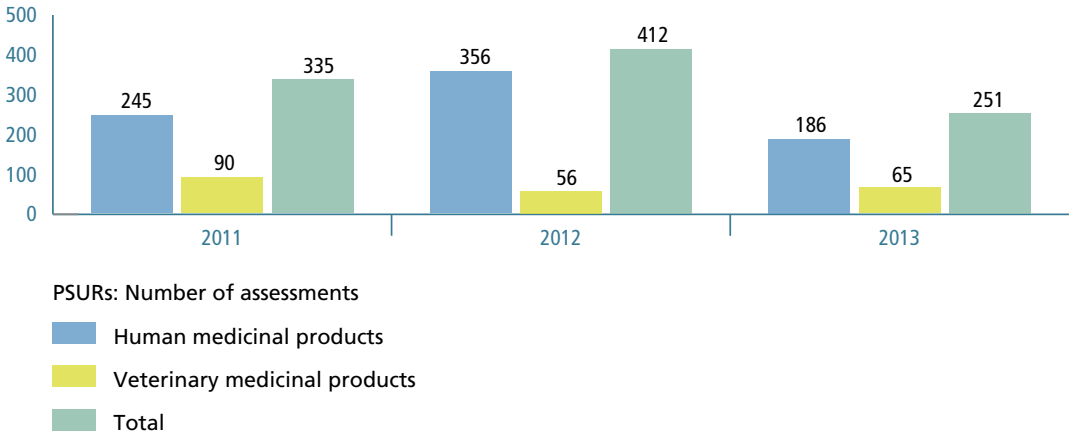
Activities

- A total of 55 first submissions or updates of pharmacovigilance plans were assessed, as were 46 answers from firms to the lists of questions (LOQs) sent to them by Swissmedic.
- A total of 186 periodic reports on the safety of human medicines (PSURs / PBRERs) were assessed by Swissmedic in 2013. The short assessment process with systematic prioritisation made it possible to reduce the time taken. Of the PSURs, 65 concerned veterinary medicines: PSURs are mandatory for most of these products. The considerable decrease in numbers compared with the previous year is partially due to the fact that at the time, it was necessary to overcome a situation whereby the assessment of a large number of reports

were pending. Swissmedic is moreover selecting the reports to be processed more strictly in order to prioritise the deployment of its resources to risk mitigating measures for current safety problems and to pharmacovigilance plans.

- In 2013, Swissmedic processed 120 safety signals concerning medicinal products, of which 26 came from Switzerland and 94 were identified from international sources. Most of the signals called for longer processing times, either for a more in-depth assessment or because the signal concerned several products and thus several firms. Five pharmacovigilance inspections were carried out jointly with the Licensing division. Representatives of Swissmedic accompanied a pharmacovigilance inspection carried out in Switzerland by foreign authorities.





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

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. If appropriate, Swissmedic also provides information, under its own responsibility, on risks related to medicinal products.

Activities

- Swissmedic completed eight reviews. In some cases, risk mitigation measures could be taken without initiating a review procedure.
- In 36 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.
- To address the risk of acute hypersensitivity reactions, comprehensive precautionary measures were taken within the framework of a review concerning the product Ferinject. Appropriate adjustments to the product information were also made for Venofer (iron sucrose). By means of a short publication, Swissmedic issued a reminder that anaphylaxis has also been observed with the antiseptic Chlorhexidine, used in medicinal products, medical devices, cosmetics, etc. Among other aspects, Swissmedic referred to the therapy guidelines (use of adrenalin).
- Because of the risk of haemorrhage, Swissmedic issued a publication on the necessary precautionary measures when taking the newly introduced oral anticoagulants.

Performance indicator	Target	Result
Number of administrative proceedings completed (including review procedures)	30	37

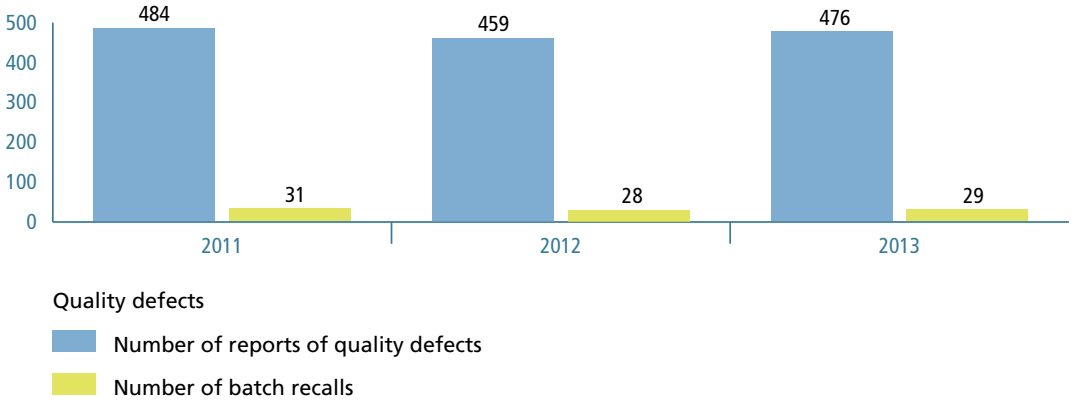
QUALITY DEFECTS AND BATCH RECALLS

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

Activities

- In 2013, Swissmedic received a total of 476 reports on quality defects. Switzerland was concerned by 285 of them. Measures were taken with regard to 119 of these reports. Six of them were classified as being highly urgent (life-threatening).
- Official decisions to carry out 29 batch recalls were taken, and for 2 batches of one product, it was necessary to take measures reaching as far as recalls from patients, given the high degree of risk.
- In 20 cases, products produced for other countries were temporarily placed on the market in order to overcome supply shortages.
- In the 3rd quarter of 2013, certain batches of an adrenalin pen, for emergency treatment in the case of allergic reactions, had to be recalled from the market because the manufacturing company had discovered that in rare cases, the pens could malfunction. The recall took place under difficult circumstances, because there were not enough replacement products available for an exchange product to be provided to all patients. In order to overcome a supply shortage, the pens were therefore "only" subject to recalls from retailers.

- A further case in which Swissmedic was closely involved began with a report that water had leaked from a bottle containing medical oxygen when it was being used in a Swiss hospital. Investigations indicated a manufacturing problem. As a corrective measure, all clients of the company received information on the issue, the controls when refilling the container were adapted, and the authorisation holder was ordered to equip all medicinal gas bottles with residual pressure valves as rapidly as possible. This incident demonstrates the stringent requirements for handling medicinal gases throughout the chain of distribution.
- A further recall concerned an unusual defect affecting glass vials. As a result of a material defect, the predetermined breaking point leaked. This led to a recall of batches of several products.
- Finally, one product (pre-filled syringe containing an anticoagulant) revealed a defect whereby the needle protection mechanisms did not function correctly. This constituted a risk of injury after use. The authorisation holder spontaneously ordered a recall.



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 means of 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 the 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 2013, Swissmedic received 316 reports on illegal activities related to medicinal products. Of them, 77 concerned illegal distribution with a link to Switzerland.
- Some 45 cases were transmitted to the Cantons for further follow-up, since they concerned the retail trade of illegal products that do not come under legislation on therapeutic products.
- Of the 98 reports on counterfeiting, 26 concerned Switzerland.
- A total of 19 Swiss websites offering and advertising illegal medicinal products were taken down.
- Some 1,043 unauthorised imports of medicinal products led to administrative proceedings being initiated.
- The collaboration with Antidoping Switzerland, which was launched at the end of 2012, continued and led to positive outcomes.
- As in previous years, Swissmedic took part in Operation Pangea, a joint action week during which the Agency and the customs authorities worked together to check shipments of medicinal products. The number of illegal imports decreased in comparison with the previous year, which was a positive development.

- A shipment in transit from China to Egypt, containing over one million tablets of counterfeit psychotropics was seized at Zurich airport. Internal laboratory analysis was carried out immediately and revealed that the products were counterfeits containing no active pharmaceutical ingredient. Swissmedic informed the various foreign authorities concerned and ordered the destruction of the goods. This case attracted considerable media attention.
- A press release on the subject of "Dangerous potency medicines from the Internet" drew attention to new trends related to erectile stimulants. It was explained that the ingredients were frequently overdosed or that analgesics were even added to some products. Swissmedic therefore again issued a warning about the dangers of obtaining medicinal products over the Internet.

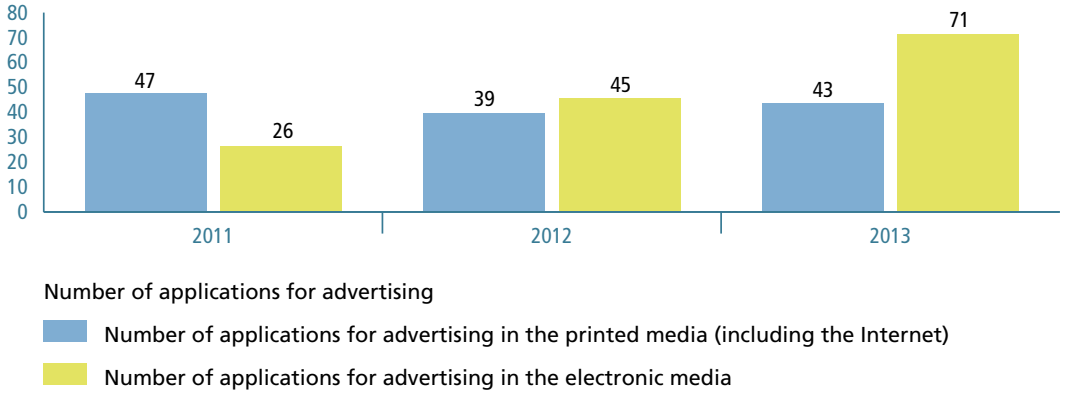
	2011	2012	2013
Illegal distribution (responsibility of Swissmedic)	69	83	77
Illegal retail trade (responsibility of the Cantons)	27	36	35
Illegal cosmetics and dietary supplements (responsibility of the Cantons)	18	10	10
Counterfeit medicinal products	118	111	98
Number of analyses of suspicious medicinal products	34	36	42

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 compliancy 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 114 applications for prior control that were submitted, 43 concerned printed advertising, 7 concerned Internet sites that are covered by the regulations governing the printed media, and the remaining 71 concerned advertising on electronic media such as television commercials or e-boards.
- A total of 68 advertisements targeting the public or healthcare professionals were processed by Swissmedic. In 40 cases, administrative proceedings were initiated and in 13 cases, an official objection was issued.
- In 2013, Swissmedic responded to 12 comprehensive enquiries on various topics relating to advertising.
- In connection with the launch of the new publication platform for medicinal product information, Swissmedic published information explaining the resulting adjustments to advertising for the public and for healthcare professionals. It is now necessary to include a reference to the full product information on the Swissmedic publication platform, at www.swissmedicinfo.ch.
- Numerous procedures were also initiated in 2013 concerning prohibited advertising for the general public on medicinal products containing botulinum toxin. A second judgement issued by the Federal Administrative Court once more supported Swissmedic's argument. The provisions of the Ordinance on advertising for medicinal products also apply to healthcare professionals, meaning that advertising for prescription-only medicinal products is prohibited.
- With the revised Ordinance on Fees, which entered into force on 1 January 2013, a flat fee is no longer charged for advertising applications: the fees are now calculated more appropriately, in line with the resources deployed.



Performance indicator	Target	Result
Prior control of advertising: proportion of cases where a preliminary decision was taken within 4 weeks of receipt of application	100%	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%	96%
Number of presentations, publications and circulars to raise awareness among stakeholders	12	12

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 2013, appeals were lodged with the Federal Administrative court against eleven 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 seven cases, the appeals were not admitted by the court. For the others, the judgment is still outstanding.
- Of the appeals already pending before the Federal Administrative Court or the Federal Supreme Court, judgements were passed on 16 cases. The Federal Administrative Court dismissed nine appeals and did not admit one. Two appeals were partially upheld: one concerned the amount of the fees and another concerned the scope of the administrative measures imposed. In another case, the appeal was upheld and it was ruled that the advertising for the product concerned was not subject to mandatory advertising control. In another case, the Court returned the issue to the agency in order for additional material to be provided. The Federal Supreme Court did not admit one appeal. In one case, the decision was to write off the appeal.

SPECIAL ACTIVITIES AND EVENTS: MARKET MONITORING OF MEDICINAL PRODUCTS

Supply shortfalls – criteria for import applications
Given the increase in the number of cases of supply shortfalls, Swissmedic is receiving more applications for import. In order to ensure that this process is transparent, the relevant legal requirements and criteria were published. In addition, all approved out of stock applications have been published on the Swissmedic website since January 2013.

Risks of thromboembolisms under hormonal contraceptives
Swissmedic continues to take a comprehensive approach, including all of the products concerned, with regard to the risk of venous and arterial thromboembolisms under hormonal contraceptives. As the re-evaluation on the part of the European Medicines Agency, EMA confirmed, the evaluation of the risk is unchanged. The decisive factor is now for healthcare professionals and users to be familiar with the guidelines for use, the differences between the product groups, and the precautionary measures and to take them into account in daily use. Swissmedic therefore also approached the Swiss Society for Gynaecology and Obstetrics, which published information material and checklists relating to the risk of venous and arterial thromboembolisms under combined contraceptives in July. Swissmedic's own publications on this subject demonstrate its commitment to ensuring that this material is used as widely as possible.

Increase in adverse effects leads to preventive withdrawal from the market
The product Rienso (Ferumoxitol) authorised a few months previously for intravenous administration of iron to patients with chronic kidney failure was provisionally withdrawn from the Swiss market. An unexpected increase of acute hypersensitivity reactions, some of which were severe, when treated with one batch in Switzerland raised suspicions of a quality defect.

Strict restrictions to the use of products containing hydroxyethyl starches
The use of products containing hydroxyethyl starches, primarily administered to replace blood volume, was subjected to stringent restrictions in line with measures taken by the EU. The reason for the restriction was the increased mortality rate and a greater risk of kidney damage when treating septic shock. With regard to the benefits of these products, no advantages have been proved in comparison with the use of crystalloids (salt solutions).

MEDICAL DEVICES

MARKET MONITORING OF MEDICAL DEVICES

Medical devices encompass an extremely large range of products, including implants such as hip prostheses and heart pacemakers, in vitro diagnostics such as HIV or pregnancy tests, or products for the general public such as contact lenses. In order to be placed on the market, the manufacturer carries out its own conformity assessment procedure for its products, under its own responsibility. In the case of higher-risk products, an officially designated, so-called "notified body" – a conformity assessment bureau – 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 investigations of medical devices that are not yet authorised for the market.

PLACING ON THE MARKET

Manufacturers of medical devices with greater risks must bring in officially recognised notified bodies for the conformity assessment. Notification is mandatory for certain medicinal devices, and for these, Swissmedic receives the notifications, carries out random checks regarding 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 takes part in the meetings of high-level bodies of the Member States in this respect, i.e. meetings of the Competent Authorities Medical Devices (CAMD) and its working groups; the Central Management Committee (CMC), 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), New and Emerging Technologies (NET), EUDAMED, and as needed in ad hoc working groups such as the Software Group.

Activities

- In 2013, 276 notifications for class I medical devices were recorded, e.g. for reusable surgical instruments, adhesive plasters or rolling walkers.
- Swissmedic received 125 notifications for in vitro diagnostic medical devices (IVDs).
- In 5 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 2013, Swissmedic took part in 22 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 serve to resolve a life-threatening situation for a patient. In 2013, a total of four such special permits were issued.

	2011	2012	2013
Class 1 notifications	465	283	276
IVD notifications (Switzerland)	595	180	125
Notifications rejected	19	66	5
EU enquiries	35	30	22
Special permits	2	7	4

EUROPEAN MARKET MONITORING ACTIVITIES

Since Switzerland is integrated in 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

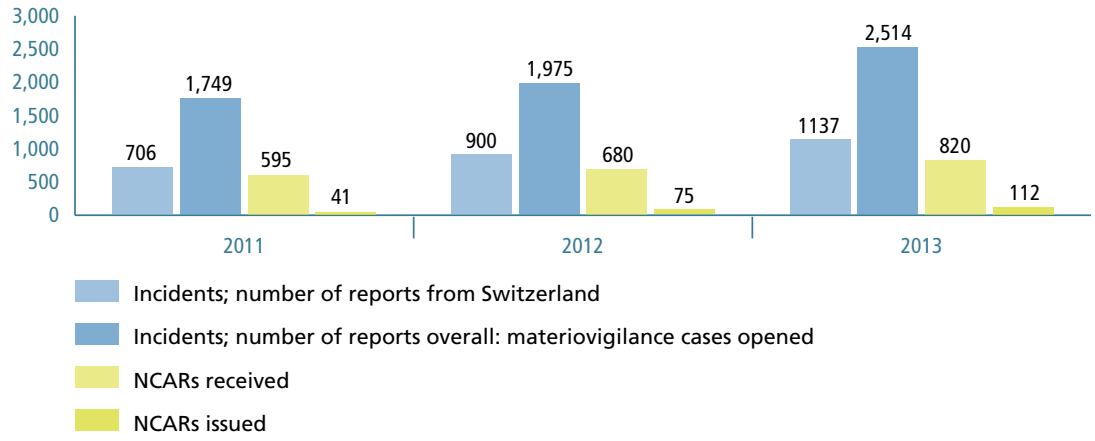
- In 2013, Swissmedic received 55 requests for mutual assistance from its European partner authorities.
- Swissmedic issued five requests for mutual assistance to our European partner authorities.
- Co-ordinated actions to cleanse the market with regard to dental bleach and pipettes was carried out throughout Europe.
- Swissmedic took on the role of co-leader of the European project on resterilisable products.

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 2,514 cases of materiovigilance were processed, of which 1,137 occurred in Switzerland. This means that the reporting rate increased by 27% compared with the previous year. This increase is above all the result of the increased use of medical devices and greater awareness among users, the industry and the media regarding the fact that reporting is mandatory.
- New cases of suspected incidents or concrete actions to be taken on pending cases were discussed within the framework of monthly telephone conference with the other European monitoring authorities.
- In 708 cases, the implementation of corrective safety measures in Switzerland was monitored. A total of 112 reports on defective medical devices (National Competent Authority Reports, NCARs) were drawn up for the attention of foreign authorities, and Swissmedic received 820 NCARs from the European partner authorities.
- In 625 cases, a public safety report was published on the Swissmedic website for the information of users.



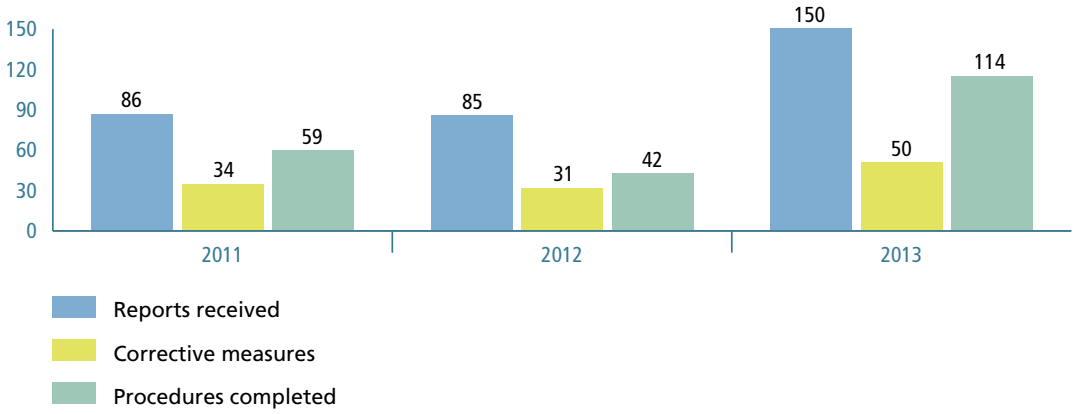
Performance indicator	Target	Result
Reports requiring immediate action: first measures taken within 10 days	100%	100%

MARKET CONTROLS

In order to guarantee a high level of safety for patients, efficient state-organised controls are of decisive importance. 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 respect.

Activities

- A total of 150 reports where an infringement of conformity was suspected were received by Swissmedic in 2013.
- In 50 of the cases opened as the result of the reports, corrective measures were imposed: for example adjustments to the product descriptions or halting distribution.
- A total of 114 reports were completed in 2013.
- A new process and a software application for recording suspicion reports were launched in the second half of the year.



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, and for priority 3 cases 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. Since 1 January 2014, the investigations require approval. 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

- A total of 42 notifications for new investigations of medical devices not yet authorised for the market were assessed, meaning an increase of 40% in comparison with the previous year.
- A total of 614 notifications relating to clinical trials that had already been accepted were processed.
- Swissmedic carried out more in-depth examinations for three pending clinical trials.
- Various preparatory and other work was carried out in view of the entry into force of the new Human Research Act (HRA).

Performance indicator	Target	Result
Notifications of clinical investigations: proportion assessed within 30 days	100%	100%

MONITORING OF CONFORMITY ASSESSMENT BODIES (CABS) AND INSPECTIONS

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

Activities

- Swissmedic has carried out an inspection in the area of medical devices at all 4 CABs in Switzerland.
- In 2013, Swiss experts took part in four inspections of CABs in Europe.
- Within the framework of inspections of clinical investigations, specific emphasis was placed on the activities of the sponsors in the case of serious events, and the suitability of their procedures for handling such events.
- In 2013, did not carry out inspections in the area of reprocessing, maintenance or hospital reporting systems.
- Swissmedic co-ordinates inspections carried out in Switzerland by foreign authorities with the State Secretariat for Economic Affairs (SECO) and if needed, accompanies the inspectors on site.

	2011	2012	2013
CAB inspections (excl. ISO 13485)	2	1	4
Joint assessments	n/a	n/a	4
On-site inspections of clinical investigations	2	0	2
Hospital audits: reprocessing and maintenance	1	0	0
Hospital audits: reporting system	0	0	0
Inspections by foreign authorities*	22	39	30
Inspections of market controls	0	0	1

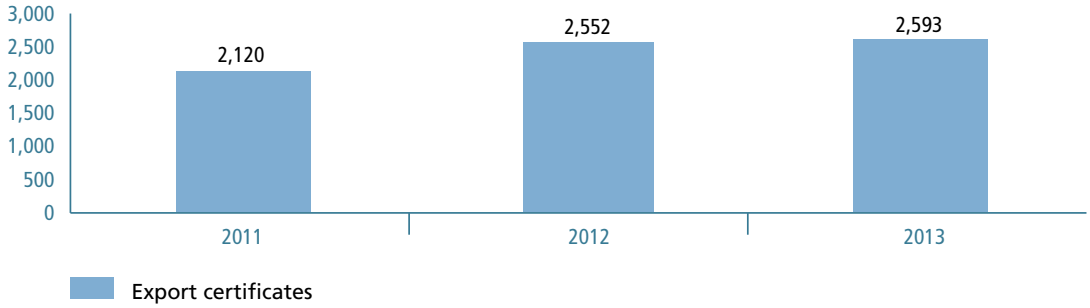
* (Co-ordination with SECO, incl. accompanying inspectors on site if needed)

EXPORT AND MANUFACTURING 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 2,593 export certificates were issued. Thanks to improved processes, it was possible to provide this service within 30 days in 99.5% of cases.



APPEALS PROCEDURES REGARDING THE MARKET MONITORING OF MEDICINAL 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 2013, 2 appeals were lodged in connection with the market monitoring of medicinal devices. The cases are still pending.

SPECIAL ACTIVITIES AND EVENTS: MARKET MONITORING OF MEDICAL DEVICES

Activities related to the entry into force of the new Human Research Act (HRA)
Within the framework of the entry into force of the new Human Research Act (HRA), Swissmedic made a considerable contribution in order to transfer the knowledge to the stakeholders and to provide them with the appropriate information (workshop for sponsors and investigators, work with the Federal Office of Public Health and the Ethics Committees for the concrete implementation of the HRA).

Revision of medical devices regulation within Europe
In connection with the revision of medical devices regulation within Europe, Swissmedic worked actively and comprehensively with the Federal Office of Public Health on the preliminary project for assessing the impact on Swiss regulations.

STANDARDS

LEGAL MATTERS

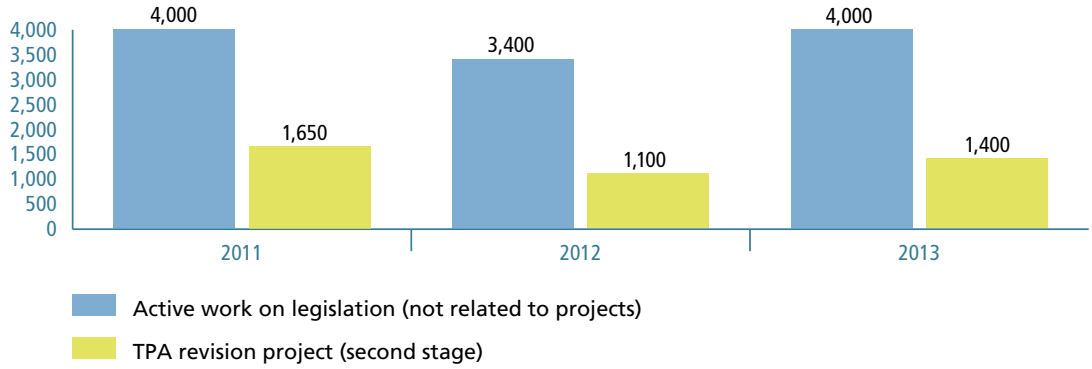
LEGISLATION

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

- The parliamentary consultation process for the ordinary revision of the Therapeutic Products Act (second stage) began in 2013. The National Council Committee for Social Security and Health began work on the comprehensive revision project during several sessions, at which Swissmedic participated within the framework of the joint project work with the Federal Office of Public Health, which is leading the preparatory work for the revision. The parliamentary consultation process will continue in 2014.
- The Federal Act on Research involving Human Beings (Human Research Act, HRA) entered into force on 1 January 2014. The legislation, which previously took the form of an ordinance, has become a new Federal Act, in collaboration with the Federal Office of Public Health. It specifies the ethical, scientific and legal requirements that must be respected regarding research involving humans, and encompasses three ordinances: the Ordinance on Clinical Trials in Human Research, the Ordinance on Human Research with the Exception of Clinical Trials, and the Ordinance on Organisational Aspects of the Human Research Act. The Federal Council approved the Ordinances on 20 September 2013, and they came into force simultaneously with the HRA on 1 January 2014.

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 of 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 2013, Swissmedic – together with Swiss experts from industry, universities, the pharmaceutical sector and the authorities – devoted a total of 11.2 man years to specialised work in this area, with 60% being carried out by the Swiss Agency for Therapeutic Products. The Agency's Pharmacopoeia division is Switzerland's national pharmacopoeia authority. A total of 134 experts from Switzerland were mandated to work in the various national and European committees and groups working on the pharmacopoeia.
- Switzerland made a significant contribution to the preparation of the three supplements 7.6, 7.7 and 7.8 of the 7th edition of the Ph. Eur., which entered into force in 2013 together with the translation into German. In addition, preparations were begun for the publication of the 8th edition of the Ph. Eur.
- In 2013, in the elections held every three years for the Ph. Eur. experts, 97 of the approximately 800 posts on the specialised committees and groups were filled by Swiss experts. 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.
- Supplement 11.1 to the Ph. Helv. was published in 2013 and came into force on 1 September. In the supplement, and with the involvement of the Swiss Pharmacopoeia Commission, various texts were adapted to reflect the current status of science and technology and their wording was brought into line with the Ph. Eur. A resolution adopted by the Council of Europe led to the alignment of the rules of Good Manufacturing Practice for medicinal products in small quantities in the Ph. Helv. with those of the corresponding international regulations. As has been the case to date, the supplement is available as a bound paper version. The online version was updated accordingly on 1 September 2013, and was completed by additional information in some texts.
- In Switzerland, the Agency Council provided new regulations for Swiss pharmacopoeia expert groups that constitute a future-oriented basis for the work. To date, the work of these groups, their terms of reference and the procedure for the appointment of members were regulated separately for each group. The various aspects are now included in a single set of regulations valid for all of them. These regulations also define aspects of conflicts of interest regarding work on the pharmacopoeia. In this way, the need for transparency in politics and public administration is taken into consideration.

TECHNICAL STANDARDS

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 once again updated in 2013, in accordance with Swissmedic's mandate, 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 297 standards: 20 fewer than in the previous year.
- Swissmedic was active in four national standards committees in 2013. In collaboration with the Swiss Association for Standardization (SNV), the Agency checks proposals for international standards concerning medical devices on an ongoing basis, takes a stance on them, and represents its interests by taking part in the voting.

SPECIAL ACTIVITIES AND EVENTS: TECHNICAL STANDARDS

New Presidium of the European Pharmacopoeia Commission
Within the framework of the election of new members, the European Pharmacopoeia Commission (COM) also voted on its new Presidium. The COM is the decision-taking body of the Ph. Eur. The Presidium of the COM prepares the meetings of the Commission and consists of the Chair, two Vice-Chairs and the Secretariat of the Ph. Eur., whose services are provided by the EDQM. For the new period in office that began in 2013, the COM elected Dr. Tobias Gosdschan, Head of Swissmedic's Pharmacopoeia division and head of the Swiss delegation to the COM.

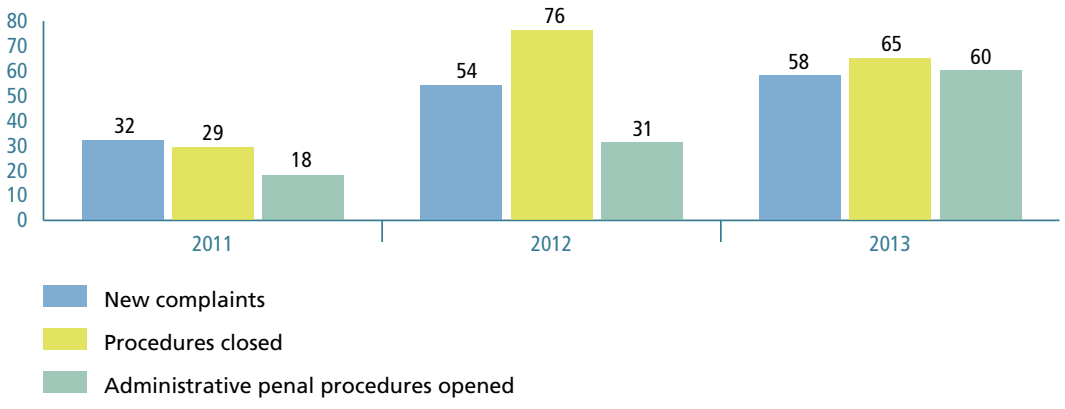
PENAL LAW

GENERAL DEVELOPMENTS

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

Activities

- The Penal division received 58 new complaints. It opened 60 administrative penal proceedings and 65 cases were closed.
- The number of cases handled and of investigations carried out has increased considerably. It was possible to resolve long-standing cases in parallel to opening new ones during 2013. The time limits for handling proceedings and their quality were aspects that were further optimised. This development is not least the result of additional human resources for penal prosecutions being attributed in 2012.
- The subjects of the proceedings that were opened became more diverse, and notably included the area of stem cells and treatments using fresh cells. The Penal division moreover opened investigations relating to the misappropriation of medicines intended for humanitarian purposes. The related proceedings are still ongoing.
- Work with a view to ratifying the Medicrime Convention continued. The consultation procedure was initiated by the Federal Council on 18 December 2013 and will continue until 2 April 2014.



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

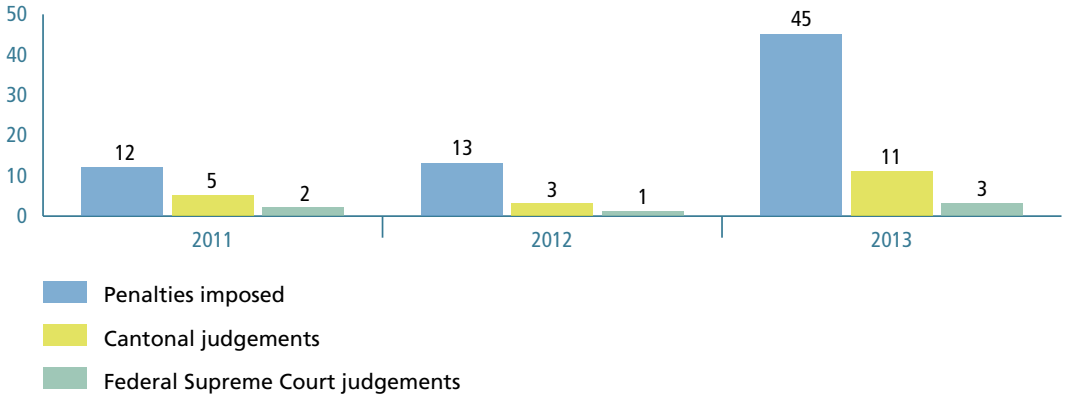
- In 2013, Swissmedic carried out 25 house searches and 54 hearings.
- A request by Swissmedic to remove the seals affixed to seized documents was approved by the Federal Criminal Court.
- The refusal to release seized objects, documents and assets was the subject of a complaint lodged with the Federal Criminal Court. The decision will be published early in 2014.
- In 2013, and for the first time, the Penal division requested and obtained the provisional detention of an accused person because of the risk of absconding. The accused was released after 17 days of detention.
- With regard to international mutual assistance on penal matters, Swissmedic lodged two requests to Germany, handled a request for additional information from France concerning a request initially received in 2011, and also handled a new request from the French authorities.
- Six cases were the subject of procedural unification, i.e. the association of the prosecution with the Cantonal proceedings (Art. 20, para. 3, Federal Act on Administrative Penal Law, RS 313.0). Several of them concerned, in parallel, suspicions of infringements to the Federal Act on the Promotion of Sport and Exercise (SpoFG, RS 415.0) and to the Therapeutic Products Act (TPA). The cases mainly concerned the illegal import of medicines. With regard to the first law, the actions to be taken fell within the competence of the Cantons and for the second, they were within the competence of Swissmedic. The unification of procedures in such cases permits the Canton to hand down a conviction by virtue of the TPA when the suspicions concerning the SpoFG are not confirmed.

DECISIONS / JUDGEMENTS BY SWISSMEDIC AND BY COURTS

After the investigation phases, 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 45 penalties were imposed, of which 14 followed an investigation on an illegal clinical trial carried out by a group of doctors. Two procedures related to illegal activities (manufacturing, wholesale trading, placing on the market) regarding skin whitening products led to sentences of 140 daily penalty units of CHF 150.- and 60 daily penalty units of CHF 160.- with – in both cases – fines of CHF 4,500.- and in the first case a claim for damages of CHF 38,000.-. A sentence of 60 daily penalty units of CHF 350.-, a fine of CHF 5,000.-, and a claim for damages of CHF 181,000 were handed down in a case of wholesale trade. In the last case, the decision was contested and the case will be brought before the competent court for the proceedings. Seven fines were imposed for illegal publicity, notably for products based on botulinum toxin, and 2 for violating the provision that prohibits the acceptance of material advantages (Art. 33, TPA). The other cases concerned cases of different scales with regard to illegal imports and trade.
- The Cantonal penal authorities issued various decisions on cases concerning the dispensing by doctors of medicinal products for which authorisation was mandatory but that were not authorised. Several of the decisions, on the proposal of Swissmedic and in application of the Ordinance on the Notification of Cantonal Criminal Judgments (RS 312.3), were the subject of appeals on a Cantonal level or to the Federal Supreme Court; either because the Cantons acquitted the persons concerned or because they did not impose the payment of damages or a penalty.
- In two cases concerning the dispensing by doctors of medicinal products for which authorisation was mandatory but that were not authorised, the Federal Supreme Court confirmed that the acts concerned were illegal: in one, it rejected the appeal by a person sentenced at the Cantonal court of second instance, and in the other it accepted the appeal by the Office of the Attorney General of Switzerland against the dismissal of the case by the Cantonal court.



STAKEHOLDER MANAGEMENT

INFORMATION

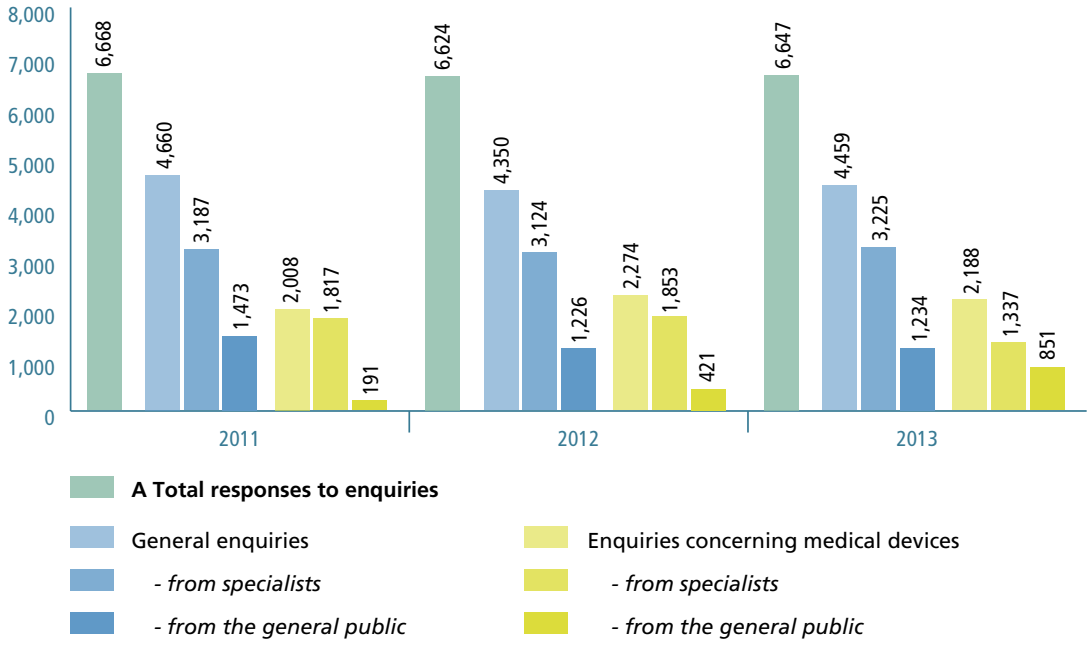
Swissmedic provides fast, targeted information on new findings concerning therapeutic products that could constitute health hazards. In addition to safety-relevant information, new authorisation decisions or major changes to medicinal product information are of considerable interest.

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 2013, Swissmedic responded to 6,647 enquiries, which represents a slight increase compared with the previous year.
- A total of 96% of all enquiries were answered within ten calendar days.
- Many of the enquiries concerned Swissmedic's new medicinal product information system, launched in January 2013. In addition, numerous enquiries concerned the ordering of medicinal products from the Internet, the import of medicinal products by travellers requiring medication, and licences.



Performance indicator	Target	Result
General enquiries: percentage of responses sent within 10 days	97%	96%

PRESS RELATIONS

Providing information to the public is a key task for Swissmedic. Press relations are based on open, rapid communication. Information and explanations for the press need to be consistent, comprehensible and clear in order to provide factual, correct information on the risks related to medicinal products and medical devices.

Activities

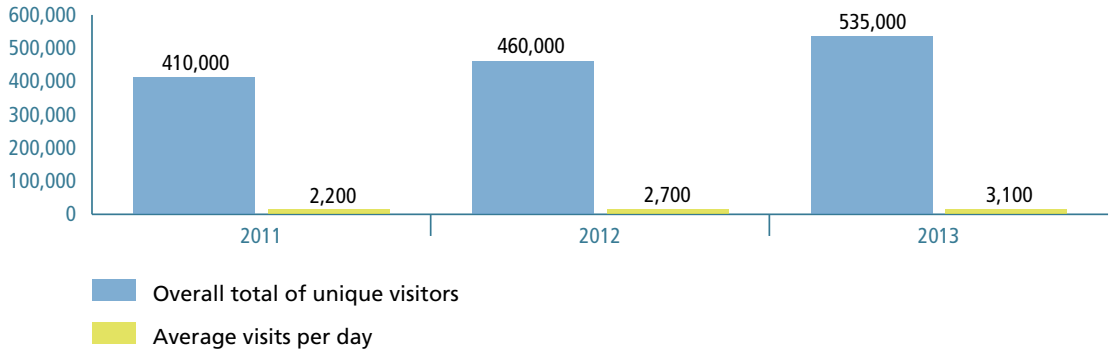
- In 2013, Swissmedic answered 726 enquiries from journalists. This represents an increase of 10% compared with the previous year.
- In 2013, Swissmedic issued eight press releases, including contributions to the ongoing discussions on hormonal contraceptives, the decrease in illegal imports of medicinal products, and the seizure of counterfeit psychotropics at Zurich airport.
- Numerous communications containing additional material were published on the Swissmedic website, such as updated information on combined hormonal contraceptives or background information on the changes to practice with regard to generics.
- Work with the press surrounding the controversy over the safety and risks of combined hormonal contraceptives was particularly intensive.
- Other press enquiries concerned Swissmedic's new medicinal product information system, launched at the beginning of the year (www.swissmedicinfo.ch), the market monitoring of medical devices, or questions on important medicinal products for rare diseases (orphan drugs).

PUBLICATIONS

In addition to its official monthly publication – the Swissmedic Journal – and its annual report, Swissmedic also publishes other types of information. This includes a newsletter, reports, guidelines, and articles on topics of current interest. These are all available on the Swissmedic website.

Activities

- In 2013, the number of visits to the Swissmedic website rose to over 500,000, which constitutes a significant increase compared to the previous year.
- The peak – reaching over 5,800 daily visits – took place in mid-November 2013, during the period in which Swissmedic reported on the risks related to combined oral contraceptives.
- Towards the end of 2013, Swissmedic's website underwent a technical overhaul, and was adapted to current user habits regarding searches and use. The clearer design and the optimised navigation and search function made it easier to find information. At present, topical news sections are available to which users can also subscribe as RSS feeds.



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 topic of the first of the 18 information events organised by Swissmedic in 2013 was the new AIPS publication platform for publishing product information intended for healthcare professionals and patients. Details were provided of the background to the new platform, its functioning, and the changes involved.
- The information events in 2013 included one on each of the following topics: the electronic submission of applications (eCTD), the new legislation on pharmacovigilance in the European Union, narcotics, and clinical trials. In addition, the Haemovigilance unit also organised one workshop in German and another in French.
- Together with the European Directorate for the Quality of Medicines & Health Care (EDQM), Swissmedic hosted the Annual OMCL Gene Therapy Meeting in 2013.
- The high point as regards the 2013 calendar of events was "Swissmedic regulatory news from the Authorisation sector", in which Swissmedic presented important new aspects in the regulatory environment.
- The final event in 2013 was the Contact Persons Meeting, held by the Medical Devices division. This event included a podium discussion for the first time. Representatives from Swissmedic, the Cantonal authorities, hospitals and industry discussed current issues within the field of medical devices.

PRESENTATIONS AND ADDRESSES

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

Activities

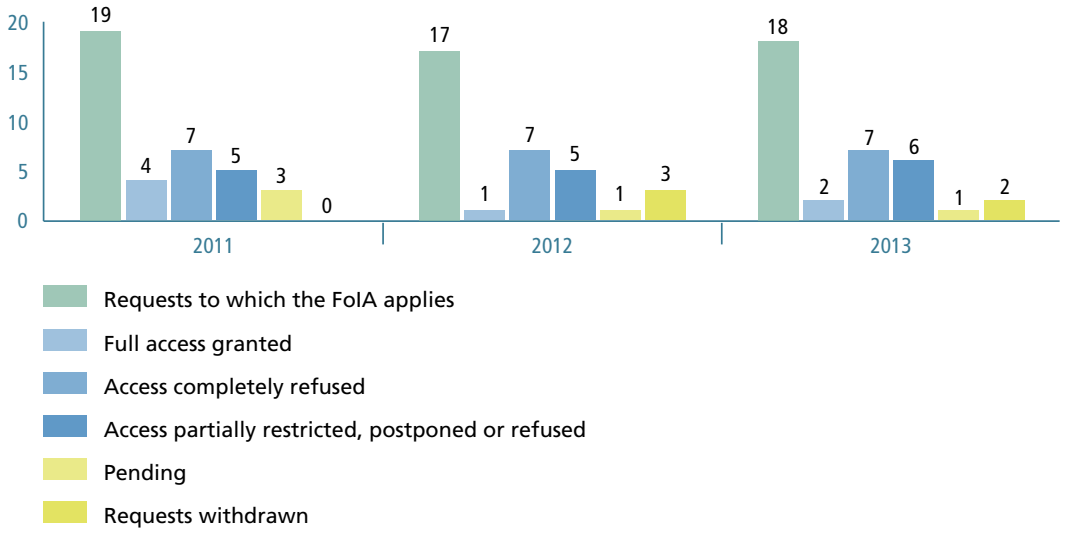
- Swissmedic staff gave 141 presentations and addresses at external and internal events in 2013, which constitutes a slight increase in comparison with the previous year.
- The events concerned were congresses, seminars or conferences intended for a specialised public from the pharmaceutical and regulatory sectors.

TRANSPARENCY

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

Activities

- In 2013, Swissmedic received 18 requests to which the FoIA applies. Their number remains stable in comparison 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 the 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 aspect that permits Swissmedic to achieve the objectives specified in its legal mandate, the service mandate and the service agreement. Guaranteeing the safety of therapeutic products is of the utmost priority in the said objectives. The following stakeholder groups comprise 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

- Within the framework of a workshop in April 2013, Swissmedic informed patient and consumer organisations, industry, and specialised associations about the planned relaunch of the Swissmedic website and obtained feedback from them on the subject.
- On 23 May 2013, Esa Heinonen, Head of the Authorisation sector, led a Swissmedic Regulatory Affairs round table meeting. A further round table took place on 17 September 2013 and concerned the change of practice at Swissmedic with regard to generics.
- In July 2013, Swissmedic invited representatives of industry, consumer, patient and healthcare associations to a round table meeting on Swissmedic's strategy for 2015 – 2018. The objective was to evaluate the previous strategy period and also to identify opportunities, possible threats, strategic risks and key areas for development.

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 2013, 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 2013 at the Zurich Institute of Applied Sciences, a group of 30 individuals active in the health sector visited Swissmedic on 8 February 2013. The Agency's work and its various sectors were presented.
- Swissmedic experts took part in further training initiatives organised by third parties by giving various presentations, and particularly on the core tasks of Swissmedic: the authorisation of medicinal products, licensing and market monitoring.

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 with regard to 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 makes it possible to identify risks at an early stage and to initiate 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.

Activities

- From 28 to 30 January 2013, the 7th edition of the DIA Asia Regulatory Conference took place in Singapore. Swissmedic was part of the programme committee for the first time, and took an active part in preparing the conference. The Agency also chaired the session "Global Review Practices: Industry & Regulatory Working Together".
- The Steering Committee and Expert Groups of the International Conference on Harmonisation met in La Hulpe, Belgium in June and in Osaka, Japan in October. Within this committee, Swissmedic represents the EFTA states and has observer status. It also plays an active role in the various Expert Working Groups.
- During a three-month visit, an employee from the Japanese authorities studied Swissmedic's structures and processes with the objective of enhancing and simplifying the collaboration between the two agencies.
- From 24 to 26 September, Swissmedic hosted an eight-member delegation from the South African Medicine Control Council (MCC) for training purposes. Swissmedic provided insights into the areas covered by its mandate and its fields of work. According to the head of the delegation, Swissmedic's organisational methods and structure will be used as a benchmark for the planned creation of an independent medicinal products authority in South Africa.
- Towards the end of the year, the Federal Council authorised Swissmedic to sign a joint statement of intent with the German Federal Institute for Drugs and Medical Devices (BfArM), with the purposes of exchanging information and documents, enhancing understanding of each authority's regulatory framework condi-

tions, requirements and processes, and of fostering collaboration. The joint statement of intent was signed by both parties on 7 January 2014 and has thus entered into force.

- In September 2013, the Federal Council approved – in addition to the renewal of Swissmedic's service mandate – an adjustment to it that authorises the Agency to collaborate on development projects.

SPECIAL ACTIVITIES AND EVENTS: STAKEHOLDER MANAGEMENT

Swissmedic organised the International Generic Drug Regulators Pilot (IGDRP) meeting
Thanks to co-sponsoring with the WHO, Swissmedic held the fifth IGDRP meeting in Geneva on 28 to 30 October 2013, and also acted as the secretariat for the event. This meeting, which takes place twice yearly, united over 50 representatives of medicinal products authorities. The objective of the initiative is to foster the harmonisation of regulations and to achieve closer collaboration regarding the authorisation of generics.

Swissmedic acts as the chair and secretariat of the International Pharmaceutical Regulators Forum (IPRF)
The newly established IPRF met for the first time from 11 to 12 November 2013 within the framework of the ICH meeting in Osaka, Japan. Swissmedic is chairing this entity, which is a unique platform for information exchange among medicinal products authorities worldwide, and is also acting as its secretariat. The forum permits its members to discuss and exchange scientific information and regulatory experience, and thus makes an important contribution to the ongoing harmonisation of technical requirements for the authorisation of medicinal products.

TELEMATICS/INFORMATION TECHNOLOGY

IT MANAGEMENT

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

Activities

- The Swissmedic strategic IT plan, launched in 2011, was not modified during 2013. The implementation of the four-year strategy was continued consistently and according to plan.
- Within the framework of the sub-strategy for the sourcing of IT, the consolidation of sourcing partners for IT development services, which began in 2012, was completed. At present, Swissmedic has 5 dedicated IT service providers that were assessed during public tenders and with which long-term contracts have been concluded. Operating and integration services will continue to be provided by the Federal Office of Information Technology, Systems and Telecommunications (FOITT).
- The portfolio of intended IT projects was critically assessed with a view to the expected benefits, and was re-prioritised. Investments in IT solutions in the coming years are focused on eGovernment solutions and internal electronic business management. The interaction between external stakeholders and Swissmedic will be further developed. It will be "paperless" to the greatest possible extent, seamless, safe, automated and accessible at all times.

SOLUTION DEVELOPMENT

The implementation of the IT road map is extremely important for achieving Swissmedic's strategic objectives. Above all, outdated IT solutions must be modernised. After establishing this basis, additional functions to support the processes will be developed as of 2013. The focus in doing so will be on eGovernment, i.e. the expansion of official business traffic with Swissmedic via the Internet.

Activities

- As of mid-2013, the SAP platform developed within project PRIME became operational as a new, specialised and economically viable backbone for Swissmedic's business processes. The largest IT project within Swissmedic's history, it was completed on time and in line with the planned costs (around CHF 13 million) thanks to the extraordinary commitment of all those involved both within Swissmedic and beyond. The new information system platform constitutes a stable basis for integrating the internal, electronic document management system and for the electronic interaction with Swissmedic stakeholders via eGovernment processes.
- Thanks to the eGov Portal project, it was possible to provide the basic IT components for the future eGovernment processes. The first eGovernment services, for the processing of applications, will be made available to the medicinal products industry in 2014.
- The technical concept for the document management system (DMS) project was completed. With the related digitisation of all incoming paper documents, "paperless" processing will be implemented within Swissmedic. The implementation will also include the organisational adjustment of the process flows to be in line with the new possibilities offered by digital document management.
- At the end of 2013, and according to plan, the overhaul of both the structure and content of the Swissmedic website was completed. The new website has a modern design, is more compatible with mobile devices, and information can be found more easily.

IT OPERATIONS, USE, MAINTENANCE AND ONGOING IMPROVEMENTS

Using IT solutions requires trained, informed users; easily accessible, secure and well-maintained infrastructures; the constant development of the potential for greater effectiveness; and rapid, simple access to support services. Service and application management has the important task of developing and managing all these aspects. The operating and support services for Swissmedic's entire system infrastructure and office automation solutions are provided by the FOITT, and other service and software suppliers are brought in for the maintenance and further development of IT resources.

Activities

- The challenging implementation and migration phase for the new SAP platform, which took several months, required operating capacities in 2013 to be focused on maintaining IT elements that were critical for Swissmedic's business. It was possible to handle the operational transfer without any major impact on the technical availability of IT systems. The expected slight impact on productivity during the changeover was rapidly overcome. The further optimisation of the IT processes implemented will continue to be a key issue over the coming year.
- Within the framework of the information security measures implemented throughout Switzerland, all internal Swissmedic users of IT systems were provided with new means of identification and access. The use of Swissmedic IT workplaces now offers greater security, since they can only be accessed using a personal smart card with a digital ID certificate.
- Increased expenditure in 2013 concerned the area of service management. The preparation of the move to the new premises on Freiburgstrasse, the removal and transfer of equipment from the premises on Erlachstrasse were aspects that required particular efforts in terms of providing and maintaining IT infrastructures and workplaces. The activities concerned were completed on schedule.
- The nearly 40 smaller projects completed all contributed to maintaining a robust IT structure, to adapting specialised applications in line with modified legal requirements and to optimising the business processes.

ORGANISATION

SWISSMEDIC AGENCY COUNCIL

Composition in December 2013

Chairwoman: Beerli Christine

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

MEMBERS OF THE SWISSMEDIC HUMAN MEDICINES EXPERT COMMITTEE (HMEC)

Composition in December 2013

Chairman: Krähenbühl Stephan, Prof. Dr. med.

Ordinary members

Castiglione Monica, Prof. Dr. med.
Cerny Andreas, Prof. Dr. med.
Dayer Pierre, Prof. Dr. med.
Schaffner Thomas, Prof. Dr. med.
Schild Laurent, Prof. Dr. med.
Vogt Markus, Prof. Dr. med.

Extraordinary members

Aicher Lothar, Dr. Phil. nat.
von Ammon Klaus, Dr. med.
Bauer Matthias, PD Dr. med.
Bauer Rudolf, Univ.-Prof. Dr. rer. nat.
Bonnabry Pascal, Prof. Dr. pharm.
Brunner-Ferber Françoise, Ph.D.
Brutsche Martin Hugo, Prof. Dr. med.
Caldelari Reto, Ph.D.
Cavin Frédy, phil. nat.
Cerny Thomas, Prof. Dr. med.
Cotting Jacques Ernest, Dr. med.
Eberli Franz Robert, Prof. Dr. med.
Egger Matthias, Prof. Dr. med.
Erne Paul Josef Erwin, Prof. Dr. med.
FitzGerald Reginald Edward, Dr. Phil. nat.
Follath Ferenc, Prof. Dr. med.
Frost Heiner, Dr. med.
De Geyter Christian, Prof. Dr. med.
Genton Blaise, Prof. Dr. med.
Giannopoulou-Politakis Catherine, PD Dr. med.
Henkel Verena, Prof. Dr. med.
Heusser Peter, Prof. Dr. med.
Hüsler Jürg, Prof. Dr. Phil. nat.
Itin Peter Hans, Prof. Dr. med.
Köfüncü Evra, Dr. med.
Kraenzlin Marius Edgar, Prof. Dr. med.
Lauterburg Bernhard, Prof. Dr. med.
Leniger Tobias, PD Dr. med.
Ludwig Christian, Prof. Dr. med.
Marbet German Albert, Prof. Dr. med.
Meier Christoph Rudolf, Prof. Dr. pharm.
Meier Rémy Friedrich, Prof. Dr. med.
Messerli Jürg, Dr. med.
Möller Burkhard, Prof. Dr. med.
Munier Francis Louis Paul, Prof. Dr. med.
Nägeli Hanspeter, Prof. Dr. med. vet.
Pfeifer Dina, Dr. med.
Pittner Heribert, Prof. Dr. med.
Schädelin Jürg, Dr. med.
Schär Peyer Beatrice, Dr. sc. nat.
Schimmelmann Benno G., Prof. Dr. med.
Schmid Beat, Dr. Phil. nat.
Schmid-Grendelmeier Peter, PD Dr. med.
Seger Reinhard A., Prof. Dr. med.
Strik Werner Konrad, Prof. Dr. med.
Thomi Matthes Brigitte, Dipl. pharm.
Tramèr Martin Richard, Prof. Dr. med.
Vogt Bruno, Prof. Dr. med.
Weber Klaus, Dr. rer. nat.
Wilks Martin F., Prof. Dr. med.
Wolf Ursula, PD Dr. med.
Yerly Daniel, Dr. Phil. nat.
Zangemeister Uwe, Prof. Dr. Phil. nat.
Zimlich Klaus-Heinrich, Dr. rer. nat.
Zimmerli Werner, Prof. Dr. med.

MEMBERS OF THE SWISSMEDIC VETERINARY MEDICINES EXPERT COMMITTEE (VMEC)

Composition in December 2013

Chairman: Wüthrich Andreas, Dr. med. vet.

Ordinary members

Bieri Peter, Dr. med. vet.
Bürgi Esther, Dr. med. vet.
Glaus Tony, PD Dr. med. vet.
Knutti Barbara Katharina, Dr. med. vet.
Meylan Mireille, Prof. Dr. med. vet.
Perreten Vincent, Prof. Dr. sc. tech

Extraordinary members

Hoop Richard, Prof. Dr. med. vet.
Nägeli Hanspeter, Prof. Dr. med. vet.
Ruoff Kaspar, Ph.D.
Schmidt Andreas, Dr. med. vet.
Spadavecchia Claudia, Prof. Dr. med. vet.
Wahli Thomas, PD Dr. Phil. nat.
Wenker Christian, Dr. med. vet.
Zinsstag Jakob, Dr. med. vet. Ph.D.

AUDITORS

Swiss Federal Audit Office

OUR STAFF – OUR CAPITAL

status December 2013

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Schnetzer Jürg H.

MANAGEMENT BOARD

Balsiger Betts Andreas, Dörr Petra, Heinonen Esa, Jenny Hans-Beat, Mathys Badertscher Karoline, Schütz Baumgartner Barbara, Tschannen Adrian

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Messari Annemarie, Messerli Nicole, Messi Mara, Meusburger Madeleine, Meyer Rita, Meyer Simon, Meyer Urs, Minnig Sabine Monique, Mooser Guido, Mosimann Lenzin Ruth, Müller Markus-Peter, Müller-Mook Renate, Munz Thomas, Mutti Sven, Nava Gabriela, Neeser Zaugg Rosmarie, Nick André, Niggli Urs, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Oberli Aurelia, Op den Camp Roeland, Osswald Tschan Marco, Paniga Nicoletta, Pavelic Ferretti Danijela, Perez Eugen, Perret Irene, Peter Nicole, Petitpierre Claude-Philippe, Pfäffli Chantal, Philippekin Frédéric, Pinsard François, Plüss Ruth, Polatti Daniela, Porporini Lucio, Prisching Andrea, Pürro Michel, Putzke Jörg, Ramelli Monica, Ramseier Isabelle, Rätz Katerina, Renaudin Michael, Renftle Wolfgang, Rethage Janine, Reusser Daniel, Richter Thomas, Rieder Barbara, Riedl Jutta, Riesen-Beer Sabine, Rizk Sviatlana, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Roux Catherine, Ruch Claudia, Rüegsegger Ruth, Rüfenacht Francine, Rumo Anton, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sänger Michael, Saurer Isabella, Scalise-Boes Claudia, Schaffner Nils, Schärer Andrea, Schärer Christian, Schäublin Martina, Scheidegger Anita, Scheidegger Michelle, Scheidegger René, Schläfli Ernst, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Eggler Dorit, Schnyder Benno, Schnyder Franz-Lukas, Schnyder Renato, Schochat Thomas, Schöni Damian, Schönthal Cornelia, Schumacher Thérèse, Schütz Frikart Andrea, Schwab-Stampfli Rebekka, Schwartz Thomas, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Senessie Charles, Seyffert Bernadette, Sieg Anna, Skoko Lena, Sofic Luana, Spicher Andrea, Spohn Margot, Spörri Bernhard, Stacchetti Matthias, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stalder Barbara, Stämpfli Ursula, Stäuble Elisabeth, Stauffer Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Stettler-Michel Marianne, Stoller Denise, Stoller Rudolf, Stötter Hans-Wolfgang, Strack Guido, Straub Andrea Katharina, Studer Peter, Sulser Mario, Tanner Yvonne, Tanner Soland Eveline, Terkovics Attila Leo, Teuscher Françoise, Thiess Maria, Thomas Sabine, Thürig Soltermann Eva, Toma Valeriu, Torriani Wymann Kay Isabella, Tromp Jan, Tschalär Yolanda, Tschirren Markus, Tschümperlin Heidi, Utiger Christoph, van den Ouweland Frank, van Hoef Marlies, Velic Medina, Vihertola Mari, von Mühlenen Eva, Vuilleumier Monika, Wacker Christoph, Wagner Jan, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Wälti Markus, Wälti Rudolf, Waser René, Weber Heidi, Wegmann Barbara, Weissmahr Richard, Weitz Manfred, Weix Janine, Wenng Andreas, Weyermann Philipp, Whitehead Frances, Whitehead Margaret, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wittwer Stefanie, Wüthrich Karin, Wyss Brigitte, Wyss Martin, Wyss-Romanello Sabine, Zabala Ruiz Arantzazu, Zaugg Kunz Sandra, Zbinden Raphael, Zbinden Kaessner Eva, Zemp Markus, Zenhäusern Gabriela, Ziak Martin, Ziehli Salvisberg Mariette, Zimmermann Esther, Zimmermann Marion, Zumbrunn Severin, Zurbuchen Andreas, Zürcher Jasmin, Zurkinden Tanja, Zwahlen Roland

INCOME STATEMENT 2013

in KCHF	2013	2012
Procedural fees and income further to art. 69 TPA	35,900	26,598
Levies on sales	41,095	40,138
Other income	48	41
Federal contribution	14,700	15,200
Other operating income	173	177
Loss of revenues	-6,335	0
Total income	**85,581**	**82,154**
Services for third parties	-1,625	-1,586
Personnel	-63,259	-59,920
Rental, maintenance, energy, transport and insurance	-3,022	-3,274
Administration	-4,894	-5,001
IT	-11,570	-8,999
Other expenditure	-445	-425
Amortisation	-3,447	-3,050
Total operating expenditure	**-88,262**	**-82,255**
Operating income before financial result	**-2,681**	**-101**
Financial income	**8**	**7**
Financial expenditure	**-273**	**-246**
LOSS FOR THE FINANCIAL YEAR	**-2,946**	**-340**

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

PRODUCT ACCOUNTING 2013

in KCHF

Products Products groups	Principal funding of products based on 2011–2014	Expenditure	Procedural fees income	Results
Legal foundations	Federal contributions	-6,366	0	-6,366
Technical standards	Fees	-3,197	0	-3,197
Total Standards products group		**-9,563**	**0**	**-9,563**
Information for the general public	Federal contributions	-6,425	0	-6,425
Information for the therapeutic products branch	Fees	-1,440	281	-1,159
Total Information products group		**-7,865**	**281**	**-7,584**
Marketing authorisation	Fees	-33,458	17,567	-15,891
Licences	Fees	-11,499	9,466	-2,033
Total Market Access products group		**-44,957**	**27,033**	**-17,924**
Vigilance of medicinal products	Fees	-8,493	282	-8,211
Vigilance of medical devices	Federal contributions	-3,360	0	-3,360
Market monitoring of medicinal products	Fees	-8,750	836	-7,914
Market monitoring of medical devices	Federal contributions	-2,302	0	-2,302
Total Market Surveillance products group		**-22,905**	**1,118**	**-21,787**
Penal law	Federal contributions	-2,365	539	-1,826
Total Penal Law products group		**-2,365**	**539**	**-1,826**
Services for third parties	Fees	-681	661	-20
Total Services for third parties products group		**-681**	**661**	**-20**
Other operating expenditure		9		9
Total products		**-88,261**	**29,566**	**-58,695**
Levies on sales				41,095
Federal contributions				14,700
Other income				220
Financial result				-265
Operating income				-2,946

PRODUCTS FUNDED MAINLY BY THE CONFEDERATION 2013

in KCHF

Products	Expenditure based on product accounting	Procedural fees income	Result based product accounting
Legal foundations	-6,366	0	-6,366
Information for the general public	-6,425	0	-6,425
Vigilance of medical devices	-3,360	0	-3,360
Market monitoring of medicinal products	-2,302	0	-2,302
Penal law	-2,365	539	-1,826
Total products funded mainly by the Confederation	**-20,752**	**473**	**-20,279**
Total Federal contributions			**14,700**
Expenditure surplus			**-5,577**

BALANCE SHEET 2013

in KCHF	Balance sheet at 31.12.2013	Balance sheet at 31.12.2012
Cash and cash equivalents	3,447	2,662
Receivables from sales and services	19,334	18,153
Other receivables	1	28
Active accruals	69	35
Current assets	**22,851**	**20,878**
Fixed assets	3,581	2,776
Immovable property	73,048	62,068
Intangible assets	10,473	9,534
Capital assets	**87,102**	**74,378**
TOTAL ASSETS	**109,953**	**95,256**
Commitments on sales and services	5,433	6,627
Other commitments	31,649	3,033
Passive accruals and short-term provisions	3,646	3,269
Short-term commitments	**40,728**	**12,929**
Firm advances	10,000	20,000
Provisions for loyalty bonuses	2,364	2,337
Provision for pension fund commitments (net)	36,005	48,210
Long-term commitments	**48,369**	**70,547**
Endowment capital	14,500	14,500
Reserves	9,302	-2,380
Loss	-2,946	-340
Own capital	**20,856**	**11,780**
TOTAL LIABILITIES	**109,953**	**95,256**

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