



ANNUAL REPORT 2011


swissmedic

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CHRISTINE BEERLI
CHAIRWOMAN OF THE AGENCY COUNCIL

“ PROVIDING TOP-QUALITY
SERVICES ON TIME.”



“SWISSMEDIC IS SET FOR THE CHALLENGES THE COMING YEARS WILL BRING.”

Swissmedic modified its authorisation process in line with that of the EMA (the European Medicines Agency) in 2008. As a result the time that a process should take is equal in length in both agencies. There is no denying that Swissmedic requires longer to process some types of applications compared to the time taken by the EMA.

However, Swissmedic's fast-track authorisation procedure for innovative medicinal products, particularly those for illnesses for which there is as yet no treatment, is highly competitive.

In addition to the “standard” and “fast-track” authorisation procedures, Swissmedic is to launch an “advanced registration procedure” early in 2013. This procedure will be used for those innovative medicinal products not fulfilling the criteria of the current fast-track procedure.

Swissmedic is ready to do its part to ensure that patients are given prompt access to innovative medicinal products. Such an approach will ensure the preservation, and indeed improvement of the environment for research within Switzerland. Further improvement, where still required, should be achieved through dialogue with all those concerned.

Swissmedic needs more resources in order to ensure that deadlines are met, the advanced registration procedure is introduced and its infrastructure is modernised. For these reasons, the Agency Council reviewed the fees ordinance in 2011, with the aim of increasing its income and boosting resources with 30 additional full-time positions. Notwithstanding the Agency Council wants the available resources to be used both efficiently and effectively, whilst also striving to ensure transparency of its processes for external partners.

Such transparency is the purpose of the new Annual Report. The new module “reports” contains, for the first time, performance indicators with targets and statements of achievement. Swissmedic wishes to further improve its measurability in this respect over the coming years.

Swissmedic has not yet reached its goal – but it is well on the way to becoming a modern, high-performing authority.

SWISSMEDIC HAS MADE ITSELF MORE PUBLICALLY VISIBLE IN RECENT YEARS. THE REQUIREMENT FOR CONSISTENCY AND TRANSPARENCY IS TAKEN SERIOUSLY. THE EXPERTISE OF OUR STAFF IS APPRECIATED BY OUR NATIONAL AND INTERNATIONAL STAKEHOLDERS. OUR STAFF MEMBERS ARE ESSENTIAL FOR HIGH QUALITY DELIVERY.

However, the expectations for efficiency in contractual fulfilment have also increased in recent years. Performance measurement on all levels, using appropriate indicators, has become an inherent part of our daily management activities.

From the industry's point of view, the focus here is on punctuality – especially with regard to authorisations. Since the introduction of a planning tool in July 2011, it has been possible to monitor and control all applications submitted for authorisation and their current progress and scheduling status. The monthly evaluations provide the management board and the Agency Council with information on both the submitted applications and the number of applications being processed, and consequently the performance of the authorisation process.

Compliance with deadlines, however, is only one aspect of the key performance indicator and control systems that encompass the entire Agency, and which are incorporated in the reporting system to the Agency Council and the Federal Department of Home Affairs. The figures that are revealed in this Annual Report for 2011 are also based on this system.

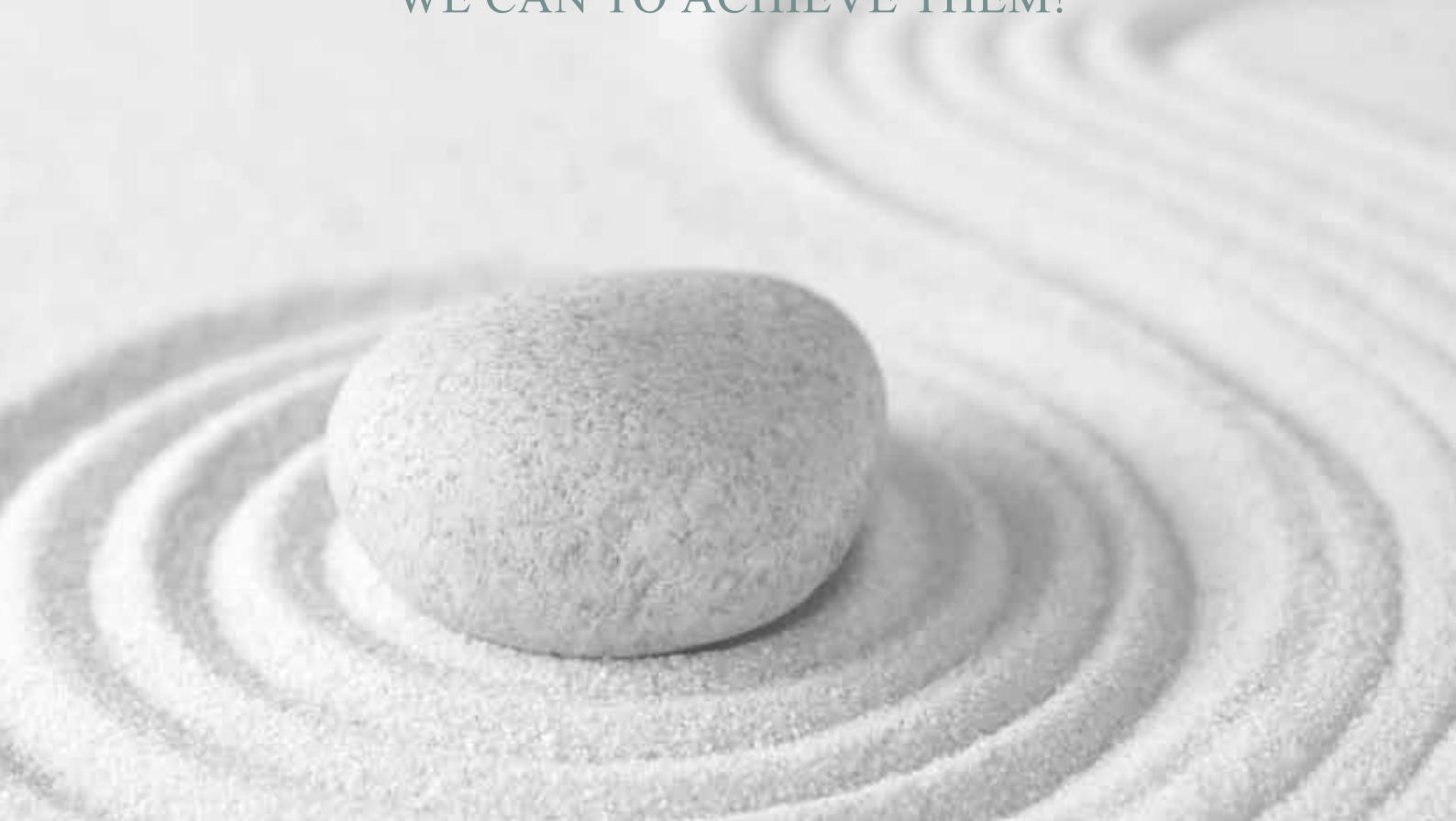
In 2011, Swissmedic successfully completed the first stages of the modernisation of its IT infrastructure, elements in the so called IT roadmap. The financial and invoicing applications, and in addition activity recording have been converted to SAP. Further components are to be introduced over the coming years to make process control easier, to provide and facilitate processing of management information, and to aid better management of the Agency and its divisions.

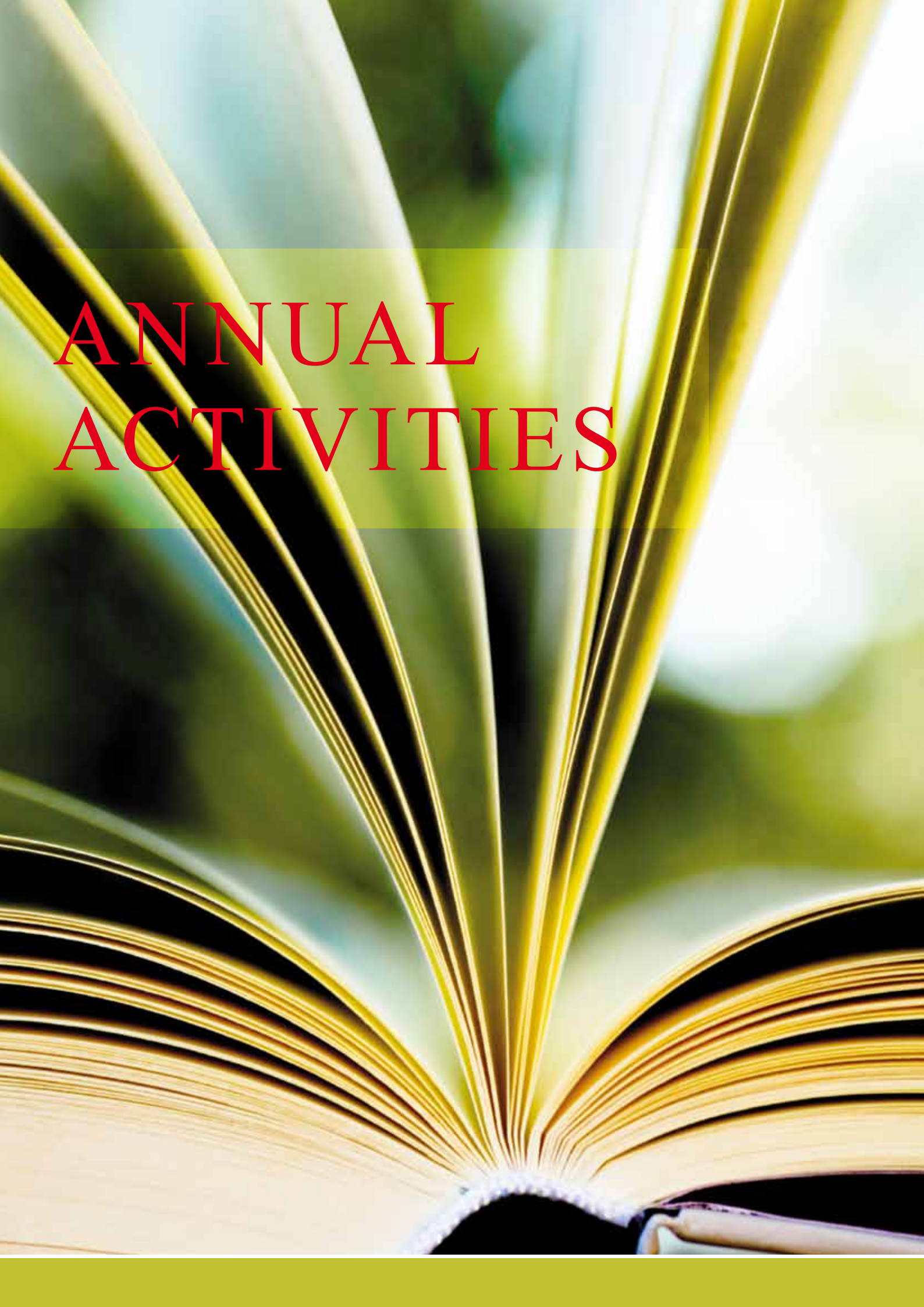
A high level of scientific quality and efficiency go hand in hand – to us, they are not a contradiction in terms, but elements of equal standing, and essential to achieving our mission.



JÜRIG H. SCHNETZER
DIRECTOR EXECUTIVE, SWISSMEDIC

“THE FEDERAL COUNCIL’S
NEW SERVICE MANDATE AND THE AGENCY
COUNCIL’S STRATEGY ARE AMBITIOUS
GOALS FOR US – AND WE SHALL DO EVERYTHING
WE CAN TO ACHIEVE THEM!”





ANNUAL ACTIVITIES

AN IMPORTANT STEP IN THE BATTLE AGAINST DESIGNER DRUGS

Switzerland has a new weapon to use in the battle against illegal designer drugs. Since the amendment of the narcotics legislation of 1 December 2011, 50 individual substances and seven compound classes have been classified as being equal to narcotics. As a result, customs and police can now confiscate any goods containing these substances.

TRANSPARENCY SURROUNDING SWISSMEDIC EXPERTS

Swissmedic has adjusted the code of the "Swissmedic Medicines Expert Committees" (SMEC) to be in line with the regulations which is applied by the EMA to its experts. What is new is that the interests of both the ordinary and extraordinary SMEC experts have been published and can be viewed on Swissmedic's website. The code also states which interests are not compatible when holding the office of Swissmedic expert.

A NEW INSTRUMENT FOR BETTER APPLICATION PLANNING

Following a pilot phase, a planning tool was implemented mid-2011 for the planning and management of the around 10,000 applications submitted each year. This means that for the first time since the introduction of the matrix structure in 2007, a professional planning tool to handle and manage applications is available to the Case Management Division. In parallel to the rollout of this tool, the application planning process was been successfully revised. Application processing will be planned centrally by the Case Management Division. The newly introduced planning board, with representatives from all divisions of the Authorisation Sector, will address planning conflicts by means of twice-monthly meetings.

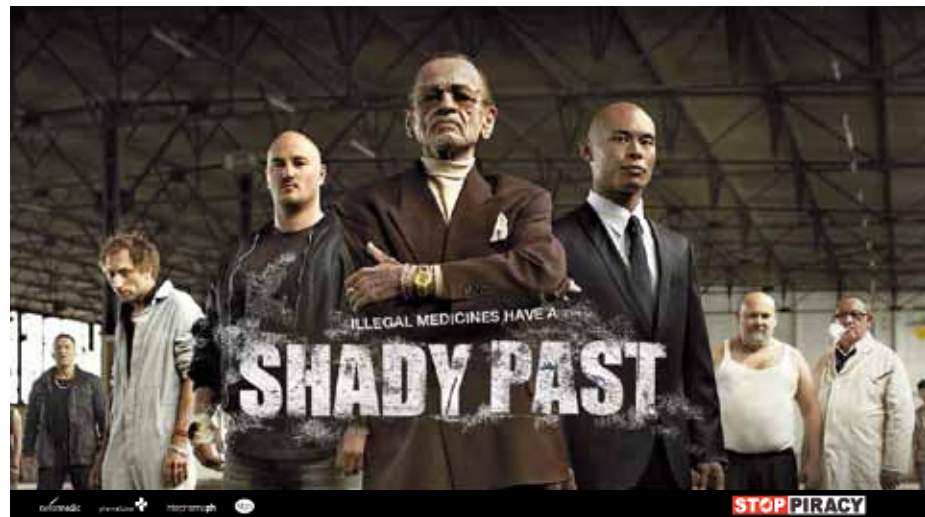
SIGNATURE AT THE MEDICRIME CONVENTION

On 28 October 2011, at an international conference on pharmaceutical crime in Moscow Switzerland signed the European Council's "Medicrime" convention. In doing so, the Federal Council has expressed its

desire to fight the counterfeiting of medicinal products and similar crimes. Switzerland was one of the first countries to sign the agreement.

UNITED IN THE FIGHT AGAINST MEDICINES WITH A DIRTY PAST

"Illegal medicines are deadly". This was the main message of a major international campaign conducted in Switzerland in 2011 by Swissmedic, Swiss pharmacies and the associations of the pharmaceutical industries. Under the umbrella of STOP PIRACY, consumers were asked not to buy medicinal products through the Internet. Concerned parties could take any medicinal products that they had already bought to any of 760 pharmacies around the country for testing (free of charge) where they could also seek advice.



NARCOTICS – OPTIMISED PROCESS FOR IMPORT/EXPORT LICENCES

Swiss companies importing or exporting controlled substances (narcotics) require a Swissmedic licence for every shipment. A new information system to provide a better overview of processing time lines was established in 2011. With an annual volume of around 8,000 licences, the processing times for this activity, which is so critical for the companies' logistical procedures, should be shortened. This new eGovernment system facilitates the optimum processing of on-line applications for import/export licences between Swiss companies and Swissmedic.

MEDIATOR AND “PIP” BREAST IMPLANTS: TWO CASES AND THEIR CONSEQUENCES

DURING THE COURSE OF 2011, TWO CASES, DESCRIBED BY THE MEDIA AS SCANDALOUS, CHALLENGED THE SYSTEM FOR THE CONTROL OF THERAPEUTIC PRODUCTS.



THE MEDIATOR CASE

BACKGROUND

The first case concerned the medicinal product Mediator authorised since the 1970s in a number of countries for use in patients with type 2 diabetes, and authorised in Switzerland as Medi axial until 1998. The company stopped selling this product in Switzerland in 1998 after questions were raised concerning its safety during post-marketing surveillance. Over the following years, it was removed from the markets of most other countries as a result of potentially fatal side effects. Mediator remained

available in France until 2010, where it was widely prescribed and used off-label as a slimming aid.

In the middle of November 2010, the French authority, the Agence française de sécurité sanitaire des produits de santé (Afssaps), published a warning and advised patients who had previously taken medicinal products containing the active pharmaceutical ingredient benfluorex, to undergo regular medical monitoring. In numerous media reports in France, the product was held responsible for the deaths of up to 500 people. The French parliament consequently demanded both a full investigation of the case and the monitoring of Afssaps' activities.

IMPACT

France itself is the country most affected by the impact of the Mediator case. A preliminary report by the “Inspection générale des affaires sociales” was published in January 2011. President Sarkozy himself commissioned a further report which concluded that far-reaching reform was necessary – a defining moment indeed.

As part of the reform the French health authority will now focus more closely on safety. Furthermore, the authority is to be entirely financed in future by the state, and will be renamed the “Agence nationale de sécurité du médicament” (ANSM). One other aspect of the reform is aimed at achieving greater transparency in the

financial relationships between physicians and the industry. Other countries, including Switzerland, were challenged to explain their systems for the control of therapeutic products, and the independence from the pharmaceutical industry of their market surveillance.

MEASURES ADOPTED

In the EU, the new pharmacovigilance regulations were stress-tested to ensure an appropriate response in the event of a Mediator case, the weaknesses identified, and necessary improvements implemented. These new extended pharmacovigilance requirements were developed in order to prevent the occurrence of regulatory failures in monitoring and decision-making on the safety of medicines. This has been achieved by improving the European pharmacovigilance database "Eudrapharm", ensuring good reporting mechanisms, and a clear system of the declaration of interests by the scientists advising the European Medicines Agency and National Competent Authorities on authorisations of medicinal products.

Even though Switzerland is not bound by the EU's pharmacovigilance system, it is important to tighten market surveillance, particularly with respect to integration into other international systems, and the rapid exchange of information with other health authorities in order to quickly identify new safety signals. As part of the on-going revision of the Therapeutic Products Act, it is important to gauge the extent to which regulations of the new EU pharmacovigilance legislation need to be integrated into Swiss legislation.



In addition to international signals, pharmacovigilance in Switzerland is based primarily on reports received from users in Switzerland. These reports are collected by the established pharmacovigilance network of university hospitals and via companies, and passed on to Swissmedic. A higher reporting frequency, and in particular more reporting quality by medical staff, may aid the earlier identification of new risks.

SWISSMEDIC TO PUBLISH VESTED INTERESTS OF EXTERNAL EXPERTS FROM 1 JANUARY 2012

In connection with the Mediator case, there has been a call in Switzerland for greater transparency with regard to the experts who support Swissmedic in their work, and their conflicting interests. In line with research for the programme "Temps présent", Swissmedic declared all interests to the TSR (Télévision Suisse Romande). In the meantime, the rules for the external experts have been updated, and their vested interests have been published on the Swissmedic website since January 2012.

IN ORDER TO GUARANTEE INDEPENDENCE WITH REGARD TO THE ADVICE THEY PROVIDE, SWISS-MEDIC EXPERTS DISCLOSE THEIR VESTED INTERESTS EACH YEAR.



THE “PIP” BREAST IMPLANTS CASE

BACKGROUND

Breast implants manufactured by the French company Poly Implant Prothèse (PIP) were filled with non-medical grade silicone, and the quality knowingly falsely declared. The inferior quality grade was used intentionally by PIP in order to gain a financial advantage in the market place. PIP had deliberately misled both the relevant notified body (NB), which had rated the product as compliant on the basis of falsified documents, and TÜV Rheinland, with regard to the quality of its breast implants, since 1993. The deception was uncovered in the spring of 2010 by Afssaps, following an increase in the rate of ruptures involving these implants and a higher number of reports of inflammatory responses by users. At the end of March 2010, Afssaps issued a recall of all PIP breast implants, and the company was banned from marketing them further. Swissmedic issued a corresponding withdrawal at the beginning of April 2010.

IMPACT

The number of affected women is estimated at several hundred thousand (400,000 – 500,000). Most of the women concerned in Europe are in France, with up to 30,000 affected women, and the UK, where over 40,000 are affected.

In Switzerland, around 300 women have received PIP implants. This figure does not include women who have had surgery abroad where they may have received PIP implants.

Internationally, a number of investigations have been carried out to collect information on the effects of the inferior silicone. Information received from market surveillance has also been evaluated. Differing assessments of the risk associated with these implants have resulted from these studies. While some countries (especially France and Germany) advised their removal as a precautionary measure, most other authorities – including the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) and Swissmedic – advised women to have their implants checked regularly and to determine the further course of action with their medical practitioner (e.g. closer monitoring, or if necessary surgical removal of the implants). It is essential that a physician be consulted without delay if any problems do arise (see graphic).

Overview of the recommendations of the European health authorities and the Directorate General for Health and Consumer Affairs (DG SANCO):

Country	Measures
France	Removal recommended as a precaution
Germany, Estonia, Czech Republic	Removal recommended as a precaution (based on the French decision)
UK	Medical check recommended, no need for removal as a precaution
Other EU countries, Switzerland	Medical check recommended, no need for removal as a precaution
Group of experts EU Commission (DG SANCO)	Regular medical checks recommended, no need for removal as a precaution

REPORTS OF ADVERSE REACTIONS OR EVENTS: MEDICINAL PRODUCTS AND MEDICAL DEVICES

All specialist personnel are to notify Swissmedic of any adverse drug reactions or serious adverse events involving medicinal products. This obligation applies to both medicinal products and medical devices. Further information on the reporting requirements concerning medicinal products, along with the relevant forms, can be found at: www.swissmedic.ch/00397/index.html

Further information on the reporting requirements concerning medical devices can be found at: www.swissmedic.ch/md.asp

Every single report helps to improve the safety of therapeutic products in Switzerland.

MEASURES ADOPTED

The discussions taking place in the EU since 2008, concerning closer regulation of medical devices, have benefitted from a new sense of dynamism and urgency in the wake of the PIP case. Unlike medicinal products, there is no requirement for the official authorisation of medical devices. The manufacturer is solely responsible for carrying out a conformity assessment procedure of its products. In cases involving higher-risk products, inspection by an NB is required which results in CE-marking of the products. The CE-mark entitles a company to market the product within the EU and EFTA (including Switzerland), and in Turkey.

Due to its bilateral agreements concerning medical devices, Switzerland is bound by EU regulations, with little scope for implementation of its own measures. In addition to the on-going legislative revisions in the EU, which will naturally take some time, a number of "emergency measures" are under discussion which could be implemented on the basis of current legislation. These measures are aimed primarily towards a better control of the quality of the NBs responsible for issuing CE-marks, and increased market surveillance activities. The requirement for mandatory registers for implants is also being discussed at the political level.

As is often the case, the system is only as good as the information entered into it; in other words, any and all events – even if only suspected – must be reported to Swissmedic so that the appropriate measures can be taken.



The investigative report by an international group of experts appointed by the EU commission was published on 1 February 2012; the results support Swissmedic's current recommendations. The experts found that, based on the currently available clinical data, it is not possible to state categorically whether women with PIP implants are at any greater risk than users of other brands. The EU experts concluded that, as before, the risks need to be assessed individually during consultation between the patient and her medical practitioner. It is important to take into account the state of the patient's health and assess the risks of any surgical procedure. Based on the medical assessment, removal of the implants is one option available. Regular medical checks are important.

IT IS A STRATEGIC FACTOR IN BUSINESS ACTIVITIES

CONTEMPORARY IT SYSTEMS ARE
ESSENTIAL FOR ANY MODERN
AUTHORITY. THIS ALSO APPLIES TO
SWISSMEDIC, BECAUSE THE FILES
RECEIVED FOR PROCESSING CAN BE
ENORMOUS. IT IS NOT UNUSUAL
FOR A SINGLE AUTHORISATION
APPLICATION TO CONSIST OF MORE
THAN 5 TONS OF PAPER.
THE ELECTRONIC PROCESSING OF
THIS AMOUNT OF INFORMATION IS
TREMENDOUSLY IMPORTANT IN
INCREASING EFFICIENCY.



STRATEGIC REALIGNMENT OF IT

Swissmedic’s core systems for business administration, business management and data management are outdated, and are no longer supported by the suppliers. At the same time, Swissmedic’s divisions need better system support. Increasing efficiency and shortening throughput times in all areas of our business are key factors in meeting our customers’ needs.

Swissmedic’s stakeholders demand modern electronic systems for efficient and transparent collaboration. As a result, in 2010 Swissmedic redesigned its future IT architecture and created an IT roadmap.

THE IT ROADMAP

The IT roadmap proposes the implementation of the IT project in four stages.

1. Replacement of the old core systems

The old core systems are to be replaced with future-proof systems for business administration including a specialist database, and for business management, an enterprise resource planning (ERP) system integrating finance, invoicing, purchasing, and project management.

2. Introduction of document management and eGovernment

Electronic document management will be installed initially on the available core systems. The start of the implementation of the electronic data exchange by portal (eGovernment) between Swissmedic and third parties will occur in parallel.

3. Stabilisation

The database will be maintained through regularly released updates, ensuring continued high value performance.

4. Further development

The platforms will be further developed for additional applications. The functionality of eGovernment will be expanded.

ON SCHEDULE

Having received the first authorisation applications by electronic Common Technical Document (eCTD) since January 2010, Swissmedic rapidly extended the system to include other types of application. Swissmedic has supported the full lifecycle of eCTD applications since January 2011.

ERP was developed in 2011 and commissioned in the first week of January 2012.

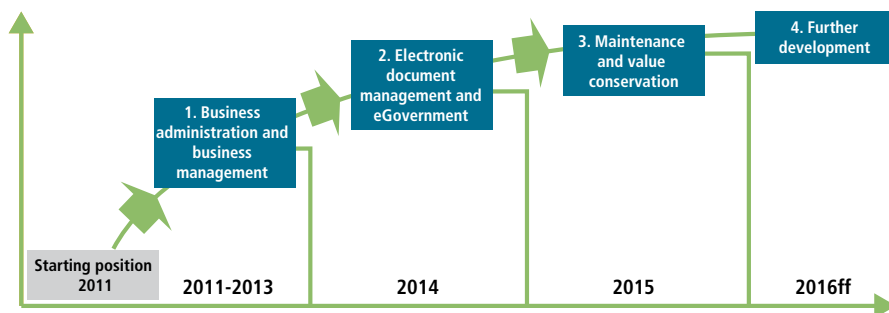
The design of both the new business administration solution and the specialised database in the PRIME project was completed to schedule.

The introduction of the core application for the laboratory (LIMS, laboratory information system) was also successfully completed in the reporting year.

The new Internet application “NDS-WEB” was developed and launched in the area of international trade of controlled substances.

The system for the electronic exchange of vigilance reports (E2B Gateway) is under development, and will be introduced next year.

SWISSMEDIC’S IT ROADMAP ILLUSTRATES WHICH PROJECTS ARE TO BE USED TO ACHIEVE ITS AIMS, AND IN WHICH ORDER THEY WILL OCCUR. THE ROADMAP WILL UNDERGO ANNUALLY UPDATED, ROLLING PLAN REVISIONS EACH OVER FIVE YEAR PERIODS.



ADDED-VALUE FOR STAKEHOLDERS

The interest of our stakeholders in the new systems for processes in the areas of authorisations, narcotics and vigilance is high. The continuous increase in authorisation applications submitted via eCTD confirms the high demand for electronic submission options.

OUTLOOK



PUBLICATION OF INFORMATION ON MEDICINAL PRODUCTS

Swissmedic will take over the publication of information of medicinal products from 2013. Until now, Swissmedic has required authorisation holders to provide information on their medicinal products to professionals and the public in the form of publications utilising private publishers. However, in 2011 the Federal Administrative Court ruled that there were insufficient legal grounds for such commitment at the authorisation holders' expense. The Federal Administrative Court was of the opinion that there was nothing to prevent the Agency itself from undertaking publication of the information on all medicinal products in a comprehensive directory. Against this background, Swissmedic will now produce a corresponding directory and a new electronic publication platform.

CHANGES IN THE REGULATORY SYSTEM FOR MEDICAL DEVICES

Switzerland is included in the EU regulatory system for medical products. The discussions that have been underway since 2008 concerning the revision of the regulation in the EU have been intensified by the case involving counterfeit breast implants.

Over the coming years there will be an extensive revision of medical device regulations in the EU with the aim of improving product safety through more stringent requirements for market access, improved monitoring tools and harmonised implementation. Switzerland is included in these discussions and will, based on existing bilateral agreements, adjust its own legal principles in order to guarantee the equality of standards that is the basis for free trade with the EU.

10 YEARS OF SWISSMEDIC

Swissmedic is celebrating its tenth anniversary this year. To mark the occasion, the Agency will be staging an international science symposium in Interlaken in the autumn of 2012. The constantly changing world of regulation will be discussed with internationally renowned specialists.





CUSTOMER SURVEY "SATISFACTION"

Swissmedic carried out a customer survey in the first half of 2012 in order to measure and improve the quality of its daily activities. The survey was conducted with companies that are monitored by the Agency, and organisations and associations with which Swissmedic regularly co-operates.

NEW ORDINANCE ON FEES TO COME INTO FORCE ON 1 JANUARY 2013

The Ordinance on Fees for Therapeutic Products of 2 December 2011 stating the new fee structure is effective from 1 January 2013. Swissmedic will set out the details of the new structure by the end of the year, in cooperation with those affected at the "Regulatory Round Table" discussions. Issues to be discussed include the procedures for applications that are submitted following advanced registration. These applications are processed within reduced timeframes, but carry a higher fee. Companies will receive detailed information on this and other subjects before the new fee regulations come into force.

LABORATORY CONSTRUCTION ON SCHEDULE

In 2010, Swissmedic decided to centralise its laboratories on the Erlachstrasse in Berne and those at the Federal Office of Public Health in Liebefeld in one place. In addition to the laboratories, the new building will also house the other licensing divisions. Construction work on the new laboratory site at 139 Freiburgstrasse in Berne started at the end of 2011, and is on schedule. The Agency plans to move into the new building in the middle of 2013.





FACTS AND FIGURES

BUSINESS STATISTICS

Companies with a Swissmedic licence

Manufacture of medicinal products:	
Manufacture of medicinal products (with a licence for wholesale distribution)	255
Manufacture of medicinal products (without a licence for wholesale distribution)	108
Wholesale distribution of medicinal products:	
Import of medicinal products	512
Wholesale trade of medicinal products	802
Export of medicinal products	408
Foreign trade of medicinal products	316
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 regard to transfusion, transplant or processing	46
Blood transfusion services or hospitals with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	43
Establishment licence for handling controlled substances	333
Laboratories with FOPH recognition	
Microbiological and serological laboratories inspected by Swissmedic	92

AUTHORISED HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINAL PRODUCTS WITHOUT INDICATION IN THE NOTIFICATION PROCEDURE ACCORDING TO OAMEDCOPY AT THE END OF 2011

Single remedies	5,322
Complex remedies	896

INVENTORY OF AUTHORISATIONS BY TYPE OF PRODUCT AT THE END OF 2011

Human medicinal products (original, generic, co-marketing medicinal products)	5,009
Phytopharmaceuticals	739
Homeopathics	683
TCM medicinal products	5
Anthroposophics	193
Ayurvedic medicinal products	1
Tibetan medicinal products	4
Bacterial and yeast products	28
Vaccines	78
Blood products	93
Radiopharmaceuticals	37
Biotechnologicals	340
Veterinary medicinal products	678
Allergens	738

INVENTORY OF AUTHORISATIONS BY SUPPLY CATEGORY AT THE END OF 2011

Supply category / authorised medicinal products

A Supply once with a prescription from a physician or veterinarian	2,055
B Supply with a prescription from a physician or veterinarian	3,737
B/C Supply with a prescription from a physician or veterinarian/Supply on technical advice from medical staff	37
B/D Supply with a prescription from a physician or veterinarian/Supply on technical advice	37
C Supply on technical advice from medical staff	599
C/D Supply on technical advice from medical staff/Supply on technical advice	21
D Supply on technical advice	1,917
E Supply without technical advice	176
Total	8,579

SWISSMEDIC AS AN AGENCY

Staff headcount as at year-end	409
Number of full-time positions as at year-end	336
Total women	58.7%
Total men	41.3%
Staff working part-time (*part-time defined as work volume up to 89% full-time post)	43%
Average staff age	45.5 years
Women	44 years
Men	47.6 years
Language composition:	
German	88.9%
French	9.7%
Italian	1.2%
Rhaeto-Romanic	0.2%
Staff turnover rate	3.2%

MARKET ACCESS

MARKETING AUTHORISATION

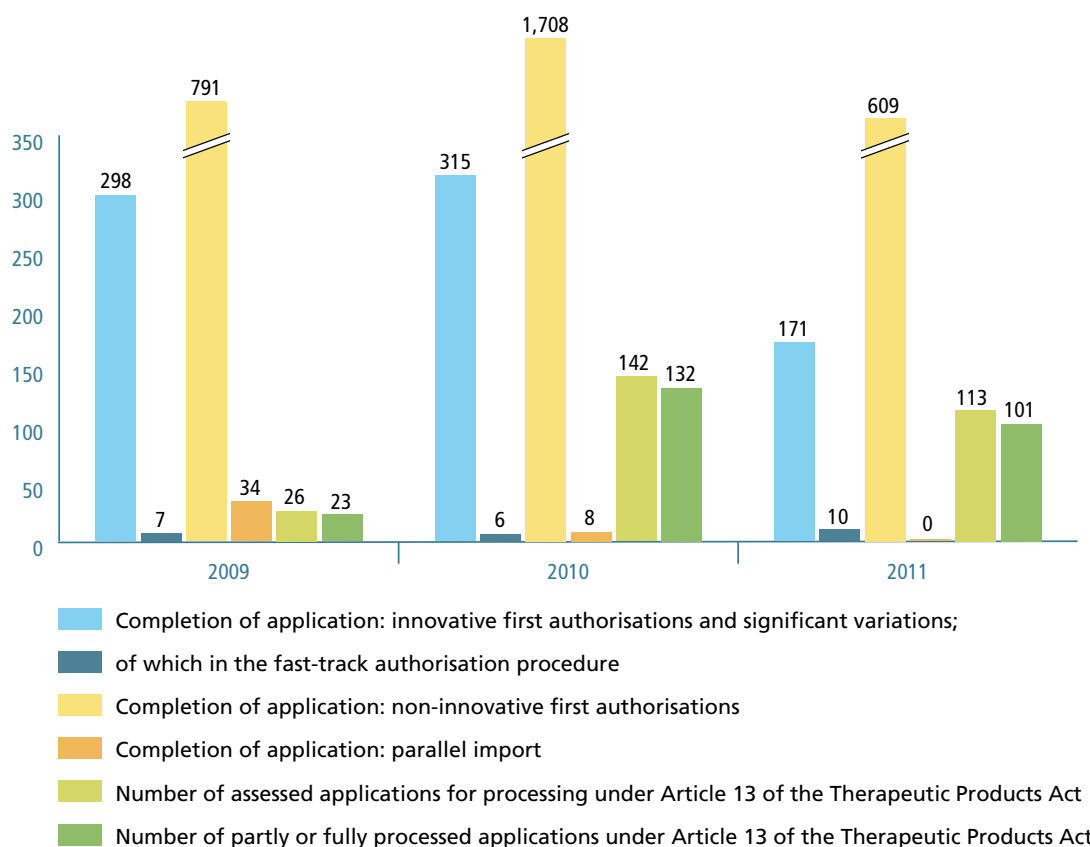
AUTHORISATION OF HUMAN MEDICINAL PRODUCTS*

FIRST MARKETING AUTHORISATIONS

A first marketing authorisation of a medicinal product is granted once the applicant has submitted all the documentation regarding its safety, efficacy and quality, and this documentation has been thoroughly checked. The authorisation procedure distinguishes between innovative medicinal products (medicinal products with new active pharmaceutical ingredients or significant variations to them), and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients, especially generic medicinal products and co-marketing medicinal products). Medicinal products that have undergone significant variations need to be re-authorised. Medicinal products of exceptional importance can be assessed in a fast-track authorisation procedure if they meet the appropriate criteria.

Activities

- In 2011, 171 applications were submitted for first marketing authorisations of innovative medicinal products and significant variations to innovative medicinal products; 171 applications were completed.
- In 2011, 20 medicinal products with a new active pharmaceutical ingredient were authorised for the first time. Ten of these applications were completed in the fast-track authorisation procedure.
- 609 applications for first marketing authorisations of non-innovative medicinal products were completed. 73 of these applications were for co-marketing medicinal products. The high figures for 2010 are a result of the large number of requests submitted for allergen products.
- There were no applications in 2011 for parallel imports of a medicinal product.
- There were 113 applications for the application of Article 13 of the Therapeutic Products Act (TPA), 101 of which were approved either completely or in part.



* The key statistics with regard to respect for deadlines can be found on page 33.

NEW ACTIVE PHARMACEUTICAL INGREDIENTS AUTHORISED IN 2011 – HUMAN MEDICINAL PRODUCTS

ACTIVE PHARMACEUTICAL INGREDIENT	BRAND NAME	APPLICATION
Blood Ticagrelorom	Brilique, film-coated tablets	Brilique is used in combination with acetylsalicylic acids (ASS) for the prevention of thrombotic events (cardiovascular death, myocardial infarction and strokes) in patients with acute coronary syndrome (unstable angina pectoris [UA], non-ST elevation myocardial infarction [NSTEMI] and ST elevation myocardial infarction [STEMI]). This includes patients under medical therapy and those treated by means of percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG).
Apixabanum	Eliquis, film-coated tablets	Prevention of venous thromboembolic events (VTE) in adult patients following elective hip or knee replacement surgery.
Heart and circulation Vernakalanti hydrochloridum	Brinavess, concentrate for solution for infusion	For the rapid conversion of newly occurring atrial fibrillation in the sinus rhythm, in adult patients with or without previous heart surgery.
Infectious diseases Telaprevirum	Incivo, film-coated tablets	In combination with Peg interferon alfa and Ribavirin, Incivo is indicated for the treatment of chronic hepatitis G, genotype 1 in adult patients with compensated liver disease (including cirrhosis), who have not been previously treated or who have been previously treated either with Interferon alfa (pegylated or non-pegylated) alone or in combination with Ribavirin, including patients with relapse, partial response or no response (see section Properties / Effects, Efficacy in previously treated adults). Incivo may not be prescribed as a monotherapy but only in combination with Peg interferon alfa and Ribavirin (both medicinal products must be included in the therapy plan) in order to prevent treatment failure. For this reason, the information for healthcare professionals on Peg interferon alfa and Ribavirin must be taken into consideration before starting a combination therapy with Incivo (here, see in particular the sections Dosage / Use, Contraindications and Warnings and Precautions). No data is available on renewed treatment of patients for whom therapy with Incivo or other HCV NS3-4A protease inhibitors (see section Properties / Effects) was unsuccessful.
Polysaccharida neisseriae meningitidis A/C/W/Y conjugatum cum proteinum corynebacteriae diphtheriae CRM ₁₉₇	Menveo, lyophilisate and solution	For the active immunisation of adolescents (as of age 11) and adults and who risk exposure to Neisseria meningitidis (meningococci) of serogroups A, C, W-135 and Y in order to avoid an invasive disease. The use of the vaccine should take official recommendations into account.
Boceprevirum	Victrelis, capsules	In combination with Peg interferon Alfa and Ribavirin, Victrelis is indicated for the treatment of chronic infection with the hepatitis C virus (HCV) of genotype 1 in adults (aged over 18) with compensated liver disease, who have not been previously treated or for whom the treatment was unsuccessful. Victrelis may never be used as a monotherapy but only in combination with Peg interferon alfa and Ribavirin. For this reason, the information for healthcare professionals on Peg interferon alfa and Ribavirin must be taken into consideration (in particular the sections Contraindications, and Warnings and Precautions). The efficacy of Victrelis

NEW ACTIVE PHARMACEUTICAL INGREDIENTS AUTHORISED IN 2011 – HUMAN MEDICINAL PRODUCTS

		in combination with Peg interferon alfa and Ribavirin has to date not been investigated in patients who were previously treated with the triple combination Peg interferon / Ribavirin plus Victrelis (or another HCV NS3/4A protease inhibitor). To date only limited findings exist with regard to the treatment of patients who did not respond at all to an earlier Peg interferon / Ribavirin treatment (so-called historical “null responders”, i.e. patients with a reduction of the HCV-RNA viral load <2-log10 in week 12 of the previous treatment with Peg interferon alfa and Ribavirin).
Lungs and respiratory system		
Roflumilastum	Daxas 500 µg, film-coated tablets	Daxas is indicated as a concomitant long-term therapy for adult patients with severe COPD (chronic obstructive pulmonary disease, FEV1 after using a bronchodilator below 50% of target) and frequent exacerbations in the past despite inhalant therapy with long-acting bronchodilators in appropriate dosages.
Nervous system		
Fingolimodum	Gilenya, capsules	Gilenya is indicated for the treatment of patients with relapsing-remitting multiple sclerosis (MS) to reduce the frequency of relapses and to delay the progression of the disability.
Tapentadolom	Palexia, film-coated tablets	Palexia is a mixed analgesic, μ -Opioid receptor agonist and noradrenaline reuptake inhibitor, indicated for the treatment of medium to severe acute pain or if non-opioid analgesics are not sufficiently effective.
Retigabium	Trobalt, film-coated tablets	Trobalt film-coated tablets are indicated as an add-on therapy to treat partial seizures with or without secondary generalisation.
Metabolism		
Ofatumumabum	Arzerra, concentrate for solution for infusion	Treatment of patients with progression of chronic lymphatic leukaemia (CLL) after treatment with Fludara, Alemtuzumab and Rituximab, or those for whom corresponding combinations and other therapeutic alternatives are not appropriate.
Bilastinum	Bilaxten, tablets	Symptomatic treatment of seasonal allergic rhino-conjunctivitis and urticaria.
Cabazitaxelum	Jevtana, concentrate and solvent	In association with prednisone or prednisolone, Jevtana is indicated for the treatment of patients with hormone-refractory metastatic prostate cancer (mHRPC) who have previously been treated with chemotherapy based on docetaxel.
Belataceptum	Nulojix, powder for concentrate for solution for infusion	For the prophylaxis of transplant rejection in patients having undergone a kidney transplant with an induction therapy with an interleukin-2 (IL-2) receptor antagonist in combination with mycophenolic acid and corticosteroids.
Velaglucerasum alfa	VPRIV, powder for solution for infusion	VPRIV is indicated for long-term enzyme replacement therapy (ERT) in paediatric and adult patients with Morbus Gaucher Type 1.
Collagenasum clostridium clostridium histolyticum	Xiapex, powder and solvent for solution for infusion	Xiapex is used in adults to treat a Dupuytren’s contracture with palpable cord.
Ipilimumabum	Yervoy, concentrate for solution for infusion	Treatment of advanced (non-resectable or metastasised) melanomas in adults who have already undergone a treatment.

NEW ACTIVE PHARMACEUTICAL INGREDIENTS AUTHORISED IN 2011 – HUMAN MEDICINAL PRODUCTS

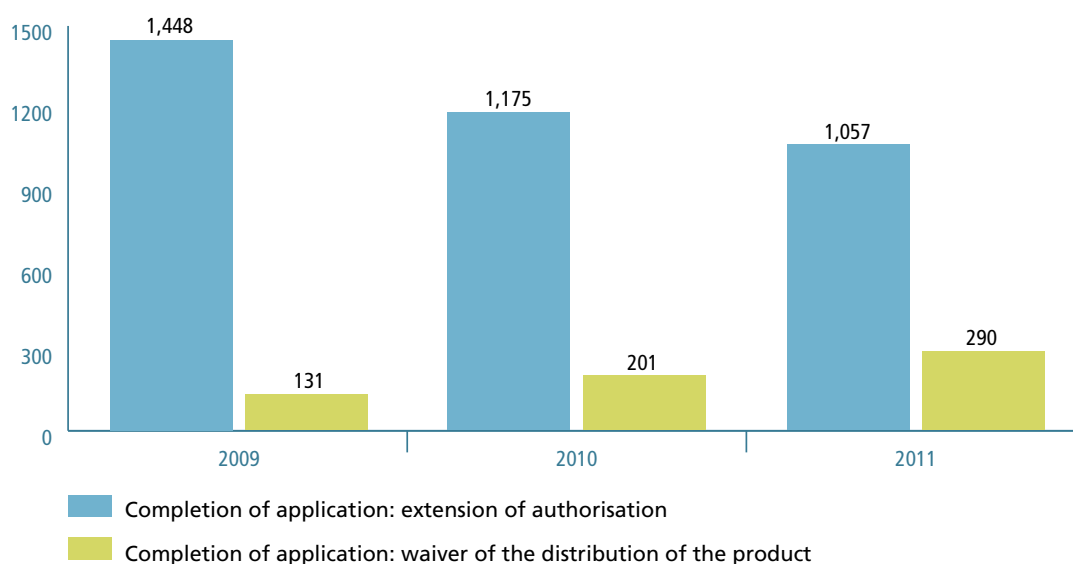
Vemurafenibum	Zelboraf, film-coated tablets	Treatment of non-resectable or metastised melanoma patients with a BRAF V600 mutation.
Abirateronum	Zytiga, tablets	For the treatment, in combination with LHRH agonists and Prednisone or Prednisolone of patients with advanced metastising prostate carcinoma in the case of progression following treatment with Docetaxel.
Eribulini mesilas	Halaven, solution for injection	Halaven is indicated for the treatment of locally advanced or metastising mammary carcinoma with progression following previous therapy with an anthracycline, a taxane and Capecitabine.

EXTENSIONS AND WAIVERS

A human medicinal product is authorised for five years. The marketing authorisation holder must apply for the authorisation to be extended. The authorisation is extended for five years if the conditions continue to be met. Notification is required if a medicinal product or a "sequence" of a product is no longer distributed: notification must be given at least two months before distribution ceases.

Activities

- In 2011, there were 1,048 applications for extensions of marketing authorisations; 1,057 applications were completed.
- In 2011, there were also 553 applications for waivers concerning a product and 32 applications for waivers concerning a "sequence" of a product; 290 applications for waivers of a product and 33 applications for waivers of a "sequence" of a product were completed.

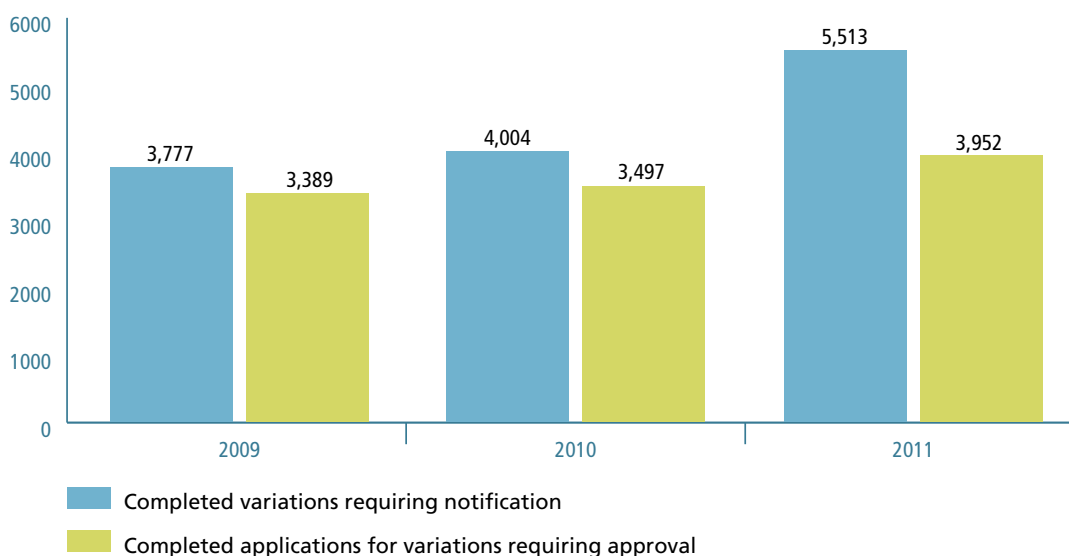


VARIATIONS REQUIRING APPROVAL AND NOTIFICATION

Applications must be made for any variations to medicinal products that have been authorised by Swissmedic. A final list of minor variations can be submitted as variations that are subject to notification. Any other variations to a medicinal product are subject to approval. These applications are evaluated with or without scientific assessment.

Activities

- In 2011, 5,716 variations requiring notification were submitted; 5,513 notifications were completed.
- 3,868 applications for variations requiring approval were submitted; 3,952 applications were completed.



COMPANY MEETINGS

Swissmedic holds meetings with applicants to clarify content and procedural issues (Presubmission Advice, Scientific Advice and Clarification Meetings) in the interest of efficiency and transparency of the authorisation procedures.

Activities

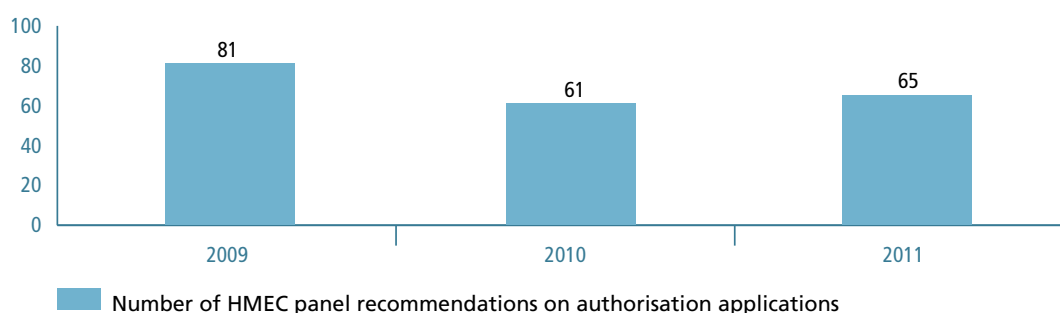
- In 2011, a total of 64 company meetings were held with applicants. Six of these were Clarification Meetings, 24 Presubmission Meetings and 34 Scientific Advice Meetings.

HUMAN MEDICINES EXPERT COMMITTEE (HMEC)

A panel of experts supports Swissmedic in assessment and provision of advice relating to the scientific evaluations of the authorisation documents for human medicinal products.

Activities

- During the course of its 12 meetings, the consulting HMEC panel issued 65 recommendations on authorisation applications. These related in particular to new marketing authorisations of medicinal products or additional indications of them. A total of 143 individual expert reports were provided by HMEC experts, approximately 20% of which were in the pre-clinical field.
- Swissmedic has made improvements to the code applying to the members of the “Swissmedic Medicines Expert Committees” (SMEC) on behalf of the Agency Council. The code was adapted from the regulations of the European Medicines Agency (EMA).
The vested interests will be published annually, starting from 1 January, 2012.
- The efficient and time-bound cooperation between SMEC members and Swissmedic reviewers has been enhanced by means of a secure, electronic SharePoint-based collaboration platform.



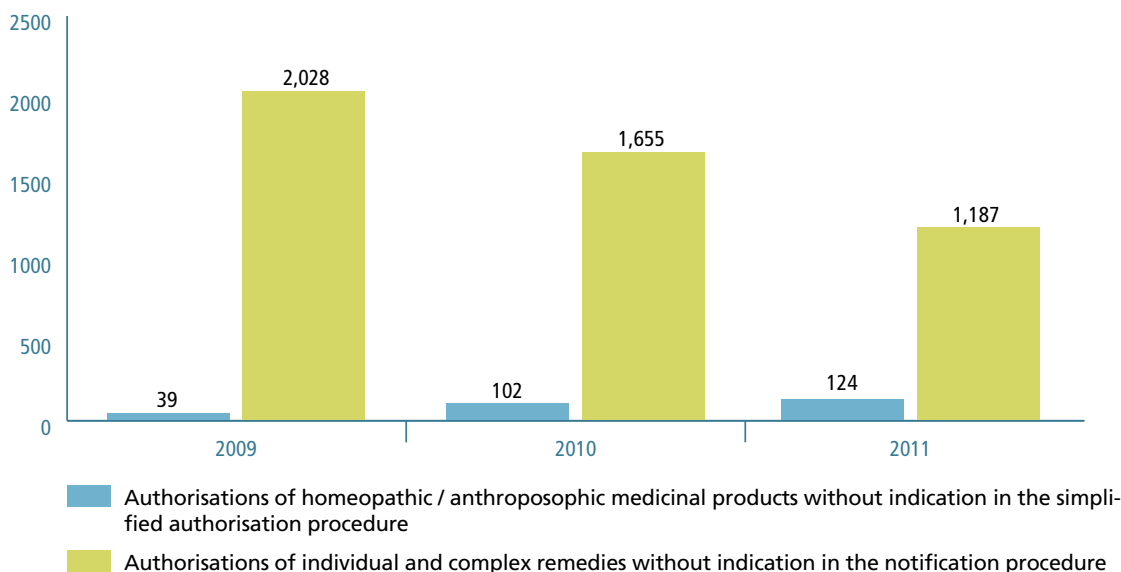
SPECIAL CATEGORIES OF HUMAN MEDICINAL PRODUCTS

COMPLEMENTARY AND HERBAL MEDICINAL PRODUCTS

Herbal medicines or preparations consist solely of plant substances. Complementary medicines include homeopathic, anthroposophic and Asian medicinal products. A distinction is made between those medicinal products with and those without a therapeutic scope (indication). The authorisation procedures are greatly simplified. Quality and safety must be assured in all cases.

Activities

- The list of documented traditional Asian substances (TAS) has been revised in collaboration with external experts with reference to the current state of scientific knowledge.
- In 2011, there were 27 applications for the first marketing authorisation of herbal and complementary medicinal products. These were, almost exclusively, known active pharmaceutical ingredients. Eight first marketing authorisations were completed (this figure is included in the total number of marketing authorisations of human medicinal products).
- In 2011, 124 homeopathic/anthroposophic products were authorised without indication in the simplified authorisation procedure, and 1187 products in the notification procedure. In accordance with the transitional provision of the Therapeutic Products Act (Article 95 of the TPA), the majority of these products are already available on the Swiss market.



PAEDIATRIC MEDICINAL PRODUCTS

Since the introduction of EU Regulation EC 1902/2006 and the FDA Amendment Act (FDAAA), pharmaceutical companies have been obliged to submit their Paediatric Investigation Plans (PIPs) to the authorities and 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 pending issues.

Activities

- TPA Revision II addresses the adaptation of the Therapeutic Products Act from EU Paediatric Regulation 1902/2006.
- In March 2011, Swissmedic set up the Swissmedic Paediatrics Working Group which has the following key responsibilities: respond to internal and external questions, assess clinical studies, provide information on the development of medicinal products in paediatrics, coordinate paediatric issues between the relevant divisions, and provision of training (internal and external).
- The Paediatric Investigation Plan (PIP) forms the basis for the development and authorisation of paediatric medicinal products in the EU. The authorisation divisions collected information from the 40 PIPs submitted in association with authorisation applications.
- Submission of the PIPs proved to be of benefit in the notification of paediatric clinical studies. Notification for a total of 12 paediatric studies was given.
- In 2011, two Good Clinical Practice (GCP) inspections were carried out in association with paediatric clinical studies.
- In 2011, approximately 5% of all adverse drug reactions (ADRs) reported to Swissmedic affected children and young adults. There were no gender-based differences. It would be beneficial to develop a paediatric pharmacovigilance system beyond the current vaccine vigilance systems. The actual implementation of such a system is still under discussion.
- In 2011, members of the Working Group took part in various international paediatric activities.

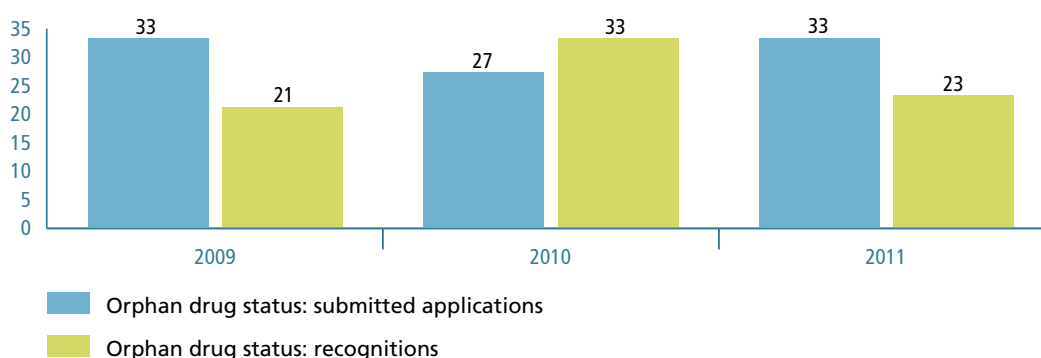
ORPHAN DRUGS

Swissmedic will recognise status as a medicinal product for rare diseases (orphan drug) on application. The applicant is obliged to prove that the medicinal product is used for the diagnosis, prevention or treatment of a rare, life-threatening or chronically invalidating disease that affects a maximum of 5 people in 10,000.

Most applications are based on the recognition status in another country having a comparable medicine control system, in particular those regulated by the European Medicines Agency (EMA) or the American Food and Drug Administration (FDA). Distinction is made between recognition of the status as an orphan drug and authorisation of a medicinal product as an orphan drug.

Activities

- In 2011, there were 33 applications for recognition of orphan drug status. Twenty-three products were granted this status, and one application was withdrawn.
- One product was newly authorised as an orphan drug.
- Twenty further orphan indications were authorised in previously authorised orphan drugs.

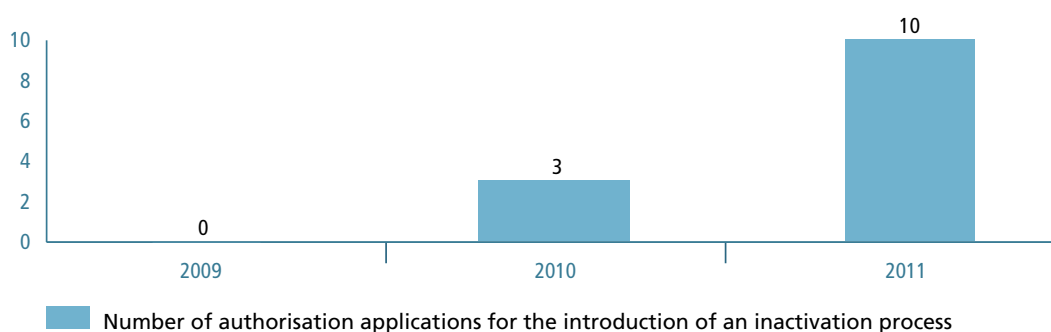


NEW PROCESSES

Swissmedic also issues authorisations of special manufacturing processes. This is necessary when comprehensive definition of the quality of the end product is not possible, or can only be achieved by ensuring backup of the manufacturing process. This process is typical for labile blood products and transplant products.

Activities

- Two applications for processes for the inactivation of pathogens for the treatment of thrombocytes or plasma for transfusions were assessed.
- Simplified authorisation is required before such processes can be introduced in blood transfusion services. Following approval of the specific validation programmes of the blood transfusion services, the introduction of the process for thrombocytes was authorised in all 13 blood transfusion services. The application for plasma is currently undergoing assessment.

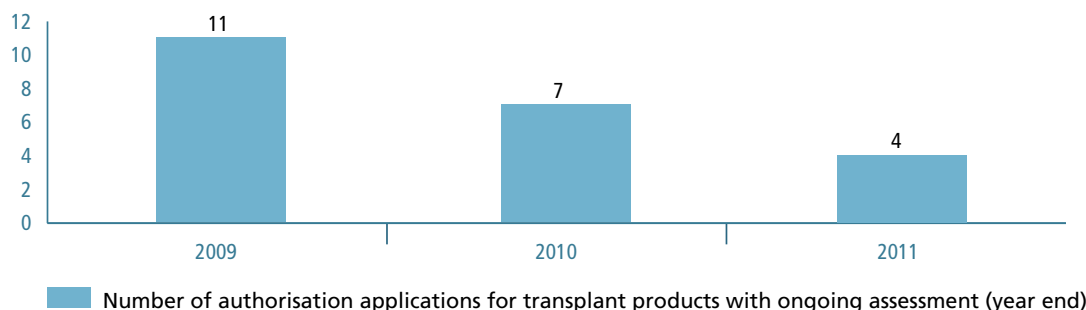


TRANSPLANT PRODUCTS

The products of somatic cell treatment, tissue cultures and ex vivo gene therapy are, in accordance with the Transplantation Act, on a par with medicinal products, and as such are subject to the Therapeutic Products Act. Inspections are carried out on behalf of the Federal Office of Public Health (FOPH) in companies and institutions that work with cells, tissue and organs. Assessments are undertaken to ensure that the legal conditions of the Transplantation Act are observed and that cells, tissue and organs are handled appropriately in accordance with the standards laid down in the Transplantation Act.

Activities

- Since the Transplantation Act was passed in 2007, there have been 16 applications for authorisation of a transplant product; twelve of these applications had been completed by the end of 2011. Due to the often incomplete documentation and lack of relevant clinical data, no marketing authorisations have yet been issued.
- Four authorisation applications for transplant products were being processed at the end of 2011.
- In 2011, Swissmedic held a total of 9 Scientific Advice Meetings, Presubmission Meetings and Clarification Meetings.



APPEALS AGAINST DECISIONS IN ASSOCIATION WITH THE AUTHORISATION PROCEDURE

Appeals against decisions in association with the authorisation procedure may be lodged with the Federal Administrative Court within 30 days. That Court's judgment may, in turn, be contested at the Federal Supreme Court.

Activities

- In 2011, appeals were lodged with the Federal Administrative Court against four decisions taken by the Agency in association with product authorisations. The issues in question concerned procedures and fees. One of these appeals procedures is currently suspended in court. Judgement is still outstanding in all procedures.
- Of the proceedings that had already been pending before the Federal Administrative Court or Federal Supreme Court, judgements were passed on three. One appeal was rejected by the Federal Supreme Court, and one by the Federal Administrative Court. One appeal was upheld by the Federal Administrative Court.

SPECIAL ACTIVITIES AND EVENTS IN THE AUTHORISATION OF HUMAN MEDICINAL PRODUCTS

Introduction of a central planning tool for authorisation applications

The following improvements were achieved with the new planning tool:

- Planning principles for the definition of realistic dates for case management
- Transparent availability of personnel resources
- Clearly defined responsibilities
- Improved overview of applications with actual and predicted status to improve management of bottlenecks.

Conclusion of the eCTD project (electronic Common Technical Document)

Step 3 of eCTD was introduced in January 2011. As a consequence, an extended range of types of application can now be submitted electronically (PSUR, parallel import, application for document protection, extension to 5 years, co-marketing, extension, extension waiver, waiver of authorised product, application as per Article 13 of the Therapeutic Products Act). The project was therefore successfully completed.

New: Swissmedic Geriatrics Working Group

From a medical perspective, there are tremendous differences between older patients and younger ones. Accordingly, Swissmedic established a Geriatrics Working Group at the beginning of the year, which serves to contribute to the international harmonisation of the requirements regarding the clinical testing of medicinal products for older patients.

New Complementary Medicines Division (KPA)

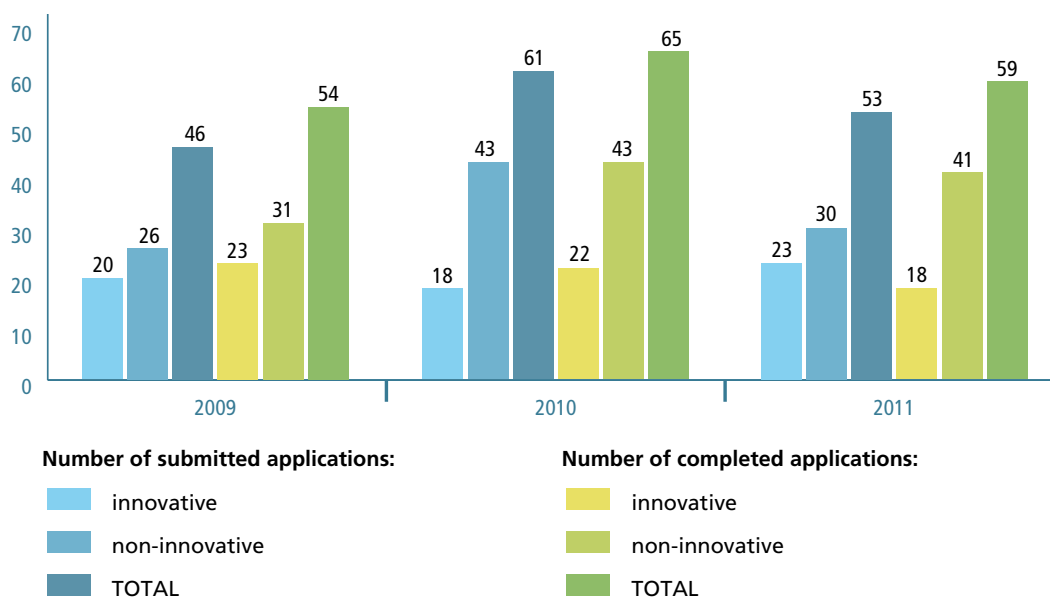
On 1 September 2011, the Case Management Assistant, Case Manager and Quality Reviewer of the newly formed KPA division commenced operation. The division is supported by the Clinical Review and Preclinical Review divisions for clinical and preclinical issues. Additional support is provided by the Quality Review Division in cases of a temporary excess of quality applications.

AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS

A first marketing authorisation of a veterinary medicinal product is granted once the applicant has submitted all the documentation on its safety, effectiveness and quality, and this documentation has been examined. The authorisation procedure differentiates between innovative medicinal products (medicinal products with new active pharmaceutical ingredients or significant variations to the same), and non-innovative medicinal products (medicinal products with known active pharmaceutical ingredients, especially generic medicinal products and co-marketing medicinal products). Medicinal products that have undergone significant variations need to be re-authorised. One important aspect of the safety assessment of veterinary medicinal products for food producing animals concerns their effects on foodstuffs. Within the marketing authorisation procedure the maximal allowed residual levels of a veterinary medicinal product in meat, milk, eggs or honey are determined based on the valid food safety standards.

Activities

- In 2011, 23 applications were submitted for first marketing authorisations and significant variations to innovative medicinal products; 18 applications were completed.
- Of these 23 applications, ten were first marketing authorisations of a medicinal product with a new active pharmaceutical ingredient.
- In 2011, two medicinal products with a new active pharmaceutical ingredient were authorised for the first time.
- The indications of five products were extended, and four products were authorised for a new (additional) target species.
- Thirty new applications were submitted for first marketing authorisation of non-innovative medicinal products; 41 applications were completed.
- Of these 41 applications, 26 concerned the first marketing authorisation of a medicinal product with a new combination of known active pharmaceutical ingredients. The therapeutic spectrum was extended by the first protein kinase inhibitor, which is now available as an antineoplastic medicine for the treatment of dogs.



NEW ACTIVE PHARMACEUTICAL INGREDIENTS AUTHORISED IN 2011 – VETERINARY MEDICINAL PRODUCTS

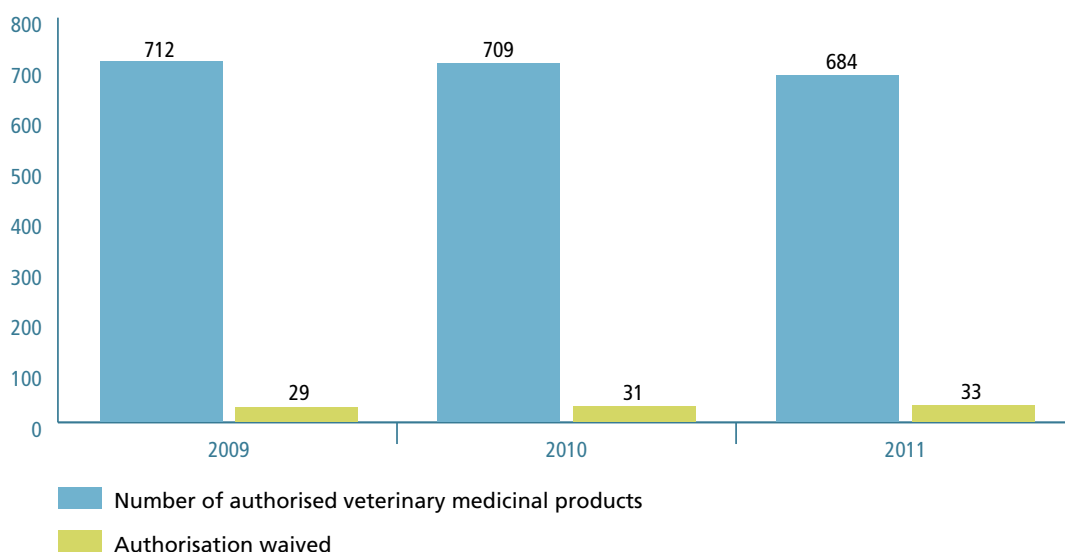
ACTIVE PHARMACEUTICAL INGREDIENT	BRAND NAME	APPLICATION
Imidocarbium	Carbesia, ad us.vet., solution for injection	For the treatment and prevention of bovine and equine babesiosis. For the prevention and treatment of canine babesiosis.
Cimicoxibum	Cimalgex, ad us. vet., tablets	For the treatment of pain and inflammations resulting from osteoarthritis and pain following orthopaedic or soft tissue surgery on dogs.

EXTENSIONS AND WAIVERS

A veterinary medicinal product is authorised for five years. The marketing authorisation holder has to apply for the authorisation to be extended. The marketing authorisation is extended for five years if the conditions are met. Notification is required if a medicinal product or a sequence of a product is no longer distributed, and must be given at least two months before the cessation of distribution.

Activities

- In 2011, the marketing authorisations of 129 products were extended.
- The number of authorised veterinary medicinal products decreased over the course of the year by 25 products from 709 to 684 because the marketing authorisation holders waived the extension of the marketing authorisations for various well-trying products. Consequently, veterinarians frequently complain that these products are no longer available.

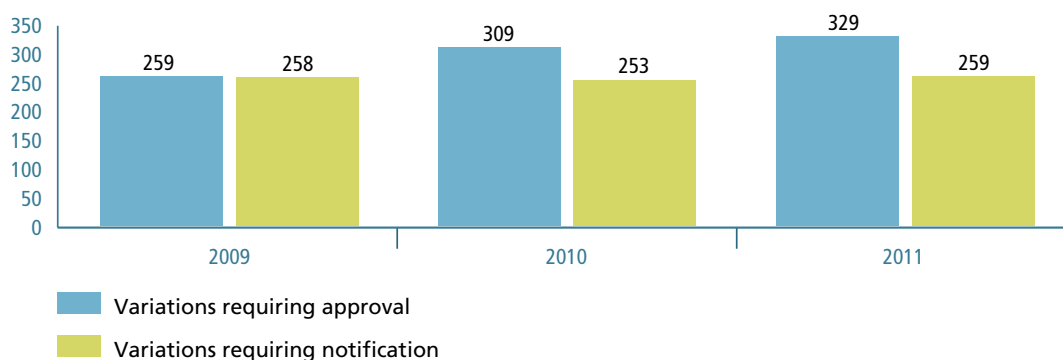


VARIATIONS REQUIRING APPROVAL AND NOTIFICATION

The MA holder must submit a variation application to Swissmedic in order to obtain approval. Those variations are evaluated with or without a scientific assessment. Minor variations must be notified by the agency.

Activities

- In 2011, 329 variations requiring approval and 259 variations requiring notification were completed.
- The main focus of these applications was on quality and manufacture of products.

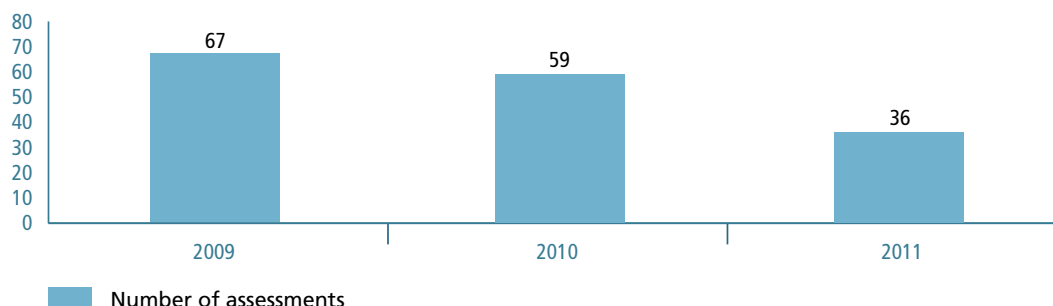


VETERINARY MEDICINES EXPERT COMMITTEE (VMEC)

A board of experts (VMEC) supports Swissmedic by assessing and advising the scientific evaluations of the authorisation documents for veterinary medicinal products.

Activities

- In 2011, applications for the authorisation or indication extension of 18 products were evaluated.
- The development of resistance to antibiotics and the discussion of measures that require careful handling of antibiotics and their targeted use in veterinary medicine remains an important focus of the committee's scientific assessments.
- Swissmedic has discussed and commented on new "Concept and reflection papers" by the European Medicines Agency; they illustrate the permanent development of the standards that apply to veterinary medicinal products.

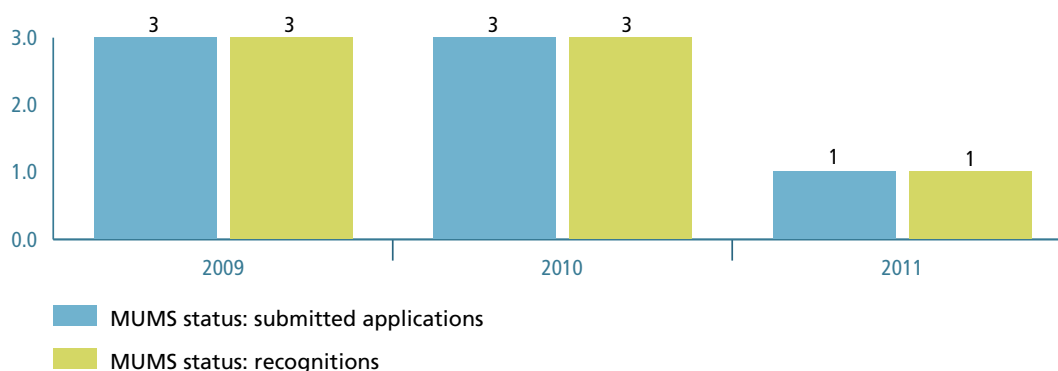


MINOR USE – MINOR SPECIES

Veterinary medicinal products that are only used for minor species or for rarely occurring indications (Minor Use – Minor Species, MUMS) are difficult to place on the market because of the low turnover. However, from the clinical point of view, these products are necessary so that every animal can receive the appropriate treatment. According to Swiss legislation on therapeutic products, the Agency can give its support to these products in the authorisation procedure. One differentiates between recognition of MUMS status and the subsequent authorisation of a veterinary medicinal product as a MUMS product.

Activities

- Swissmedic has granted MUMS status to the active pharmaceutical ingredient pergolide for the treatment of equine Cushing syndrome.
- In 2011, one other product was authorised for the treatment of varroa disease in bees.
- An antiprotozoic containing the active pharmaceutical ingredient imidocarb has been authorised for the treatment of babesiosis in cattle, horses and dogs.



SPECIAL ACTIVITIES AND EVENTS IN THE AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS

New Veterinary Medicines Division

The division of Veterinary Medicines was founded in the Authorisation Sector on 1 January, 2011. It combines the functions of Case Management Assistant, Case Manager, Veterinary Reviewer and Quality Reviewer for the processing of all applications for authorisation of veterinary medicinal products.

Introduction of eCTD (electronic Common Technical Document) for veterinary medicinal products

In future, it will also be possible to submit applications for marketing authorisations and variations for veterinary medicinal products electronically (eSubmission). In the first step, as of 2011 marketing authorisation holders have been able to submit the authorisation documentation (parts II - IV) in paper form with only one copy, provided the file is also submitted electronically (VNees) at the same time.

TABLE OF PERFORMANCE INDICATORS FOR HUMAN AND VETERINARY MEDICINAL PRODUCTS

Key figures for deadlines include the totality of human and veterinary medicinal products.

Performance indicator	Target	Result
Authorisation procedure (all application categories), proportion of procedures completed within the prescribed deadlines.	90%	91.8%
First authorisations innovative medicinal products (ZL1a); proportion of procedures completed within the prescribed deadlines.	90%	64%
First authorisations non-innovative medicinal products (ZL1b); proportion of procedures completed within the prescribed deadlines.	90%	69%
Extensions/waivers (ZL2); proportion of procedures completed within the prescribed deadlines.	90%	82%
Scientific variations (ZL3a); proportion of procedures completed within the prescribed deadlines.	90%	89%
Administrative variations (ZL3b); proportion of procedures completed within the prescribed deadlines.	90%	93%

LICENSING OF MEDICINAL AND TRANSPLANT PRODUCTS

ESTABLISHMENT LICENCES FOR MEDICINAL AND TRANSPLANT PRODUCTS

Companies that manufacture or distribute (import, wholesale, export and trade in foreign countries) medicinal or transplant products in Switzerland must have an establishment licence. Swissmedic issues these licences, on the basis of a successful inspection.

Activities

- At the end of 2011, 1,080 companies held an establishment licence for the manufacture, wholesale, import, export and trade in foreign countries of medicinal and transplant products. This represents an increase of 24 companies on the previous year.
- In 2011, 662 establishment licences were issued for the first time, extended or amended.

Performance indicator	Target	Result
Establishment licences; proportion of procedures that were completed within six months	90%	89.7%

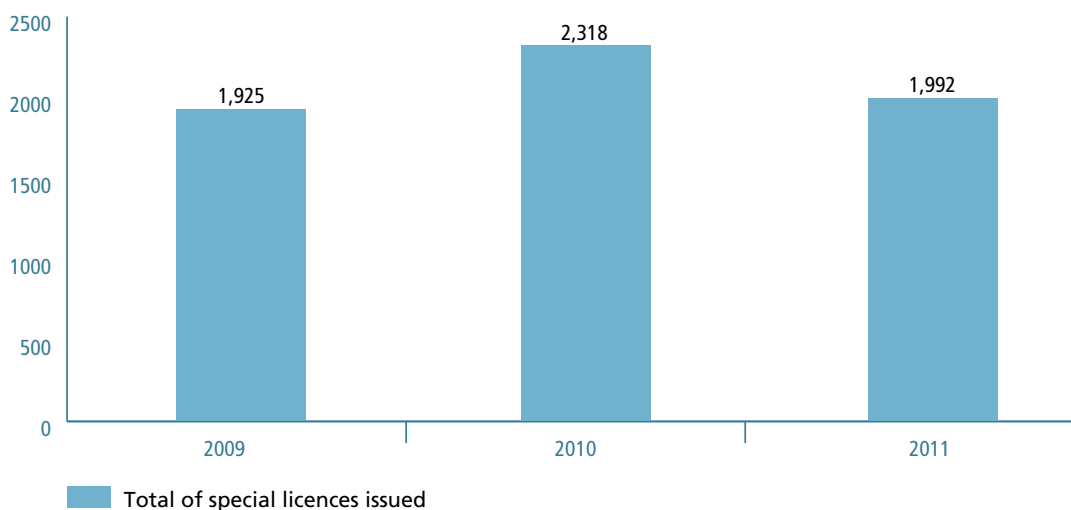
SPECIAL LICENCES FOR MEDICINAL AND TRANSPLANT PRODUCTS

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

Activities

- The effects of the amendments of October 2010 to the Ordinance on Establishment Licences were evident in 2011. As the result of the restriction on the requirement for licensing, the total number of special licences dropped to a total of 1,992.
- Two-thirds of the special licences issued for human medicinal products came from Cantons with a university hospital. One-third of the special licences were for radiopharmaceuticals, in particular for diagnostic purposes.

- One-sixth of the special licences were for medicinal products used to treat tumours that are currently undergoing the authorisation procedure in Switzerland.



Performance indicator	Target	Result
Special licences; proportion of procedures that were completed within 24 hours	90%	83.2%

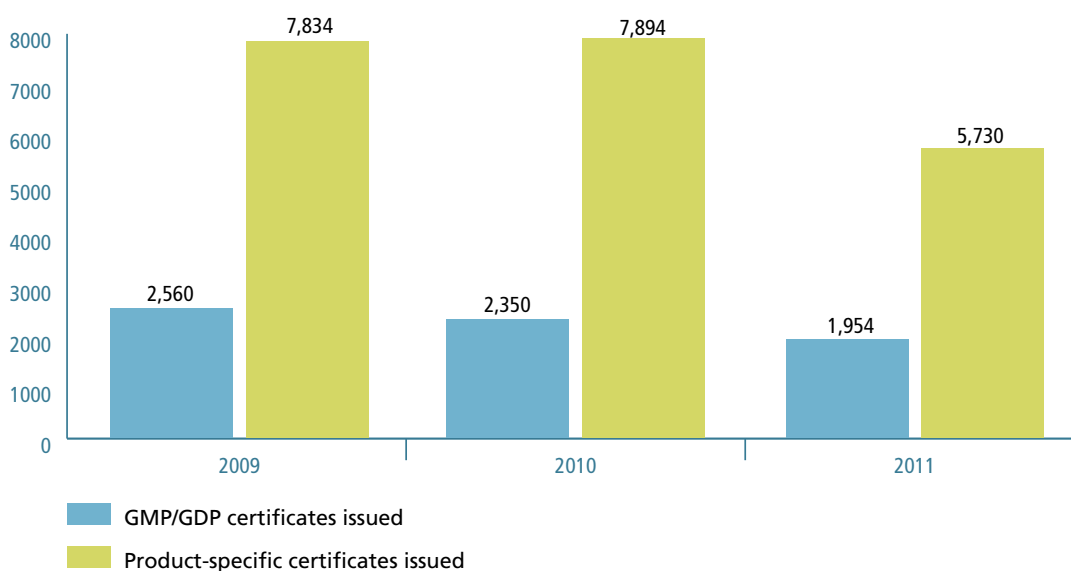
CERTIFICATES FOR MEDICINAL AND TRANSPLANT PRODUCTS

Companies with establishment licences can request copies of their licences (certificates) in German, French, English or Spanish. These certificates are confirmation for foreign companies 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 2011, 1,954 certificates were issued for Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).
- 5,730 product-specific certificates were issued in 2011.



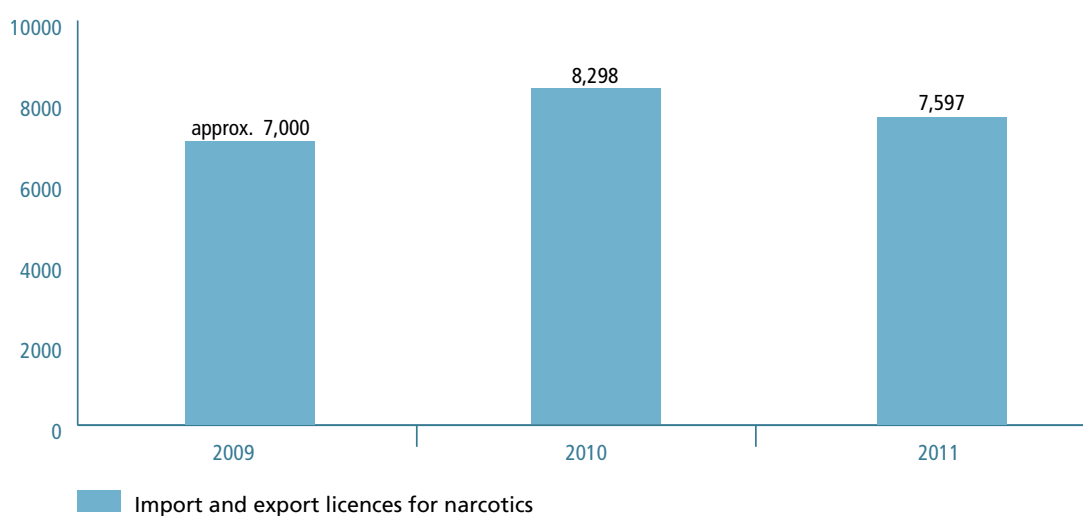
Performance indicator	Target	Result
GMP/GDP certificates and product-specific certificates; proportion of procedures completed within 14 respectively 28 days	95%	75.2%

CONTROL OF THE FLOW OF NARCOTICS

Swissmedic issues establishment licences for companies and individuals who manufacture, obtain, procure, import, export, dispense or trade in controlled substances. Establishment licences are issued by Swissmedic on the basis of prior inspections and at the recommendation of the Cantonal Pharmacist Departments. Furthermore, Swissmedic also records and keeps a tally of every national delivery of narcotics of "Directory a" as per Annex 2 of the Ordinance of the Federal Department of Home Affairs on the Directories of Narcotics, Psychotropic Substances, Precursors and Auxiliary Chemicals.

Activities

- In 2011, 333 companies were in possession of an establishment licence for the use of controlled substances. There were 132 applications for modifications, renewals or commencement of operations.
- Swissmedic issued around 7,600 import or export licences for companies for international trade. The system NDS-WEB was developed for the automatic submission of applications in order to shorten processing times, and will be available to companies from March 2012.
- Swissmedic received a total of 945,000 notifications of national narcotic deliveries.



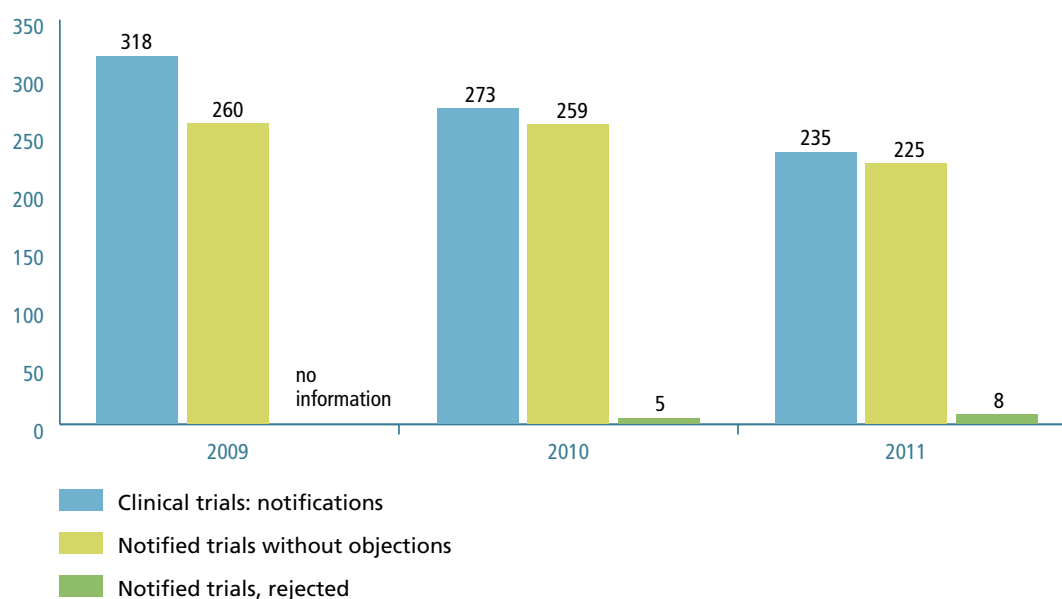
Performance indicator	Target	Result
NDS certificates; proportion of procedures completed within 10 working days	100%	70.9%

CLINICAL TRIALS ON MEDICINAL PRODUCTS AND TRANSPLANT PRODUCTS

Clinical trials are used for the systematic gathering of information on medicinal products used on persons. Swissmedic monitors health protection, the personal rights of the trial subjects and of the patients 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 commission, then reported to Swissmedic, and Swissmedic raises no objections within 30 days (notification procedure). Adverse reactions and modifications are to be reported to the ethics commissions and/or Swissmedic during the trials.

Activities

- Swissmedic was notified of 225 clinical trials with medicinal products; 135 of them were released after retention. Eight clinical trials were refused.
- Swissmedic worked closely with the Federal Office of Public Health (FOPH) to prepare for the ordinance in association with the new Human Research Act.
- The collaboration between Swissmedic and the Swiss Ethics Committees (AGEK) was continued in 2011 with the aim of easing the transition to the new Human Research Act.
- In 2011, the staff of the Clinical Trials Division attended various training courses, for instance for Clinical Trial Units (CTU).
- In the area of transplant products, two clinical trials were notified and four variation applications processed. These were clinical "First-in-man trials" with products based on stem or foetal cells.



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

INSPECTIONS

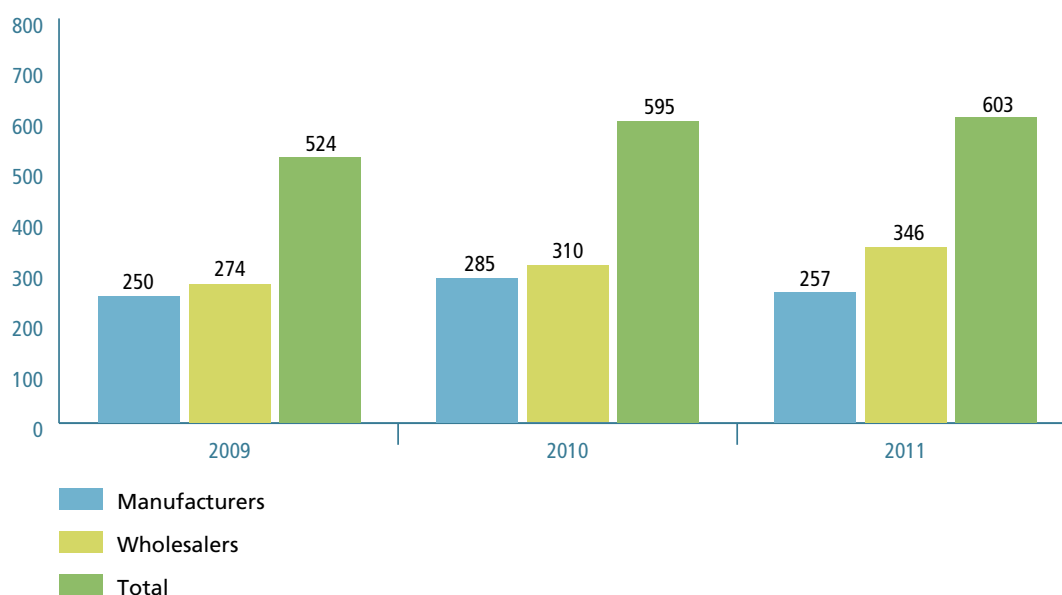
GMP and GDP Inspections

Swissmedic and four regional inspectorates of the Cantons carry out inspections as prerequisites for issuing or maintaining a pharmaceutical establishment licence. Adherence to the quality standard GMP (Good Manufacturing Practice) is checked for the manufacturers of pharmaceutical products and/or the GDP (Good Distribution Practice) for wholesalers.

Activities

- In 2011, the Swissmedic Inspectorate completed the reaccreditation audit of the Swiss Accreditation Body SAS successfully and unconditionally for the renewal of accreditation as an inspection body according to ISO 17020.
- A total of 603 GMP/GDP inspections were carried out of manufacturers and wholesalers, 70 of them by the Swissmedic Inspectorate and 530 by the regional inspectorates.
- Swissmedic carried out three special inspections. A more in-depth risk-based follow-up of notified quality defects or other problems was also established. Between 1 June 2010 and 31 December 2011, seventeen inspection requests were issued to the responsible regional inspectorates.
- Swissmedic and the regional inspectorates also took part in inspections by partner organisations in 2011 and in two assessments of partner authorities in line with the "Pharmaceutical Inspection Co-operation Scheme" (PIC/S). Swiss inspectors participated in international inspection programs: five inspections were performed with the WHO of manufacturers of medicinal products in India, and five inspections of manufacturers of active pharmaceutical ingredients in India and China with the European Directorate for the Quality of Medicines & HealthCare (EDQM).

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



Performance indicator	Target	Result
Licensing inspections; proportion of implementation of annual plan	100%	100%

GCP INSPECTIONS

All clinical trials carried out in Switzerland can be inspected by Swissmedic to evaluate their adherence to Good Clinical Practice (GCP). Random checks are carried out to ensure that the safety and personal rights of the trial subjects and of the patients are guaranteed. They also establish whether the study results satisfy the scientific criteria for correctness and traceability.

Activities

- Swissmedic carried out an inspection to assess adherence to the provisions on GCP in 11 clinical trials.
- Following the development of the Clinical Trial Units (CTU) network in 2010, Swissmedic carried out in 2011 a GCP inspection in the six existing CTUs with the aim of supporting the quality system created by the Swiss Clinical Trial Organisation (SCTO).
- Swissmedic carried out GCP inspections for the two notified clinical trials of transplant products.

Performance indicator	Target	Result
GCP inspections; proportion of implementation of annual plan	100%	100%

GLP INSPECTIONS

With the exception of pharmacodynamics for notification or authorisation procedures, non-clinical assessments are to be carried out in line with Good Laboratory Practice (GLP). Swissmedic's GLP unit carries out monitoring activities (inspection 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 2011, Swissmedic carried out eight routine inspections within the framework of the GLP monitoring activity for adherence to the principles of non-clinical assessments of medicinal products. A test facility was included in the GLP directory.
- Swissmedic assessed and made some minor revisions to the current GLP monitoring programme in 2011.
- The annual meeting of GLP authority representatives and the Swiss Professional Association of Quality Assurance (SPAQA) took place on 1 November 2011. Current issues such as the interface between GLP and GCP were discussed in-depth.

Performance indicator	Target	Result
GLP inspections; proportion of implementation of annual plan	100%	100%

INSPECTIONS FOR THIRD PARTIES

Swissmedic can provide remunerated services on behalf of third parties. Swissmedic carries out inspections and other implementation tasks on behalf of the Federal Office of Public Health (FOPH) in the fields of microbiological and serological laboratories, transplants, genetic examinations on persons, and heroin-based treatments. Swissmedic also carries out some inspection activities in the therapeutic products sector for the Principality of Liechtenstein.

Activities

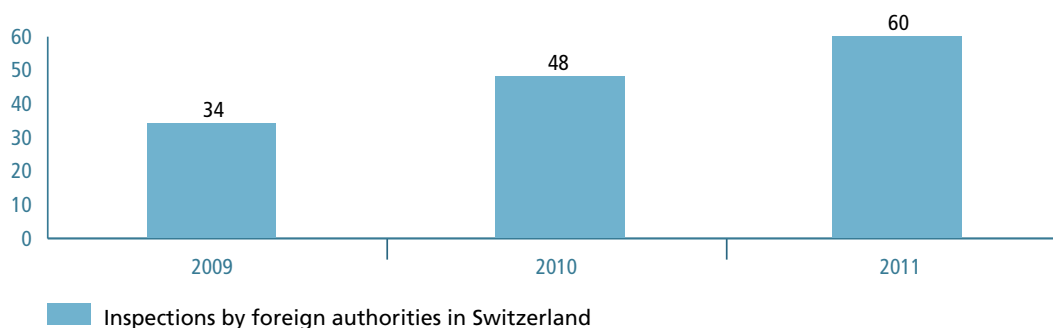
- Swissmedic has carried out approx. 30 inspections for the FOPH.
- In addition to its current inspection activities for the Principality of Liechtenstein, in 2011 Swissmedic also carried out two inspections in line with the licensing for carrying out in vitro fertilisation activities.

INSPECTIONS BY INTERNATIONAL AUTHORITIES IN SWITZERLAND

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

Activities

- Foreign competent authorities carried out 60 GMP inspections of pharmaceutical companies in Switzerland. The inspections were performed by authorities from the USA with 31, Korea with nine, Brazil with eight, Mexico with three, Saudi Arabia and Turkey with two each, and Germany, Taiwan, Japan, Kenya and Syria each with one inspection.
- The French authority carried out one GCP inspection at a study centre in Switzerland.



MONITORING OF THE BLOOD TRANSFUSION SERVICE

Swissmedic monitors the Swiss Blood transfusion activities with an inspection and establishment licensing system, market surveillance and standardisation. In accordance with the Therapeutic Products Act, blood obtained from donors and the resulting labile blood products are considered medicinal products. The collection of blood, the manufacture of labile blood products and the distribution of labile blood products have to be licensed by Swissmedic.

Activities

- The pathogen inactivation procedure for thrombocyte concentrates (TC) was successfully launched in all 13 regional blood transfusion services in Switzerland. Swissmedic assessed 13 authorisation applications for the use of the process in question within a very short period of time.
- In recent years, two deaths in Switzerland were proven to have been caused by contaminated TC. Due to the spread of the West Nile virus in Europe, southern European regions are increasingly being regarded as risky areas. As a precaution, potential blood donors who had spent time in these areas were not allowed to donate blood for one month after their return.
- Swissmedic, in cooperation with the FOPH, checked the possible blood donor activities of 15 patients who died of Creutzfeld-Jacob disease. A recall procedure had to be initiated in one case.
- Due to a quality defect in an aphaeresis machine system used to manufacture blood components, Swissmedic has banned the further use of products made using this type of machine.
- In 2011, the requirements of the disinfection procedure during blood collection were tightened. In addition, measures were also required after a recall of disinfection pads, and about 10,000 blood samples had to be re-tested as a result of the recall of a faulty test kit.

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 with laboratory analysis, method developments and assessments.

Activities

- In 2011, Swissmedic introduced a laboratory information and management system (LIMS). The system supports the processes, facilitates a central data management, and creates the conditions for order completion within deadlines despite the marked increase in the number of analysis.
- A quantum leap in the quality and reduction of the duration of analysis in the identification of unknown active pharmaceutical ingredients was achieved with the introduction of a new, high-performance mass spectrometer (qTOF).
- There has been a marked increase in the number of released batches and plasma pools, and of analysis for market surveillance.

Analysis conclusions for new marketing authorisations and market control

	2009	2010	2011
Authorisation procedure: number of medicinal products examined	100	73	4
Market surveillance: number of medicinal products examined	748	931	1,304
Total	848	1,004	1,308

Batch assessments and plasma pool analysis

	2009		2010		2011	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU and WHO)	555	143	433	128	484	162
Notifications	232	212	269	165	290	176
Plasma pool analysis	1,393	–	1,350	–	1,642	–
Product analysis as the reference laboratory of the WHO	–	690	–	7	–	28

Performance indicator	Target	Result
Batch releases; proportion assessments within a prescribed deadline	100%	99.8%

APPEALS AGAINST DECISIONS IN ASSOCIATION WITH THE LICENSING OF MEDICINAL PRODUCTS

Appeals against decisions in association with the licensing of medicinal products may be lodged with the Federal Administrative Court within 30 days. That Court's judgment may, in turn, be contested at the Federal Supreme Court.

Activities

- In 2011, an appeal was lodged with the Federal Administrative Court against one decision taken by the Agency in association with establishment licences. The main issue concerned fees. Judgement is still outstanding.
- Of the proceedings that had already been pending before the Federal Administrative Court, judgments were passed on two. One appeal was rejected by the Federal Supreme Court, and one procedure was dismissed by the Federal Administrative Court

SPECIAL ACTIVITIES AND EVENTS IN THE LICENSING OF MEDICINAL PRODUCTS**Designer drugs – improved regulation**

Swissmedic was actively involved in the revision of the ordinances. Swissmedic implemented modifications resulting from the coming into force of the Narcotics Control Ordinance and the Narcotics Directory Ordinance within the framework of its responsibilities. For the first time, designer drugs were made subject to control by the narcotics legislation by being included in "Directory e". Following an application by Swissmedic, the Federal Department of Home Affairs added seven derivatives and 52 individual substances to "Directory e" with effect from 1.12.2011.

MARKET SURVEILLANCE

The quality, safety and efficacy of medicinal products and medical devices are constantly monitored by Swissmedic, even after they have been launched on the market.

MARKET SURVEILLANCE OF MEDICINAL PRODUCTS

VIGILANCE OF MEDICINAL PRODUCTS

Swissmedic records safety signals associated with medicinal products, vaccines, labile blood products and veterinary medicinal products based on reports of adverse drug reactions (ADR) from within Switzerland. If the evaluation indicates a new risk, Swissmedic will initiate the appropriate corrective action.

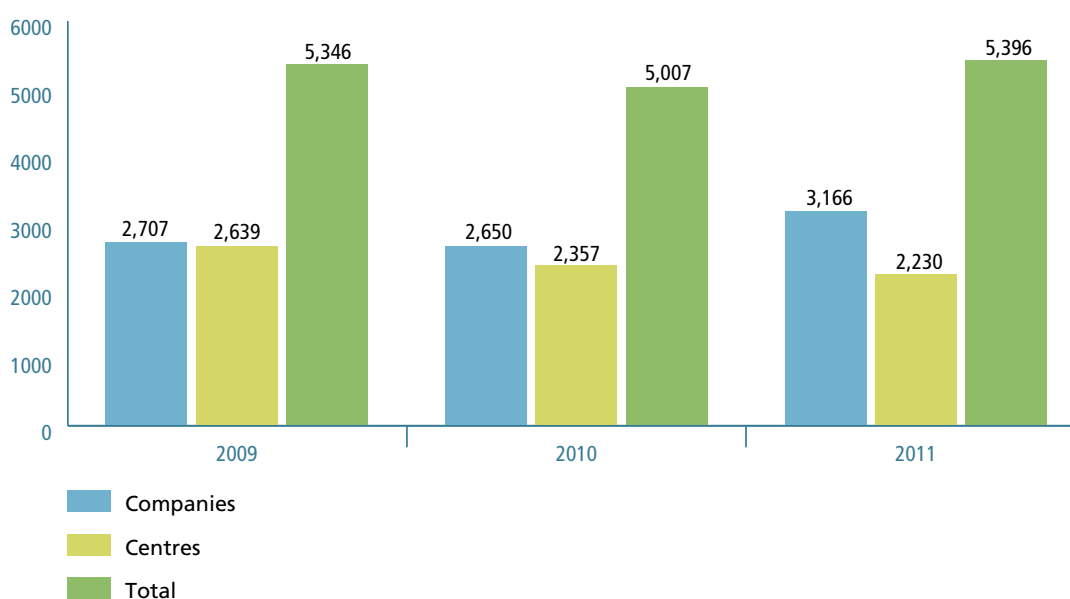
PHARMACOVIGILANCE

Reports on adverse reactions are evaluated and recorded in the national database within the framework of the pharmacovigilance network in six regional pharmacovigilance centres (RPVC) on behalf of Swissmedic. The reporting professionals receive appropriate feedback. In addition, reports of adverse reactions from within Switzerland reach Swissmedic through the pharmaceutical companies.

Activities

- In 2011, Swissmedic received and evaluated 5,396 reports of adverse reactions probably associated with therapeutic products, which had been submitted by the six RPVCs and the pharmaceutical companies. This figure represents an increase of 7% on the previous year.
- The notifications from the regional centres were immediately passed on to the respective authorisation holders.
- These reports led to the identification of new risks associated with therapeutic products. Risk-minimising measures such as restrictions of indications, the inclusion of new warnings and precautions in the product information, and product recalls were adopted as appropriate.

Adverse reactions of human medicinal products: number of reports



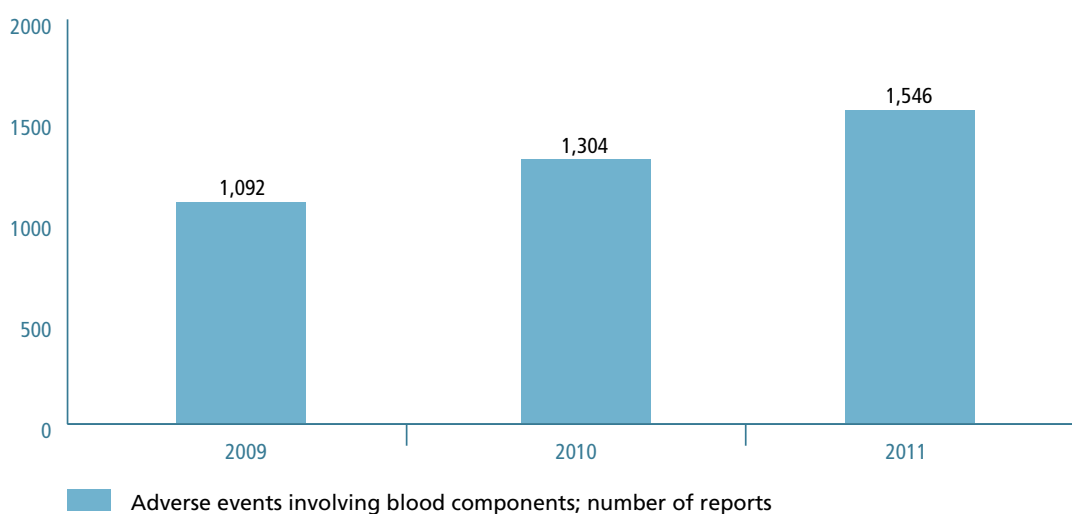
Performance indicator	Target	Result
Serious adverse reactions: assessment and forwarding of notifications to companies within 15 calendar days	95%	98%

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 components to a patient. As the detection of procedural errors is an important issue, "near-miss" events are also recorded. The evaluation of haemovigilance reports provides both a picture of the current risks of transfusion and information on the cause of preventable transfusion incidents, and indicates where corrective measures are necessary and possible. The aim of haemovigilance at Swissmedic is to improve the safety of transfusion therapy.

Activities

- A total of 1,546 reports were received and evaluated in 2011.
- 1,044 of them concerned transfusion reactions, 467 were "near-miss" events, and 35 were incorrectly transfused blood products.
- The continuous rise in the number of submitted reports illustrates the gradual increase in awareness of transfusion risks observed in hospitals over the years.
- Knowledge has been communicated in lectures and the issue of publications. Two workshops were held to provide training for persons responsible for haemovigilance.
- The results and findings are published in an annual haemovigilance report.
- "Swisstransfusion 2011", the first joint conference of the Swiss Red Cross Blood Transfusion Service (SRC BTS) the Swiss Association for Transfusion Medicine and Swissmedic, took place in Fribourg on 8 and 9 September 2011. The conference illustrated how successful cooperation can achieve the aim of enhanced safety for blood donors and patients.



Performance indicator	Target	Result
Report on new findings	1 per year	1
Training for haemovigilance responsible persons	2 per year	2

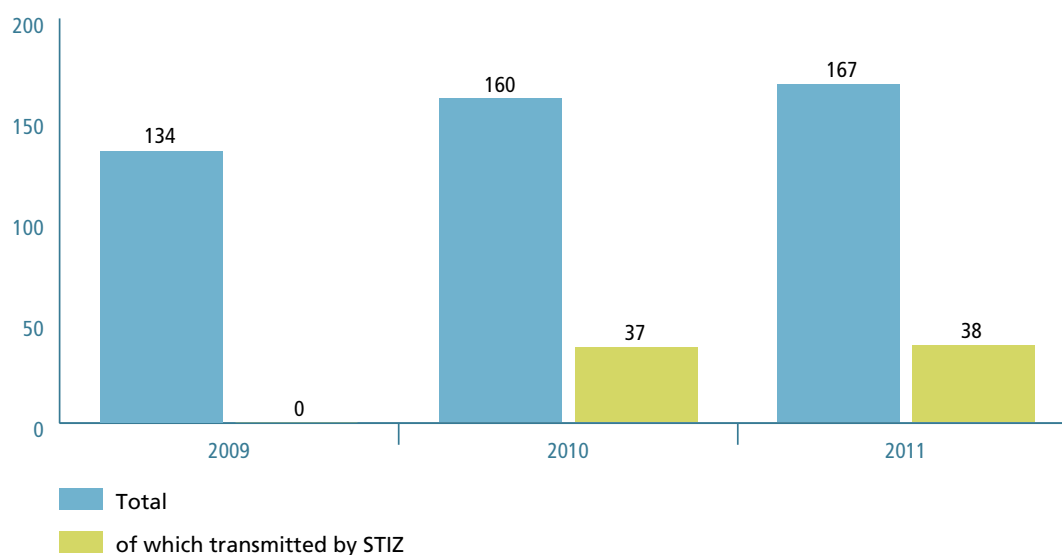
VIGILANCE OF VETERINARY MEDICINAL PRODUCTS

Swissmedic collaborates with the Institute of Veterinary Pharmacology at the University of Zurich for the collection and evaluation of reports of adverse reactions associated with veterinary medicinal products. Reports of adverse reactions of vaccines for animals are not in the responsibility of Swissmedic; these are recorded by the Federal Veterinary Office.

Activities

- The number of adverse reactions of veterinary medicinal products reported to Swissmedic has increased slightly to a total of 167. The Swiss Toxicological Information Centre (STIZ) in Zurich submitted 38 notifications.
- The distribution of the notifications with respect to animal species and drugs remained the same: 51% of the notifications concerned dogs, 16% cats, and 22% cattle or calves.
- 39% of all reports referred to products for eliminating parasites, 20% to anti-infective products, and 11% to non-steroidal anti-inflammatories.
- Three signals were generated from the 167 notifications, two of which resulted in an adjustment of the section "adverse reactions" in the information leaflets of the products concerned.

Undesired effects of veterinary medicinal products: number of reports



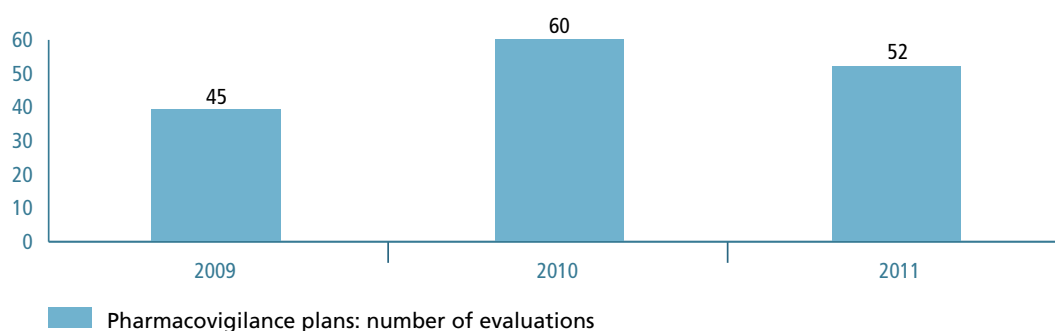
Performance indicator	Target	Result
Report on new findings	1	1

RISK MANAGEMENT

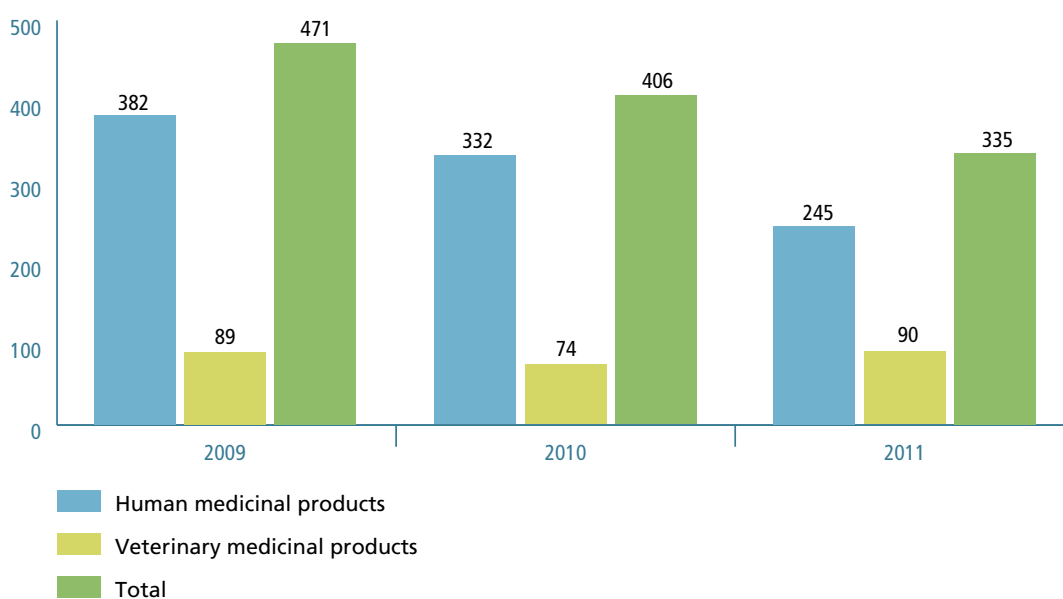
Swissmedic's tasks include the evaluation of international data on drug safety. In accordance with international ICH guidelines, companies are obliged to submit a Pharmacovigilance Plan as part of the authorisation process of new medicinal products. The marketing authorisation holder lists and comments on any possible risks associated with the new medicinal product, explains how they will be prevented and followed up, and how any lack of information will be corrected. Swissmedic also evaluates the companies' periodically submitted Periodic Safety Update Reports (PSURs) and safety signals from international sources.

Activities

- 52 Pharmacovigilance Plans pertaining to initial evaluations as part of an authorisation application or an update were assessed, and in 23 cases the company answers to a "list of questions" posed by Swissmedic were evaluated. There were 245 PSURs concerning human medicinal products, and 90 PSURs on veterinary medicinal products to evaluate: a higher proportion of the veterinary products is subject to mandatory PSUR submission compared to human medicinal products.
- Swissmedic processed 135 safety signals on medicinal products, 54 of which originated in Switzerland, and 81 were recognised through international sources.



PSUR: number of evaluations



Performance indicator	Target	Result
Number of recognised signals from notifications	120	135

RISK-REDUCING MEASURES

Companies are obliged to apply for variations to a product, in the post-authorisation phase, in order to maintain drug safety when any new information, for example on adverse drug reactions, requires action. Whenever Swissmedic becomes aware of new risks the appropriate corrective action and necessary review procedures are initiated, if the company in charge has not introduced or applied for risk-minimising measures itself. The wording of information letters to specialists (HPC, "Healthcare Professional Communications") and the list of recipients are agreed between the authorisation holders and Swissmedic, and approved by the Agency. In many cases, Swissmedic publishes information on risks of medicines on its website.

Activities

- Swissmedic launched 19 review procedures after identification of new safety signals. Six review procedures were completed. One appeal is pending.
- In 27 cases authorisation holders, either at their own initiative or at the request of Swissmedic, sent a HPC to healthcare specialists informing them of risks associated with medicinal products.
- The active pharmaceutical ingredient dolasetron (Anzemet, tablets and injection solution) mainly used to treat chemotherapy-induced nausea, was withdrawn from the international market by the authorisation holder due to an increased risk of cardiac arrhythmia.
- Based on the revised risk-benefit ratio, the authorisation holders waived the authorisation of products containing the biotechnological substances rhu-APC (Xigris) and nesiritide (Noratak). Both products had very limited fields of application.
- Deficiencies in the bioequivalence study resulted in the suspension of the authorisation of generic drugs containing the substance goserelin.
- Other significant restrictions to product indications concerned:
 - the antidiabetic pioglitazone (Actos and others) due to the small but statistically significant increase in the risk of bladder cancer.
 - the antihypertensive agent aliskiren (Rasilez and others) due to the increased occurrence of cardiovascular complications in a clinical trial with patients with pre-existing kidney damage and other risk factors.
 - Nimesulide, used as an analgesic (Aulin, Nisulid) because of possible liver damage.
 - the vaccine Pandemrix, formerly used against pandemic flu, due to an increase in cases of narcolepsy in people under 20 years of age,

Performance indicator	Target	Result
Number of completed procedures (including review procedures)	20	28

MARKET MONITORING OF MEDICINAL PRODUCTS

Quality defects and batch recalls

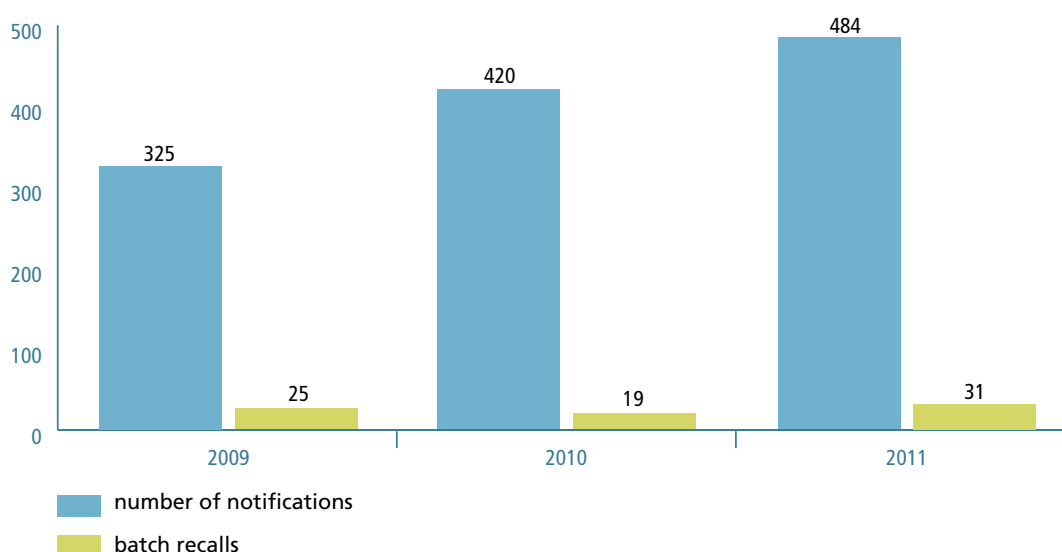
Swissmedic records quality defects in medicinal products, and initiates any necessary measures. A reported quality defect is evaluated, prioritised and processed. Depending on the risk potential of the defect in question, corrective actions may include a batch recall and/or the information of health care professionals by means of a written notification (HPC). Another important component of market monitoring is the international exchange of information and the evaluation of foreign notifications with regard to their relevance to the Swiss market.

Activities

- In 2011, a total of 484 notifications of quality defects were submitted. 300 originated in Switzerland and 184 came from foreign partner authorities. Switzerland was affected by 280 of the total 484 notifications concerning a quality defect. Measures were adopted in 270 of these cases. Seventeen notifications were rated as urgent.

- 31 batch recalls were issued, and two products had to be recalled at patient level because of the high risk.
- Swissmedic issued six so-called “rapid alerts” to notify foreign authorities of quality defects.
- 30 review procedures were completed.
- One overseas company was found to have significant deficiencies in its aseptic production facilities. The company was also responsible for the production of various products that were approved for Switzerland, leading to several recalls.
- An entire product line of parenteral nutrient solutions was affected by a packaging problem which resulted in the products being contaminated with plastic particles. These products were all recalled at hospital pharmacy level.
- A class I defect concerned medical oxygen bottles with incorrectly functioning metering valves.

Quality defects



RISK-REDUCING MEASURES

Swissmedic’s task is to warn the public also of possible dangers in the use of illegal medicinal products. This is achieved via publications and press releases. In order to reduce risks, it is particularly important to inform health care professionals and the public without delay on new findings, to encourage regular exchange with product users, and to maintain good national and international networks. In 2011, there was a strong focus on exchanging information with foreign authorities. It was evident that this intensive exchange of information with international authorities is valuable and produces quantifiable results.

Swissmedic receives notifications concerning illegal products, activities and medicines imports (in particular illegal distribution), assesses them and, if necessary, introduces appropriate measures. Medical imports are monitored and confiscated with the assistance of the customs authorities.

Activities

- Swissmedic received 313 notifications of illegal activities involving medicinal products. 69 notifications concerned illegal distribution. In 51 cases, the legal status was restored thanks to the appropriate measures.
- In 45 cases, the evaluation showed that the notification concerned the retail of illegal products or products to which the Swiss legislation on therapeutic products is not applicable. These cases were passed on to the Cantons for further action.
- Switzerland was only affected by 23 of 118 international notifications concerning counterfeit products,.

- 21 illegal Swiss websites were blocked, and adjustments were imposed on the operators of five other websites to ensure they comply with legal requirements.
- 81 countries from all over the world – including Switzerland – took part in 2011's week-long campaign "Pangea IV" with the aim of fighting the illegal online trade in therapeutic products.
- Customs passed 1,298 suspicious shipments on to Swissmedic. Administrative procedures had to be conducted in 1,132 cases.
- 33 sources of illegal medicinal products were reported abroad.
- Following a notification by the French health authority, Swissmedic became involved in one counterfeiting case concerning a company based in Switzerland. This company had marketed medicinal products in the EU with forged expiry dates and batch numbers. Swissmedic published the recall of the product concerned, suspended the company's licence and initiated criminal proceedings.

	2009	2010	2011
Illegal distribution (responsibility of Swissmedic):	74	75	69
Illegal retail trade (responsibility of the Cantons):	49	50	27
Illegal cosmetics and food supplements (responsibility of the Cantons):	17	23	18
Counterfeit medicinal products:	61	122	118
Suspected medicinal products; number of checks:	40	30	34

Performance indicator	Target	Result
Number of presentations, publications and circulars to raise awareness in stakeholders	12	22

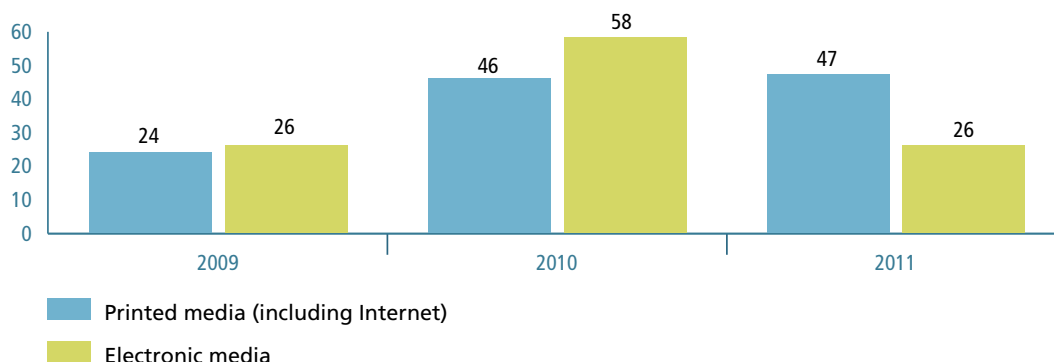
SURVEILLANCE OF ADVERTISING

Swissmedic reviews and monitors the advertising of medicinal products. Advertisements which are subject to prior reviews are evaluated and approved. Swissmedic also follows up all notifications of breaches of advertising regulations and decides whether administrative procedures need to be initiated or in which cases the legal status can be restored by means of a letter of objection. Swissmedic informs interested stakeholders continuously about the applicable legal requirements for medicine advertising.

Activities

- A total of 73 applications were submitted for preliminary evaluation. 42 concerned printed advertisements, five related to Internet websites (which are covered by regulations governing printed media), and 26 concerned electronic media such as TV adverts or eBoards.
- In addition to numerous telephone requests for information, Swissmedic also dealt with 17 complex enquiries relating to various advertising topics.
- Swissmedic was notified of 42 presumably incorrect advertisements to consumers and professionals. Four of these notifications were rated as urgent cases due to the severity of the violation, repeated violation or because of several simultaneous violations. Administrative procedures were initiated in eight cases, and objections filed in 13.
- At the request of, and in cooperation with, the Association of the Swiss Self-Medication Industry (ASSGP) Swissmedic prepared an information sheet on the design of sample packages for the public, in association with separate medicine advertising.
- Preliminary notices were issued after an average of 2 weeks after submission of the request.

Number of applications



Performance indicator	Target	Result
Preliminary check of advertising: preliminary notice issued within four weeks of receipt of application	100%	100%

The following performance indicators concern all activities for “market monitoring of medicinal products”.

Performance indicator	Target	Result
Initial activities within 10 days in cases with priority 1	100%	100%
Initial activities within 30 days in cases with priority 2, and within 90 days with priority 3	90%	94%

APPEALS AGAINST DECISIONS IN ASSOCIATION WITH THE MARKET SURVEILLANCE OF MEDICINAL PRODUCTS

Appeals against decisions in association with the market surveillance of medicinal products may be lodged with the Federal Administrative Court within 30 days. That Court’s judgment may, in turn, be contested at the Federal Supreme Court.

Activities

- In 2011, appeals were lodged with the Federal Administrative Court against 27 decisions taken by the Agency in association with the market surveillance of medicinal products. Most concerned illegal imports of medicinal products and illegal advertising. In eight cases, the court refused admittance, and in five cases the appeal was rejected. Judgement is still outstanding in all other procedures.
- Of the proceedings that had already been pending before the Federal Administrative Court or Federal Supreme Court, judgements were passed on three. One appeal was rejected, and one procedure dismissed. In the third procedure, although the appeal was rejected in the main issue, two side issues were approved

SPECIAL ACTIVITIES AND EVENTS IN THE MARKET SURVEILLANCE OF MEDICINAL PRODUCTS

Medicine advertising: Questions and answers

To facilitate a better understanding of the complex advertising legislation, Swissmedic has created a new "FAQ" section on its website, which is divided into various topics. The aim is to provide customer-oriented information on various aspects of advertising regulations, and to increase the stakeholders' awareness of pertinent issues.

Stop Piracy

A publicity campaign entitled "Counterfeit medicines have a shady past" took place in October/November 2011 under the roof of the association "Stop Piracy". This national campaign was organised in conjunction with various interested associations (Interpharma, Pharmasuisse and VIPs) and was launched with a media conference at the offices of Swissmedic. The public was informed of the health risks associated with medicinal products sold via the Internet, using various channels including websites, posters and articles. 760 pharmacies additionally provided information for their customers and also accepted samples of illegally acquired medicinal products which were subsequently examined in Swissmedic's laboratories.

Advertising ban on the word "Botox"

The Federal Administrative Court passed an important judgement for Swissmedic in October concerning advertising for prescription-only medicines by physicians and the use of the word "Botox" in advertising. The Court found that the ban on advertising prescription-only medicines to the public applies not only to the manufacturers and sellers of medicinal products, but also to all individuals. Editorial reports or notices that provide information on an illness and merely advertise the indication without providing the name of the medicinal product may, under some circumstances, be qualified as consumer advertising. The term "Botox treatment" not only refers colloquially to the treatment of lines and wrinkles: it also promotes the use of the medicinal products Botox and Vistabel used for such treatments.

Steady increase in quality problems

Notifications concerning quality problems associated with authorised medicinal products have been increasing steadily for several years (by another 15% from 2010 to 2011). Not only has the quantity been increasing, but so has the complexity of cases, the number of affected products, and the risk of supply shortages of important medicinal products. This is a consequence of the globalisation of the production of pharmaceutical products, the centralisation of the production of individual substances to a few locations, and increasing cost pressures in the industry.

MARKET SURVEILLANCE OF MEDICAL DEVICES

Unlike medicinal products, medical devices (MD) do not have to be authorised by Swissmedic. Instead, the manufacturer carries out a conformity assessment procedure for its devices under its own responsibility. In the case of higher-risk products, it has the support of a notified body (NB). The procedure results in CE-marking of the devices. Swissmedic is responsible for the monitoring of medical devices that are already available on the market and of NBs. Furthermore, Swissmedic monitors clinical investigations of medical devices that are not yet allowed on the market. Medical devices cover a very wide range of products. They include implants such as hip prostheses and heart pacemakers, in-vitro diagnostics such as HIV tests, and products for the general public such as contact lenses.

INCLUSION IN THE EUROPEAN SYSTEM

For medical devices, Swissmedic is included in a European regulatory framework. Switzerland has concluded mutual recognition agreements on conformity assessments for medical devices with EU member states, EFTA countries and Turkey. This European system provides the authorities of the contracting states with a shared database (EUDAMED) for market surveillance and as an information system. CE-marked medical devices are regarded as compliant, and may be distributed in all contracting states.

Activities

- Swissmedic was involved in the high-level committees Central Management Committee and Competent Authorities Meeting.
- Furthermore, Swissmedic was active in the Medical Devices Expert Group and its working groups, Vigilance, Borderline and Classification, IVD Technical Group, Compliance and Enforcement Group, Clinical Investigation and Evaluation, EUDAMED, Notified Bodies Operations Group (NBOG), New and Emerging Technologies (NET).

PLACING ON THE MARKET

Manufacturers of medical devices with specific risks need to call in officially recognised notified bodies (NBs) for medical devices. Swissmedic monitors the Swiss NBs in cooperation with the Swiss Accreditation Centre, designates them, receives their notifications of certificates, and records them in EUDAMED. Swissmedic takes part in quality assurance measures by the designating authorities in Europe. A number of medical devices are subject to notification. Swissmedic receives these notifications, performs random checks on the classification of the devices, initiates any necessary corrections, and records the notifications in EUDAMED, the European database. Swissmedic also issues export certificates and certificates of origin for medical devices for Swiss companies upon request.

Activities

- 465 notifications for class I medical devices and 595 notifications for in-vitro diagnostics (IVD) were recorded: in 19 cases, Swissmedic prevented the placing on the market of products with incorrect classification.
- 2,120 export certificates were issued.
- 35 EU enquiries on delimitation questions regarding devices were initiated or completed by Swissmedic. Thus, for instance, whether a product was to be classified as a medicinal product or medical device. Two inspections were carried out with Swiss NBs. One Swissmedic representation was invited by a European authority to take part in an assessment inspection of a foreign NB, and was present at an EU examination of one NB.
- Since 1 May 2011, it is no longer compulsory to notify Swissmedic of in-vitro diagnostic devices manufactured by firms from countries that have concluded agreements with Switzerland. The corresponding foreign authorities will enter the information concerned in the central EUDAMED database. For this reason, there has been a sharp decrease in the number of notifications for these devices compared with 2010. This resulted in a marked drop in IVD notifications on the previous year.

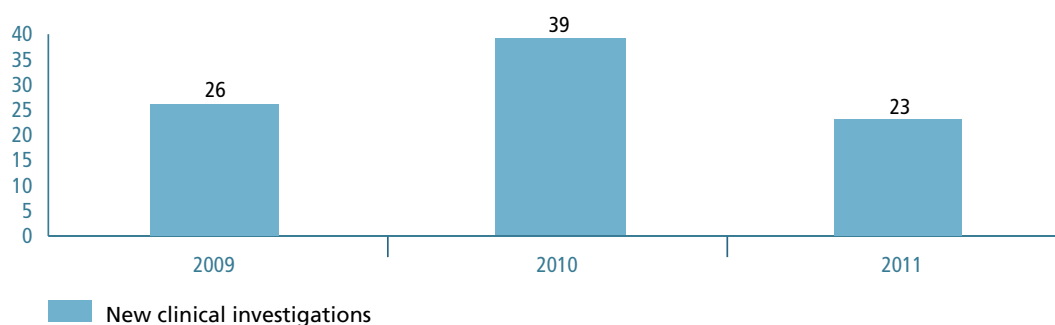
	2009	2010	2011
Notifications of class I MD	232	302	465
Notifications of IVD (Switzerland)	352	2,473	595
Notifications refused (incorrect classification)	17	40	19
EU Enquiries	27	37	35
Export certificates	1,750	1,918	2,120

CLINICAL INVESTIGATIONS OF MEDICAL DEVICES

Swissmedic monitors clinical investigations of medical devices in humans if the devices or proposed uses are not yet permissible in Switzerland. Investigations such as these are to be notified to Swissmedic, and will be evaluated. While the investigations are being carried out, Swissmedic monitors notifiable events such as serious adverse events and reports on the safety of study subjects. Swissmedic is free to inspect investigators, sponsors and clinical research organisations all over Switzerland, and records notifications and measures from Switzerland in EUDAMED. Swissmedic is also involved in the preparation of international guidelines.

Activities

- 23 notifications of new investigations of medical devices not permissible for the market were evaluated.
- 636 notifications concerning ongoing clinical investigations were processed.
- One investigation was interrupted temporarily for the safety of the trial subjects.
- Two investigations were inspected. A total of 13 deficiencies were found and corrected in five different companies or institutions.
- Eight presentations were given on the following subjects: correct performance of clinical investigations, new requirements concerning the notification of serious adverse events, and experience gathered in inspections.



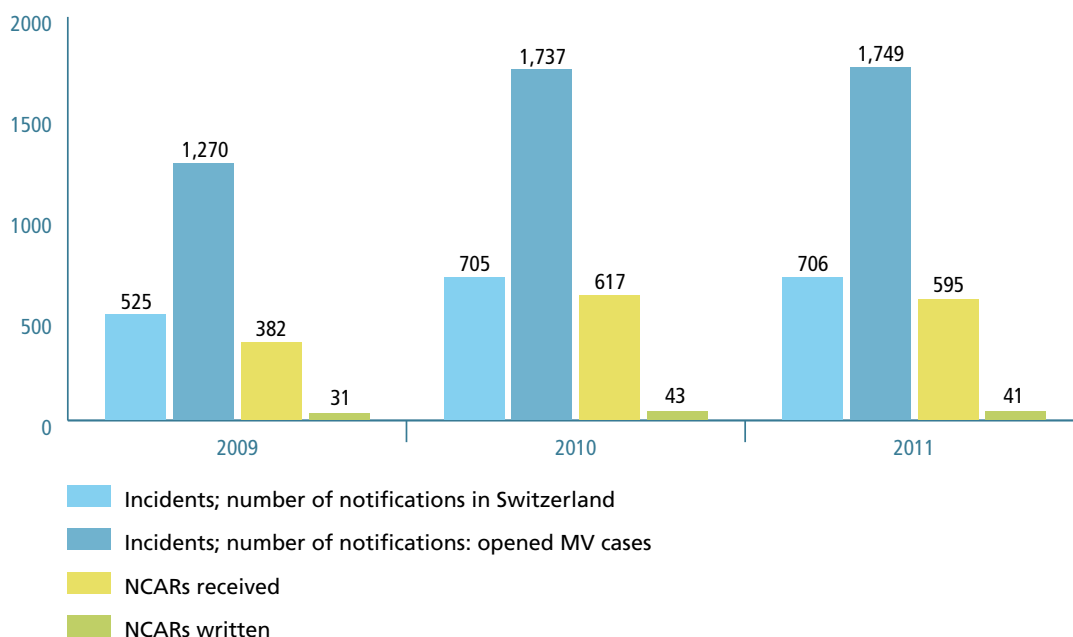
Performance indicator	Target	Result
Notifications of clinical investigations; proportion of notifications that were assessed within 30 days	100%	100%

VIGILANCE OF MEDICAL DEVICES (MATERIOVIGILANCE, MV)

The manufacturers and users are obliged to inform Swissmedic of undesirable incidents. The companies will also inform Swissmedic of the measures adopted, such as product recalls, which in turn will be monitored. Swissmedic is connected to the European reporting system, and will inform other affected EU countries of incidents and measures in Switzerland.

Activities

- A total of 1,749 materiovigilance cases were processed, 706 of which were incidents in Switzerland. In 629 cases, the implementation of field safety corrective action was monitored in Switzerland.
- 41 reports on defects in medical devices (NCARs) were issued for foreign authorities.
- A conference was organised for hospital materiovigilance contacts for information purposes.



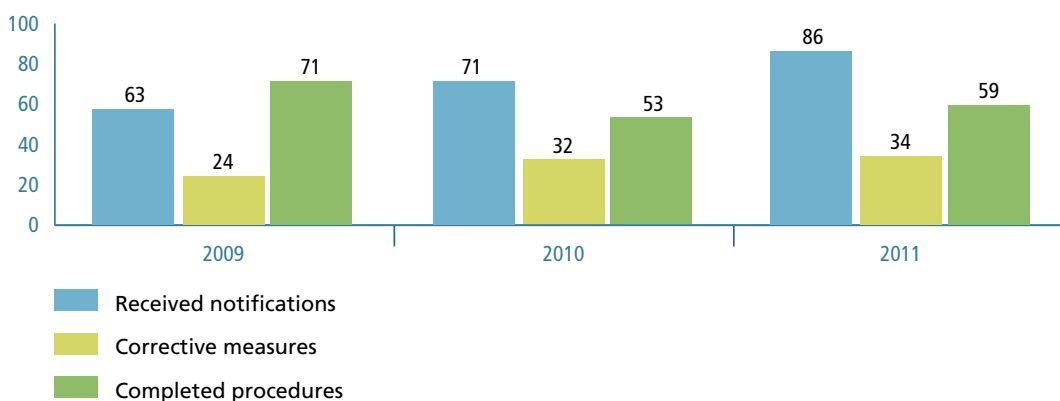
Performance indicator	Target	Result
Notifications requiring instant action; initial measures within 10 days	100%	100%

MARKET CONTROL OF MEDICAL DEVICES: SUSPICION NOTIFICATIONS AND MEASURES

In Switzerland and Europe, medical devices are placed on the market without authorisation by a governmental authority. That is why efficient state-organised controls are of critical importance. In the event of suspicion notifications, Swissmedic instigates the necessary corrective measures and, if necessary, monitors their implementation. As the same conditions apply for medical devices in Switzerland as in all EU member states, Swissmedic often takes corrective measures in agreement with international partner authorities.

Activities

- Swissmedic received 86 notifications concerning devices where an infringement of conformity was suspected. A market control procedure was opened in 49 cases.
- In 34 opened cases, corrective measures were called for, such as adjustment of the product information or cessation of distribution.
- 59 procedures were completed.



Performance indicator	Target	Result
Initial activities in priority 1 cases within 10 days	100%	100%
Initial activities in priority 2 cases within 30 days, priority 3 cases within 90 days	90%	82%

APPEALS AGAINST DECISIONS IN ASSOCIATION WITH THE MARKET SURVEILLANCE OF MEDICAL DEVICES

Appeals against decisions in association with the market surveillance of medical devices may be lodged with the Federal Administrative Court within 30 days. That Court's judgment may, in turn, be contested at the Federal Supreme Court.

Activities

- In 2011, no appeals were lodged with the Federal Administrative Court against decisions taken by the Agency in association with the market surveillance of medical devices.
- Of the proceedings that had already been pending before the Federal Administrative Court or Federal Supreme Court, judgement was passed on one; the appeal was rejected.

SPECIAL ACTIVITIES AND EVENTS IN THE MARKET SURVEILLANCE OF MEDICAL DEVICES

Improved market surveillance thanks to the extended EUDAMED EU database

EUDAMED, a European database, has been extended and has been used by the respective authorities for exchanging information on medical devices since 1 May 2011. Swissmedic is responsible for recording data in Switzerland. This required an extensive adjustment of its own databases so that the EUDAMED data transfer could be performed on time. Consistent use of the database improves transparency and coordination between the authorities of the contracting states. It simplifies a number of reporting procedures for Swiss companies in EU and EFTA member countries and in Turkey. Since 1 May 2011, it has no longer been necessary for companies in the contracting states to notify Swissmedic of medical devices for in-vitro diagnostics.

Quality defects in breast implants cause discussion on the regulatory framework for medical devices

In December 2011, suspicions reported in France that non-compliant breast implants marketed by Poly Implant Prothese (PIP) could be associated with cancer in certain women led to discussions concerning the existing regulatory framework for medical devices. PIP products were recalled on the Swiss market in April 2010 when it became known that this company had been involved in criminal activities.

STANDARDS

LEGAL FOUNDATIONS

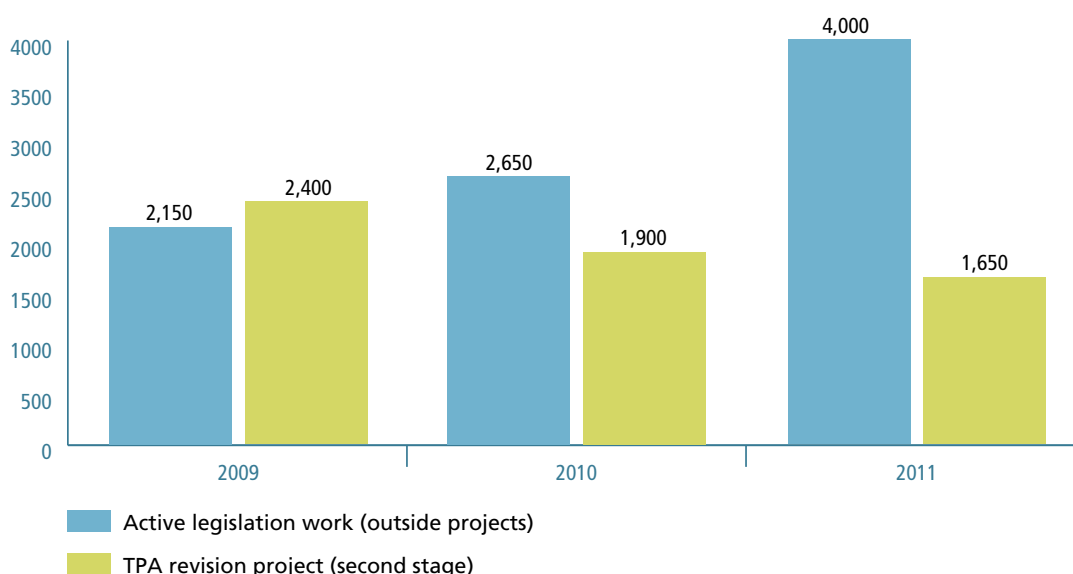
LEGISLATION

The mandate and the competences of Swissmedic, and the applicable requirements in the therapeutic products sector, are laid down in laws and ordinances. In a rapidly changing environment, legislation – i.e. tasks related to working out new and maintaining the existing legal foundations – is one of Swissmedic's key tasks. On the administrative level, the lead responsibility for these tasks concerning the Therapeutic Products Act and the corresponding execution ordinances of the Federal Council lies with the Federal Office of Public Health (FOPH); as an enforcement authority, Swissmedic is involved in these legislative tasks. The adoption and revision of the execution ordinances of Swissmedic's Agency Council (ordinances of a technical nature) however are carried out independently by Swissmedic.

Activities

- On 6 April 2011, the Federal Council acknowledged the consultation report on the ordinary revision of the Therapeutic Products Act (second stage) and determined the further course of action. The Federal Department of Home Affairs (FDHA) was tasked with drawing up a message on the amendment of the Therapeutic Products Act, based on a draft of October 2009 (consultation draft).
- The partial revision of the Therapeutic Products Act of 13 June 2008, which had been brought forward, came into force with the corresponding Federal Council ordinances on 1 October 2010. In order to correlate the existing Agency Council ordinances with the higher level law and comply with the requirements for clearer naming of medicinal products, during the reporting year the Agency initiated a partial revision of the Ordinance on the Authorisation of Medicinal Products and the Ordinance on the Simplified Authorisation of Medicinal Products and the Authorisation of Medicinal Products in the Notification Procedure.
- The valid ordinances were also adjusted with the partial revision of the legislation on narcotics, which came into force on 1 July 2011. In cooperation with the FOPH, the Ordinance on Narcotics and the Ordinance on Precursors were combined in a new ordinance, the Ordinance on the Control of Narcotics, for greater ease.
- With the aim of ensuring the future financing of Swissmedic, and thus the fulfilment of the entire mandate, the Agency Council approved the overall revision of the Ordinance on Fees for Therapeutic Products (OFTP) on 2 December 2011. The revised ordinance will come into force on 1 January 2013. The purpose of the overall revision is to make the fees' structure easier and more transparent, and to align it more closely to the 'applicant pays' principle. Based on the public interest in the easier availability of certain medicinal products, there are still plans to reduce certain fees. The internal administrative ordinances will be adapted to the revised OFTP over the course of 2012.

Personnel resources invested in the legislation:
Hours worked (rounded up to 50)



PHARMACOPOEIA

The Pharmacopoeia that is valid in Switzerland consists of the European Pharmacopoeia (Ph.Eur.) and the Swiss Pharmacopoeia (Ph.Helv.). It contains risk-appropriate legally binding quality regulations that are based on the state-of-the-art for science and technology and apply to common and known medicinal products and pharmaceutical excipients, and to some medical devices. The Pharmacopoeia is important in ensuring that all patients have access to medicinal products of the same high quality, and thus is a central condition for safe and effective medicinal products.

Swissmedic participates in the elaboration of the Ph.Eur. on the basis of a treaty, and publishes with the Ph.Helv. supplementary prescriptions of national importance.

Activities

- Together with Swiss experts from the fields of industry, universities and authorities, Swissmedic has been involved in specialist work for approximately 10.9 man years. 121 specialists are involved in the relevant works. 66 percent of this work was carried out by the Swiss Agency for Therapeutic Products which, with its Pharmacopoeia Division, constitutes the Swiss National Pharmacopoeia Authority.
- Switzerland made a significant contribution to the preparation of the 7th edition of the Ph.Eur. and to its translation into German. The basic volume 7.0 came into force on 1 January 2011. The supplements 7.1 and 7.2 followed on 1 April 2011 and 1 July 2011 respectively.
- The adjustment of chapter 5.2.8 of the Ph.Eur. came into force on 1 July 2011 by means of an urgent amendment in order to ensure that the requirements of the Pharmacopoeia take into account current scientific findings on transmissible spongiform encephalopathies and on the worldwide developments with regard to BSE (bovine spongiform encephalopathy).
- With regard to the 11th edition of the Ph.Helv., extensive work was carried out to check and update the general chapters, to review specific monographs, especially with regard to herbal medicinal products, and to implement several alterations that improve the user-friendliness of this publication.
- In October 2011, the Swiss National Pharmacopoeia Authority arranged an event for its Ph.Eur. and Ph.Helv. experts on chemistry in Berne. In addition to lectures on fundamental and current subjects, the event also provided a platform for exchanging experiences and networking.
- The annual re-elections of the Swiss Pharmacopoeia Commission (SPK), which represents the user circles of the Pharmacopoeia, took place at the end of the year. The SPK supports the Agency in interdisciplinary scientific matters concerning the Pharmacopoeia, reports on changes and additions to the Ph.Helv., approves the texts published in the Ph.Helv. for the Agency, and advises Swissmedic when required on fundamental questions relating to the Pharmacopoeia.

TECHNICAL STANDARDS

TECHNICAL STANDARDS FOR MEDICAL DEVICES

If a medical device complies with the valid harmonised standards published in Europe, then there is a presumption of conformity. Swissmedic publishes an annual list of these harmonised standards in the Federal Gazette, and is involved in various national standards committees and technical commissions. These committees analyse the effects of new or revised international standards on medical devices for Switzerland, and comment on them where required.

Activities

- As in the previous year, Swissmedic remained active on five national standards committees in 2011.

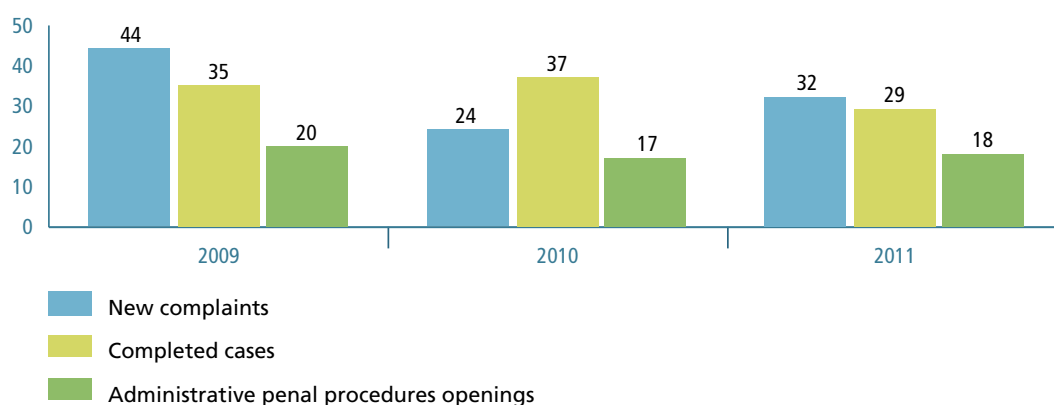
Penal Law

GENERAL DEVELOPMENT

Swissmedic is competent to conduct a significant part of the criminal proceedings in association with violations of the Therapeutic Products Act: the Agency is entitled to carry out investigations and (where there are financial penalties) issue sanctions. Swissmedic represents the charges in the courts of first instance and in the appellate courts.

Activities

- 32 new criminal complaints have been received, 18 administrative penal procedures were opened, and 29 cases were concluded.
- The trend seen in recent years for ever-more complex, time- and labour-intensive cases continues.
- With regard to skin-whitening products, extensive product classifications were carried out in order to establish which of the products could be considered as medicinal products if, for instance, they contain corticosteroids, and which are cosmetics. Work continued in 2011 on a multi-part case that opened in 2010. As it was both a medicinal product and a cosmetic, it was necessary to collaborate with the cantonal chemist. Swissmedic issued two fines in 2011.
- At legislative level, 2011 was all about working towards Switzerland's signature and ratification of the European Council's "Medicrime" convention. The Federal Council decided to sign the agreement on 10th June 2011. The document was signed in Moscow on 28th October 2011. The preparatory work for the ratification is currently underway.

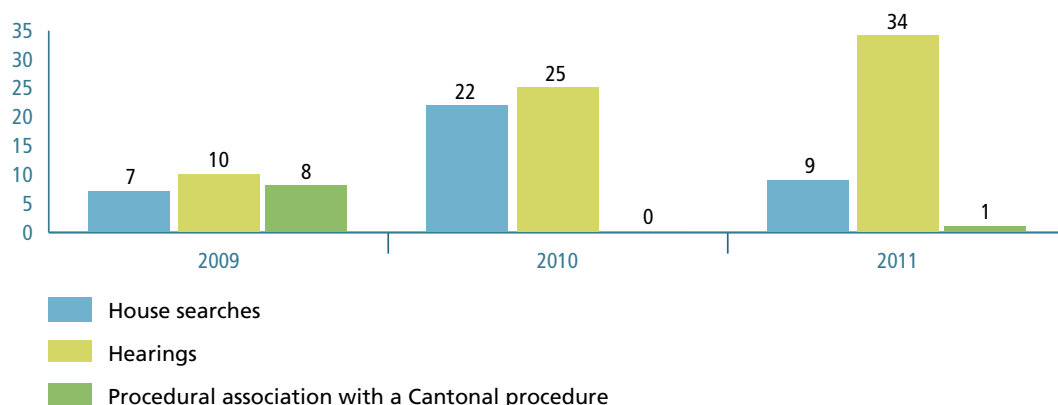


INVESTIGATIVE MEASURES

The Federal Act on Administrative Penal Law grants Swissmedic's investigators the same competences as a prosecutor of a Canton or the Confederation. They can carry out house searches, confiscate goods or conduct hearings in its name. In line with the investigation, any persons who are affected by investigative measures are free to submit complaints to the director of Swissmedic and to the Federal Criminal Court.

Activities

- Proceedings based on the suspicion of fake certificates and the sale of expired products called for five house searches and 10 hearings just during the opening stage.
- A total of nine house searches and 34 hearings were carried out.
- Two requests to unseal records were submitted to the Federal Criminal Court. Swissmedic withdrew one application on the ground of invalidity. A decision of non-occurrence was granted in the second case, as the court decided that a bank had wrongly sealed the records it provided. The Federal Criminal Court did not enter into an appeal against a ruling by Swissmedic denying access to records.
- In one case, there was a procedural association with a parallel Cantonal procedure.

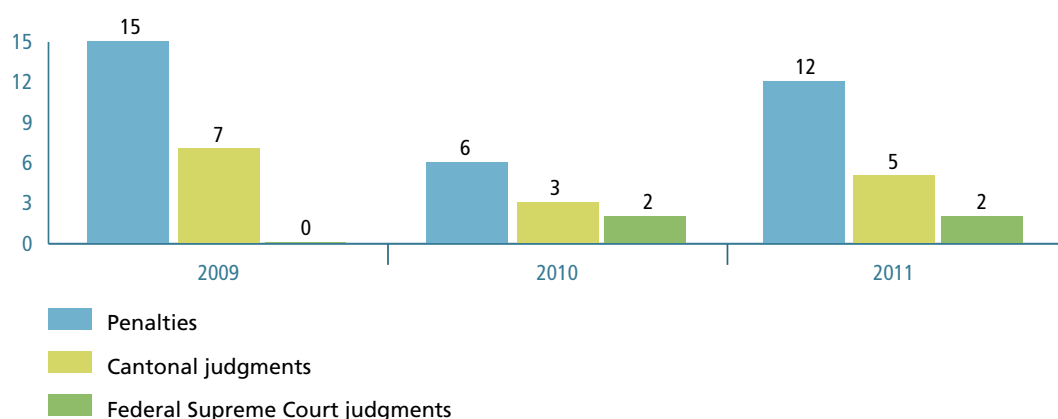


DECISIONS / JUDGEMENTS

The instruction stage is followed by a penalty, transfer to the competent court or closing of the proceedings. Swissmedic represents the prosecution in cases that go to court.

Activities

- 12 penalties were issued for illegal trading, clinical trials and advertising. Three of these penalties were confirmed by Swissmedic after objections raised by the concerned persons.
- 5 judgments were issued by Cantonal bodies: these consisted of 4 judgments by the first instance concerning illegal trading and one acquittal in association with Article 33 TPA (ban on the granting and acceptance of monetary advantages for or by persons who prescribe or issue medicinal products) by an appellate court. Swissmedic lodged an appeal against this judgment with the Federal Supreme Court.
- In two cases, the Federal Supreme Court issued a judgment concerning the danger to health as per Article 86 TPA. The first case concerned a product that was praised as being 100% natural for the treatment of multiple sclerosis, but that contained cortisone. The explicit danger to health asserted by the Agency was confirmed. In the second case, an explicit danger to health on the grounds of misleading treatment indications within the framework of the marketing of medicinal products was rejected by the court.



STAKEHOLDER MANAGEMENT

INFORMATION

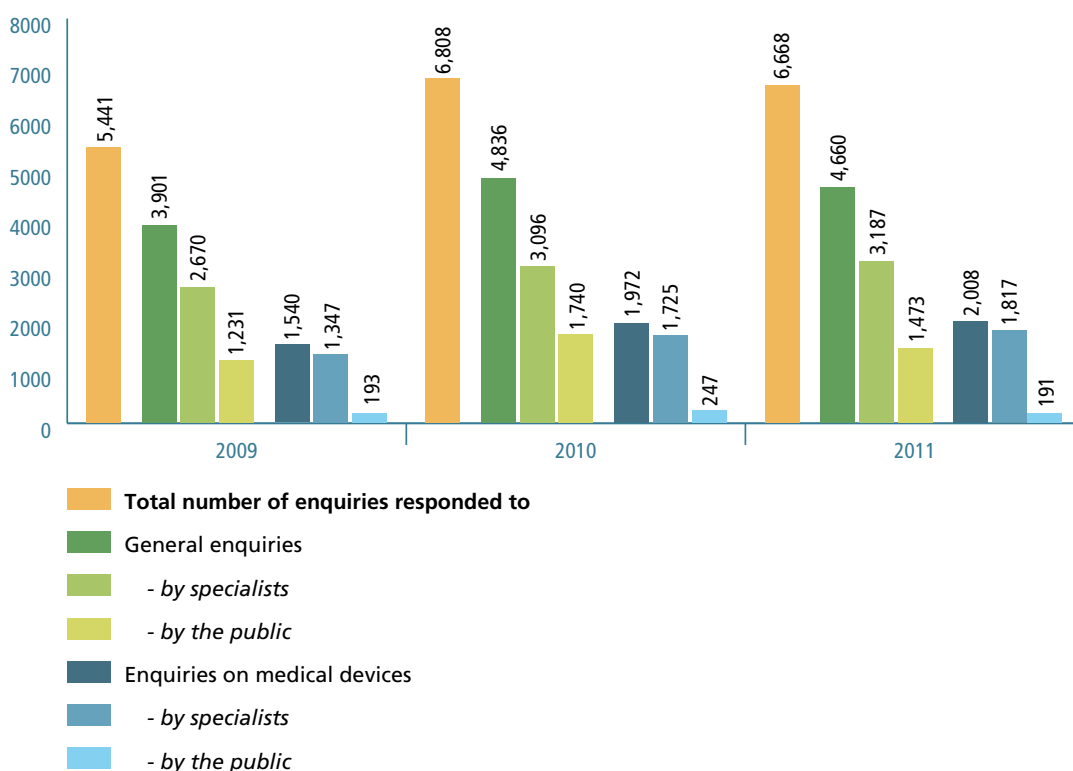
Swissmedic provides fast, specific information on new findings concerning medicinal products that could be harmful to health. As well as safety-relevant information, new authorisation decisions or significant adjustments of medicinal product information are of tremendous interest.

GENERAL ENQUIRIES

Swissmedic responds to general enquiries by consumers, patients and specialists on a wide range of subjects associated with medicinal products. Enquiries are usually responded to within 10 days.

Activities

- Swissmedic responded to 6'668 general queries and queries concerning medical devices; this is approx. 8% less than in 2010, and around 30% more than in 2009.
- 97% of all queries were responded to within 10 days.
- There was no specific focus in 2011. Many queries concerned issues of authorisation, such as eCTD, herbal medicinal products and changes to clinical trials and licences.



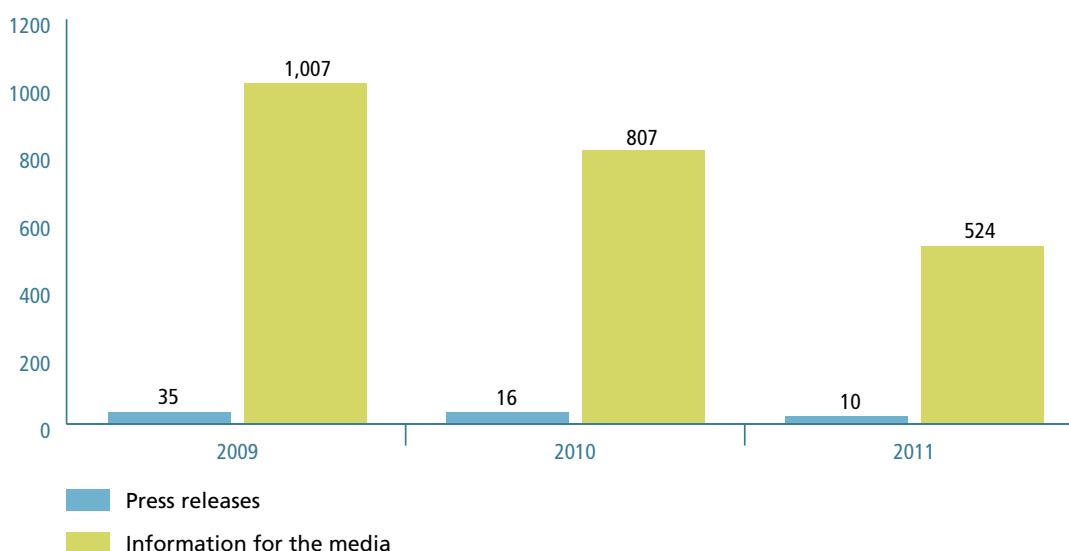
Performance indicator	Target	Result
General enquiries responded to within 10 days	90%	97%

PRESS RELATIONS

Patients and consumers want to receive easy to understand, professional, competent advice and information on the risks and benefits of medicinal products and medical devices. This is where Swissmedic's press relations work comes in. Swissmedic provides information quickly and factually. This enables us to create transparency in public and make an important contribution to the health and safety of people and animals.

Activities

- Swissmedic responded to approximately 520 queries from journalists.
- Specialists and the spokesman appeared regularly in or on almost every Swiss media - print, radio and TV.
- Swissmedic published press releases on seven different subjects. One focus was on national and international activities on the subject of "Medicines and the Internet".
- The campaign "Illegal medicines are deadly" was launched in Swissmedic's main building with a media conference that received a tremendous response.
- Swissmedic published 45 messages on the safety of medicinal products on its website. It issued especially recommendations on a number of combined hormonal contraceptives based on new epidemiological studies.

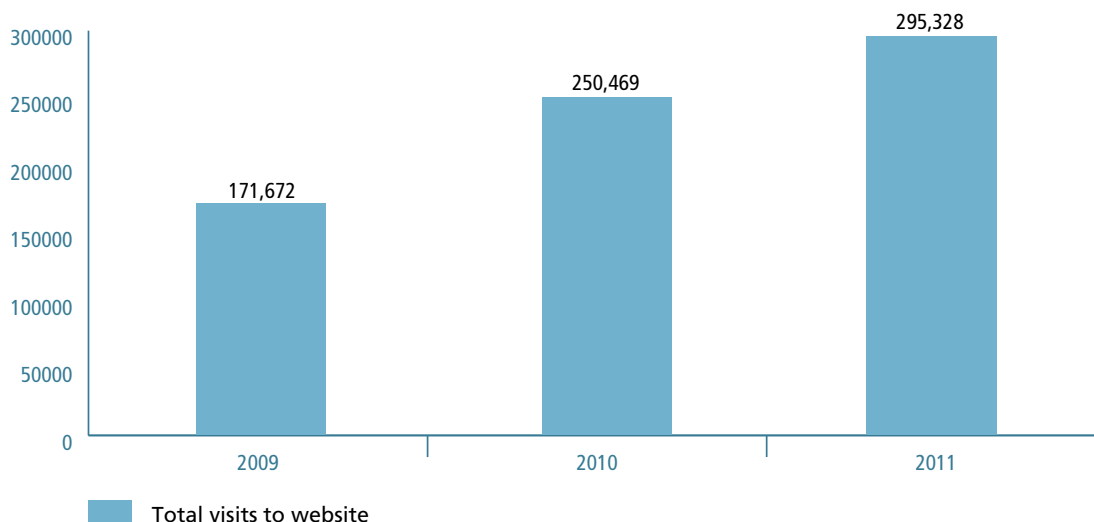


PUBLICATIONS

In addition to its official monthly publication, the *Swissmedic Journal*, and its annual report, Swissmedic also provides other information, newsletters, reports and guidelines on current topics. These publications can be found on Swissmedic's website.

Activities

- Since 1 January 2011, the *Swissmedic Journal* has been published only in an electronic format, and it appears on Swissmedic's website from the middle of the following month.
- In 2011, its columns on Health Professional Communication (HPC) and the pages with request forms were visited frequently on Swissmedic's website.
- Swissmedic's website was visited a total of 295,328 times in the reporting year.



EVENTS

Every year, Swissmedic organises a number of information events and workshops. The aim of all these events is to improve the collaboration with its stakeholders. Swissmedic staff prepare and present specialist lectures. Depending on the particular subject, the Agency may also invite guest speakers from other authorities or from the industry.

Activities

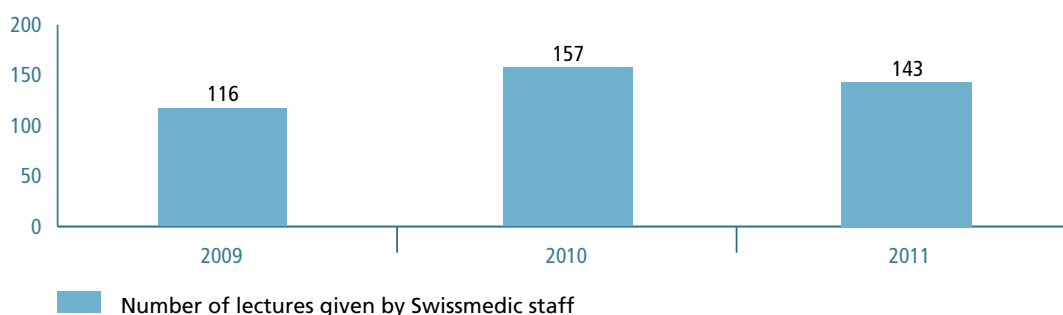
- On 29 June 2011, Swissmedic organised its first event for patient and consumer organisations, their members, and specialists from the health industry. The aim of the event was to give a clear, easy-to-understand presentation of Swissmedic's assignment using the development of a medicinal product as an example.
- In 2011, Swissmedic organised around 10 information events for the therapeutic products industry (2010:19). Over 1,000 participants attended all events.

LECTURES

Swissmedic staff give talks and lectures on current topics at internal and external events.

Activities

- A total of 143 talks were given at external and internal events. The focus was on authorisation requirements for medicinal products in Switzerland; pharmacovigilance, materiovigilance and haemovigilance, and the requirements for clinical studies in Switzerland.

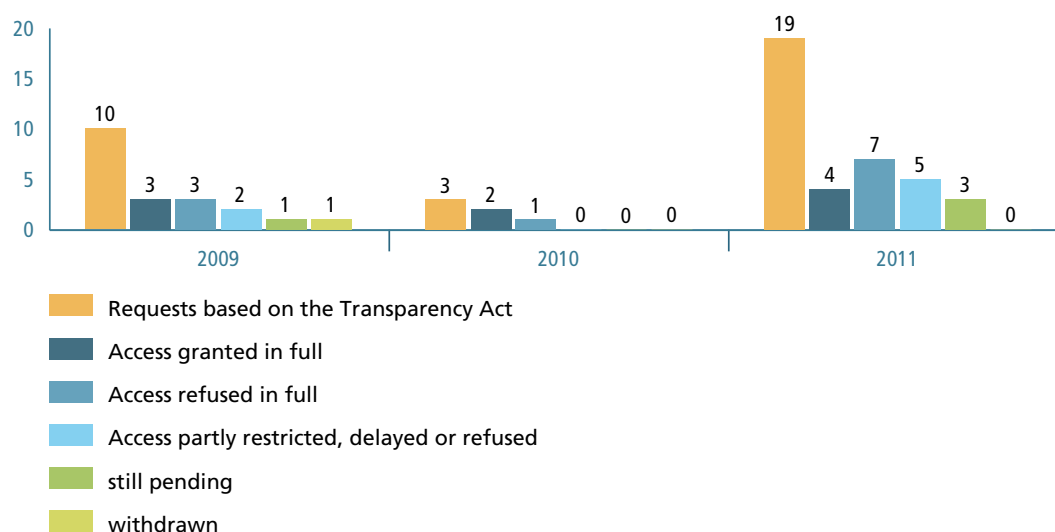


TRANSPARENCY

The Transparency Act passed on 1 July 2006, and the corresponding ordinance, grant every person a general right of access to official documents. This includes documents concerning public assignments and written or received by Swissmedic after 1 July 2006. No reason has to be given for a request for access. The right to access official documents may be restricted or refused to protect predominantly public or private interests.

Activities

- In 2011, Swissmedic received 19 requests based on the Transparency Act. The tendency is rising.



COLLABORATION

Swissmedic's collaboration with its various stakeholders is defined in the concept for national and international collaboration approved in May 2008 by the Agency Council. The concept defines the inclusion of all external stakeholders with their often diverging interests in Swissmedic's various fields of activity as a fundamental principle. The collaboration is based on a relationship that creates trust, preserves and encourages mutual understanding.

NATIONAL COLLABORATION

National network

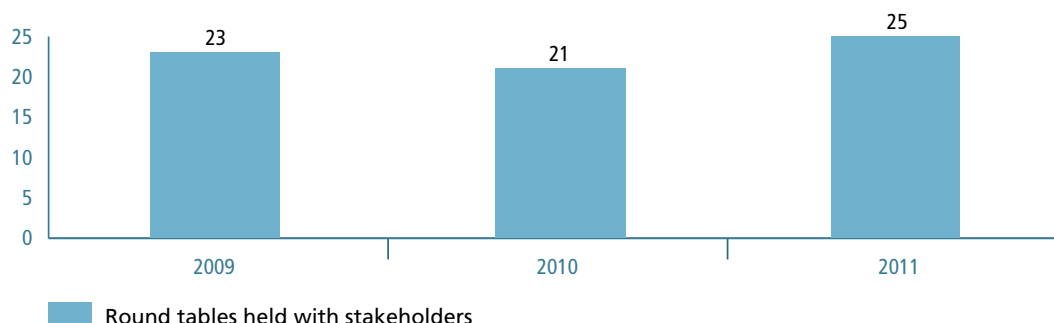
Collaboration on national level is an important foundation stone that enables Swissmedic to achieve the goals specified in its legal mandate, the service mandate and the service agreement. Guaranteeing the safety of therapeutic products is of the utmost priority. The following stakeholder groups are included in Swissmedic's national network:

- » Patients/consumers and their associations/organisations
- » Specialists from the health industry
- » The therapeutic products industry and its associations/organisations
- » Service providers from the therapeutic products industry
- » Cantonal and Federal authorities and Parliament.

Activities

- Contacts and exchanges with the individual stakeholder groups were maintained over the course of the year at 25 round tables. A number of round tables were held on regulatory issues with representatives from therapeutic products industry associations, plus one round table on strategic exchanges with representatives from patient and consumer organisations.
- In June 2011, Swissmedic held an information event entitled "Swissmedic, the Swiss Agency for Therapeutic Products, introduces itself". The event was aimed at representatives from patient and consumer organisations, their members and specialists from the health industry.

- Swissmedic invited Jacques de Haller, the President of the Swiss Medical Association (FMH), to a discussion group with Swissmedic specialists.
- On 25 October 2011, Swissmedic, Swiss pharmacists and the pharmaceutical industry again took part in the national campaign to fight pharmaceutical crime under the umbrella of "Stop Piracy".



PARTICIPATION BY SWISSMEDIC IN EXTERNAL FURTHER TRAINING INITIATIVES

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

Activities

- Once again in 2011, Swissmedic supported MEGRA StartUp Schweiz by providing specialist speakers in all its modules.
- A total of 7 Swissmedic experts lectured at the Medicinal and Industrial Pharmaceutical Sciences (MIPS) Master's Course 2011 at the Swiss Federal Institute of Technology Zurich.
- A successful seminar with the University of Neuchâtel on the subject of the legislation of therapeutic products was organised and held for the first time.

INTERNATIONAL COLLABORATION

Collaborations with authorisation and surveillance authorities, and with international organisations in the field of medicinal products and medical devices, are of extreme importance for stakeholders, for Switzerland and for Swissmedic.

Exchanging information is tremendously important in the entire process of the authorisation of medicinal products, the market surveillance, and in the process of preparing new legislation on every aspect of therapeutic products. Thus, for instance, it facilitates the collaboration with authorities in other countries and with international institutions in order to identify risks associated with therapeutic products in plenty of time and to introduce co-ordinated measures.

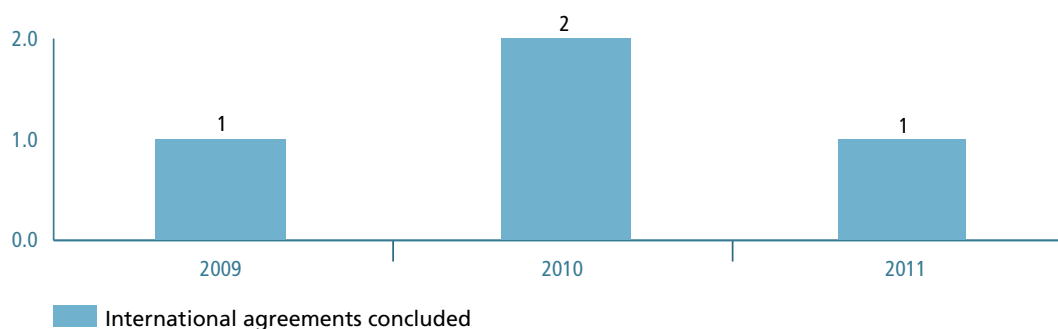
International network

In recent years, Swissmedic has consistently carried on its strategy for networking with partner organisations, and now has agreements for exchanging information with almost all the internationally recognised therapeutic products authorities of a similar standard. They include the authorities in the USA, Canada, Australia, Singapore, New Zealand and Japan. Utilising and further intensifying current collaborations and approaching further collaborations with clear objectives are important strategic goals.

Activities

- Bilateral and multilateral exchanges within the framework of existing agreements have continued, especially with the partners of the Australia, Canada and Singapore Consortium.
- At the DIA EuroMeeting in Geneva, which took place from 28–30 March 2011, Swissmedic and the WHO carried out a satellite session on the collaboration between the two institutions.

- At the Heads of Medicines Agencies (HoA) summit in Sydney, Australia, Swissmedic was represented by its director with an active contribution.
- On 27 October 2011, an agreement was signed between Swissmedic and the Irish authority (IMB) for the exchange of information in the therapeutic products sector. This is the first bilateral co-operation agreement between Swissmedic and a national EU authority.
- Swissmedic has corresponded with EMA, the European Medicines Agency, on the exchange of information on the pandemic H1N1.



SPECIAL ACTIVITIES AND EVENTS IN THE STAKEHOLDER MANAGEMENT

Successful Swissmedic stand at the DIA

Another first for Swissmedic, which also had a stand at this event. The aim of its presence was to increase its familiarity and to present the authority as the Swiss Agency for Therapeutic Products. More than 550 contacts were made at the stand in the form of talks with conference participants.

Signature of the Medicrime Convention on the counterfeiting of medical products

On 28 October 2011, Switzerland signed the European Council's "Medicrime" convention at an international conference on pharmaceutical crime in Moscow. The decision to do so was made by the Federal Council in June 2011 with the aim of fighting counterfeit therapeutic products and similar crimes more decisively. Switzerland was one of the first countries to sign the agreement.

TELEMATICS / IT

IT MANAGEMENT

IT management deals with the strategic and operational planning and provision of IT and telecommunications resources. Important instruments in this are IT strategy, IT architecture and the project, process, product and service portfolios. IT management is responsible for the economic and legal procurement, sustainable development, and stable and safe availability of IT resources and services.

Activities

- The IT strategy, which dates back to 2007, was revised. It was adapted to the current version of Swissmedic's strategic plan. IT planning, various IT processes and the organisational structure of the Information Technology Division were also adapted.
- Significant IT investments are planned for the coming years in association with the implementation of the IT roadmap (rolling 5-year-plan for IT projects). The necessary procurements can now be processed more efficiently.
- The framework agreement with the Federal Office of Information Technology, Systems and Telecommunication (FOITT) has been renegotiated and signed.

SOLUTION DEVELOPMENT

The implementation of the IT roadmap is extremely important to Swissmedic in the realisation of its strategic goals. The first step is to modernise old IT solutions and obtain replacements. After that, additional functions will be developed on this basis from 2013 to support the process. The focus is on "eGovernment", expansion of business traffic with Swissmedic via the Internet.

Activities

- 2011 was extremely successful for IT projects. The following systems were provided as planned:
 - Planning tool marketing authorisation
 - ERP (financial accounting, controlling, debtors/creditors, procurement, project management); commencement of operations in January 2012
 - Operating module of the medical register (MedReg)
 - Laboratory IT system (LIMS)
 - Internet application for importing/exporting narcotics (NDS WEB); commencement of operations from Q1/2012
 - Windows 7 Upgrade
- The PRIME project is to be the backbone of Swissmedic's business processes. Old applications will be replaced in this project by a sustainable SAP-based platform. The concept stage was expedited successfully in 2011, as scheduled. One important finding is that, because of its size and complexity, the renewal of the specialist database will form a bottleneck in the schedule for realisation in 2012. This system will be launched in 2013.

IT OPERATIONS, UTILISATION, MAINTENANCE AND CONTINUOUS IMPROVEMENT

Using IT solutions requires trained, knowledgeable users, the availability of safe, maintained infrastructures; continuous development of efficiency potentials, and quick and easy access to supporting services. Providing and managing these services is an important task that will be the responsibility of service and application management. The operating and support services for the entire Swissmedic system infrastructure and office automation solutions will be obtained from the FOITT. Additional service and software providers will be involved for the maintenance and further development of IT resources.

Activities

- An interface has been added to EUDAMED, the European database for the electronic transfer of information on medical devices.
- The application for the registration of homeopathic and anthroposophic medicinal products has been migrated.
- The workplace system has been renewed, and the operating system and office automation applications (Windows 7 and Microsoft Office 2007) updated.
- The project "Internet-based telephony" (voice-over IP) has gone to a pilot study.
- The commissioning of the SAP ERP-based processing of the IT procurement processes for all external performances has been prepared.
- Stable system availability with no particular failures is assured across the entire IT portfolio.

SPECIAL ACTIVITIES AND EVENTS IN TELEMATICS / IT

New alignment of the FOITT (Federal Office of Information Technology, Systems and Telecommunication)

The FOITT faces a new alignment with the Ordinance on Information Technology (BInfV), which was revised at the end of 2011, and the newly implemented management. Swissmedic's IT Division will analyse the effects on its IT administration with this important outsourcing partner in 2012, and make any necessary corrections in the performance with the FOITT.

ORGANISATION

SWISSMEDIC AGENCY COUNCIL

status December 2011

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.

HUMAN MEDICINES EXPERT COMMITTEE (HMEC): MEMBERS

status December 2011

President: 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

von Ammon Klaus, Dr. med.

Bauer Matthias, PD Dr. med.

Brunner-Ferber Françoise, Dr. sc. nat.

Brutsche Martin Hugo, Prof. Dr. med.

Caldelari Reto, Dr. sc. nat.

Cerny Thomas, Prof. Dr. med.

Cotting Jacques Ernest, Dr. med.

Eberli Franz Robert, Prof. Dr. med.

Egger Matthias, Prof. Dr. med.

Follath Ferenc, Prof. Dr. med.

De Geyter Christian, Prof. Dr. med.

Genton Blaise, Prof. Dr. med.

Giannopoulou-Politakis Catherine, PD Dr. med.

Heusser Peter, Prof. Dr. med.

Hüsler Jürg, Prof. Dr. phil. nat.

Itin Peter Hans, Prof. Dr. med.

Kraenzlin Marius Edgar, ww.

Lauterburg Bernhard, Prof. Dr. med.

Leniger Tobias, PD Dr. med.

Marbet German Albert, Prof. Dr. med.

Marti Eva, Dr. sc. nat.

Meier Christoph Andreas, Prof. Dr. med.

Meier Christoph Rudolf, Prof. Dr. pharm.

Meier Rémy Friedrich, Prof. Dr. med.

Messerli Jürg, Dr. med.

Munier Francis Louis Paul, Prof. Dr. med.

Nägeli Hanspeter, Prof. Dr. med. vet.

Pfeifer Dina, Dr. med.

Schädelin Jürg, Dr. med.

Schatzmann Herbert, Dr. sc. nat.

Schmid-Grendelmeier Peter, PD Dr. med.

Seger Reinhard A., Prof. Dr. med.

Strik Werner Konrad, Prof. Dr. med.

Thalmann George N., Prof. Dr. med.

Tramèr Martin Richard, Prof. Dr. med.

Weber Klaus, Dr. rer. nat.

Zangemeister Uwe, Prof. Dr. phil.

VETERINARY MEDICINES EXPERT COMMITTEE (VMEC): MEMBERS

status December 2011

President: 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

Hertzberg Hubertus, PD Dr. med. vet.

Hoop Richard, Prof. Dr. med. vet.

Nägeli Hanspeter, Prof. Dr. med. vet.

Ruoff Kaspar, Dr. sc. nat.

Schmidt Andreas, Dr. med. vet.

Wenker Christian, Dr. med. vet.

Spadavecchia Claudia, Prof. Dr. med. vet.

Wahli Thomas, PD Dr. phil. nat.

AUDITOR

Swiss Federal Audit Office

OUR STAFF – OUR CAPITAL

status December 2011

EXECUTIVE DIRECTOR: Schnetzer Jürg H.**MANAGEMENT BOARD:**

Balsiger Betts Andreas, Dörr Petra, Kopp Urs (until 31.12.2011), Jenny Hans-Beat, Mathys Badertscher Karoline, Schütz Baumgartner Barbara, Tschannen Adrian.

OUR STAFF

Abegglen Julia, Ackermann Thomas, Aeschbacher Monique, Ammann Doris, Antonov Janine, Appenzeller Katrin, Bachmann Beat, Ballif Michel, Bapst Astrid, Barandun Pia Dolores, Barbu Mirela, Bärtsch Martin, Baumann Yvonne, Begert Beat, Behncke Annik, Bellac Caroline Laetitia, Bellwald Patricia, Berdoz José, Berger Christoph, Bernhard Sarah-Anne, Bertholet Josiane, Bigler Weber Cornelia, Bill Helena, Bitschnau Monika, Blanco Philippe, Blaser Béatrice, Blaser Simon, Blum Doris, Blum Markus, Bögli-Schlüchter Franziska, Bögli-Stuber Katja, Böhlen-Walther Caroline, Bolli Richard, Bomhard Michael, Borner Stefan, Boss Doris, Boyle Charles, Bracher Max, Brockmann Silke, Brönnimann Rainer, Brunner Stefan, Bucheli Caroline, Büchi Jacqueline, Büchler Monika, Buchs Renato, Buchter Linda, Bühler Urs, Bunn Ulrike Ursula, Burgener Martin, Burgener Roger, Burkhalter Gabriele, Burkhalter Stefan, Burri Anton, Burri Bieri Michael, Caduff Pia, Carrel Nadja, Carulli Amico Sabina, Castella Marc-Etienne, Cavaliero Tania Cecilia, Cavegn Regina, Chételat Jean-Marie, Christen Tobias, Cina Susanne, Cokoja Adisa, Colangelo Elena, Cramer Mirjam, Crottet Pascal François, Czank Andreas, Dalla Torre Simon, Damke Beat, Dasen Petra, Déverin Olivier, Di Medio Steinmann Sandra, Diethelm Markus, Ditesheim Véronique, Djonova Julia, Drechsel-Weiss Bettina, Dürr-Kammer Eva, Eggenschwyler Doris, Egger Franziska, Egli Arnold, Ehrensperger Edmund, Ehrensperger Murri Eva, Eisenhauer Martin, Endress Eva-Maria, Engel Marie-Helene, Erne Franz, Escandari Markus, Eyal Eva, Fahrni Ursula, Faller Claudine, Fasel-Rossier Brigitte, Federer-Oetliker Martina, Felber Hanspeter, Feldmann Danila, Ferbitz-Scheurer Simone, Filgueira David, Fischer Lisa, Flechtner Olivier, Fleischmann Isabelle, Fohouo Lyse, Francini Nicola, Frei Claudia, Friedli Franziska, Frisch Jürgen, Frost Heiner, Fuhrer Therese, Gamma-Lauber Madeleine, Gassmann Peter, Gassner Beat, Gautschi Matthias, Gehrig Patrick, Geiser Hansruedi, Gertsch Rolf, Gilgen Michael, Girard Philippe, Glauser Daniel, Gnägi Brigitte, Gnehm Rolf, Gosdschan Tobias, Gottofrey James, Graber Fabrice, Grimm Friederike, Gross Bruno, Grubenmann Bruno, Grüter Eric, Guggisberg Stefan, Gugler Claudia, Gukic Ljubica, Gürtler Rolf, Gut Joseph, Gygax Dominik, Gysin René, Häberli Adrian, Häberli-Aioldi Isabelle, Haberstick Eva, Hahn Spielmann Véronique, Haldemann Silvia, Haldimann Heidi, Hammel Mario, Häni Brigitte, Häuptli Daniel, Heckenmeyer-Probst Clara, Hediger Ronald, Hege-Völkens Dorothea, Hein Bader Silvia, Heneka Bilkis, Henkel Verena, Herren Daniel, Herrli Stefan, Hildebrand Pius, Hitz Penitzka Cornelia, Hofmann Jennifer, Hofmann Linda, Holdener Rudolf, Horn-Lohrens Ottmar, Hottiger Thomas, Huber Adrian, Huber Cornelia, Huber Elisabeth, Hügli Muriel, Hug-Michel Christine, Hürlimann Maria, Iten Silvia, Jahn Katrin, Jaquet Françoise, Järmann Stephan, Jaus Alexandra, Jaus-Trentin Ursula, Jentsch Christoph, Jéquier Martine, Jetzer Urs, Jobaro Beatrice, Joos Monika, Jungo Jacqueline, Junker Christian, Jurt Kuster Céline, Jutzi Markus Philipp, Kammerlander Raoul, Kapossy Katrin, Käser Sandra, Käsermann Donald, Keller Michel, Kemmler Hans, Keusen-Weyermann Katrin, Kienberger Susanne, Kindler Adrian, Kläy Barbara, Klenke Elisabeth, Klensch Odette, Kocher-Guggisberg Beatrice, Koeninger Franziska, Köfüncü Evra, Kohler Scarlett, Köhli Weber Sandra, Kolb Franziska, Korschelt Lorenz, Kreit Boris, Kühni Martin, Kulik-Essen Renate, Kumli Martin, Kunz-Greub Marianne, Künzle Werner, Kuster-Weber Iris, Kwan Hiu Ying, Lachat Séverine, Landgraf Cordula, Langos-Mabboux Manuela, Lauer Gabriele, Ledermann-Fahrni Barbara, Lehmann Markus, Lehmann Thomas, Leu Martin, Leuenberger Alice, Leuenberger Bibiana, Leuenberger Hansjürg, Leuenberger-Bischoff Monika, Leuzinger Andrea, Levy Guy, Linder Ursula, Liniger-Thommen Andrea, Lippmann Hans-Georg, Lory Simon, Lucas Christine, Luginbühl-Weber Karin, Lüthi Daniel, Lüthi-Wyss Nicole, Lütolf Natalie, Maier Ralph, Mak Tippi, Manigley Catherine, Manolio Silvana, Marrer Edith, Marti Andreas, Matthes Ingo, Maurer Ruth, Meier Roger, Méroz Jean-Christophe, Meseguer Georges, Messari Annemarie, Messerli Nicole, Meyer Andrea, Meyer Rita, Meyer Simon, Meyer Urs, Mooser Guido, Moser Pia, Mosimann Lenzin Ruth, Müller Markus-Peter, Müller-Mook Renate, Munz Thomas, Mutti Sven, Nabholz Thomas, Nava Gabriela, Neeser Zaugg Rosmarie, Nick André, Nick Sonja, Niggli Urs, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Op den Camp Roeland, Oswald Walter, Paniga Nicoletta, Pavelic Ferretti Danijela, Perret Irene, Peter Nicole, Petitpierre Claude-Philippe, Pfäffli Chantal, Pfäffli

Elizabeth, Plüss Ruth, Plüss-Gross Fabienne, Polatti Daniela, Porporini Lucio, Putzke Jörg, Ramelli Monica, Ramseier Isabelle, Rätz Katerina, Renaudin Michael, Renftle Wolfgang, Rethage Janine, Reusser Daniel, Richter Thomas, Rieder Barbara, Riedl Jutta, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Roux Catherine, Ruch Claudia, Rüeegsegger Ruth, Rüesch-Kirkwood Morven, Rüfenacht Francine, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sängler Michael, Saurer Isabella, Schaffner Nils, Schärer Christian, Scheidegger Anita, Scheidegger Michelle, Scheidegger René, Scherz Bernhard, Schläfli Ernst, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Egger Dorit, Schmitt Klaus, Schnyder Benno, Schnyder Franz-Lukas, Schnyder Renato, Schöni Damian, Schönthal Cornelia, Schumacher Thérèse, Schütz Frikart Andrea, Schwab-Stampfli Rebekka, Scognamiglio-Weber Patricia, Scuntaro Zurlinden Isabel, Senessie Charles, Sift Carter Rosemarie, Sigel Ursula, Sivapatham Prashanthni, Spicher Andrea, Spohn Margot, Spörri Bernhard, Stacchetti Matthias, Stadelmann Pia, Staempfli-Zahnd Barbara, Stalder Anna Barbara, Stalder Barbara, Stämpfli Ursula, Stäuble Elisabeth, Stauffer-Lehmann Mirjam, Stebler-Frauchiger Rosa, Stefanovic Dragan, Steinhuber Franz Peter, Stettler-Michel Marianne, Stoller Denise, Stoller Rudolf, Stötter Hans-Wolfgang, Strack Guido, Straub Andrea Katharina, Stucki Gnehm Flurina, Studer Peter, Sulser Margrit, Tanner Yvonne, Tanner Soland Eveline, Terkovic Attila Leo, Teuscher Françoise, Thiess Maria, Thomas Sabine, Thürig Soltermann Eva, Torriani Wymann Kay Isabella, Trapp Christiane, Tschalär Yolanda, Tschirren Markus, Tschümperlin Heidi, Urich Karin, von Mühlener Eva, Vozeh Beatrix, Vuilleumier Monika, Wacker Christoph, Wagner Jan, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Wälti Rudolf, Weber Heidi, Wegmann Barbara, Weiss Markus, Weissmahr Richard, Weitz Manfred, Wever Sabine, Weyermann Philipp, Whitehead Frances, Whitehead Margaret, Widmann Margit, Widmer Nina, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wüest Patrick, Wüthrich Karin, Wüthrich Tamara, Wyss Brigitte, Wyss Martin, Wyss Sonja, Wyss-Romanello Sabine, Zaugg Kunz Sandra, Zbinden Kaessner Eva, Zehäusern Gabriela, Ziak Martin, Ziehli Salvisberg Mariette, Zimmermann Esther, Zurbuchen Andreas, Zurkinden Tanja, Zwahlen Roland, Zwahlen Susanne.

INCOME STATEMENT 2011

(in KCHF)	2011	2010
Procedural fees and income further to art. 69 TPA	24,346	24,493
Levies on sales	39,789	39,486
Other income	58	82
Federal contribution	15,624	15,943
Other operating income	180	175
Total income	79,997	80,179
Services for third parties	-1,668	-2,000
Personnel	-59,195	-52,968
Rental, maintenance, energy, transport and insurance	-3,153	-3,130
Administration	-4,798	-5,029
IT	-8,692	-8,947
Other expenditure	-294	-297
Amortisation	-2,431	-2,275
Total operating expenditure	-80,231	-74,646
Operating income before financial result	-234	5,533
Financial income	49	34
Financial expenditure	-245	-237
OPERATING INCOME	-430	5,330

PRODUCT ACCOUNTING 2011

(in KCHF)

Products Products groups	Principal funding of products based on 2011-2014 SM	Expenditure	Procedural fees income	Results
Legal foundations	Federal contributions	-5,959	4	-5,955
Technical standards	Fees	-2,352	0	-2,352
Total Standards products group		-8,311	4	-8,307
Information for the general public	Federal contributions	-4,374	2	-4,372
Information for the therapeutic products branch	Fees	-1,802	274	-1,528
Total Information products group		-6,176	276	-5,900
Marketing authorisation	Fees	-32,394	14,059	-18,335
Licences	Fees	-14,226	7,792	-6,434
Total Market Access products group		-46,620	21,851	-24,769
Vigilance of medicinal products	Fees	-6,130	0	-6,130
Vigilance of medical devices	Federal contributions	-2,321	0	-2,321
Market monitoring of medicinal products	Fees	-6,498	1,561	-4,937
Market monitoring of medical devices	Federal contributions	-1,219	0	-1,219
Total Market Surveillance products group		-16,168	1,561	-14,607
Penal law	Federal contributions	-2,013	43	-1,970
Total Penal Law products group		-2,013	43	-1,970
Services for third parties	Fees	-941	611	-330
Total Products*		-80,229	24,346	-55,883
Levies on sales				39,789
Federal contributions				15,624
Other income				239
Financial result				-199
Operating income				-430

* The difference in expenditure (total products) on the income statement is a result of the closure in accordance with the IFRS. In the income statement, the bank charges (in accordance with the IFRS) are booked under "other expenditure". In the product accounting statement, they are attributed to the financial result.

PRODUCTS FUNDED MAINLY BY THE CONFEDERATION 2011

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result based product accounting
Legal foundations	-5,959	4	-5,955
Information for the general public	-4,374	2	-4,372
Vigilance of medical devices	-2,321	0	-2,321
Market monitoring of medicinal products	-1,219	0	-1,219
Penal law	-2,013	43	-1,970
Total products funded mainly by the Confederation	-15,886	48	-15,837
Total Federal contributions			15,624
Expenditure surplus			-213

During the performance period 2011 – 2014, the number of products funded mainly by the Confederation is reduced by 2 (Market monitoring of medicinal products, and Technical Standards) to 5 products (previously 7).

BALANCE SHEET 2011

(in KCHF)	Balance sheet at 31.12.2011	Balance sheet at 31.12.2011
Cash and cash equivalents	2,416	4,370
Receivables from sales and services	16,967	15,859
Other receivables	28	5
Active accruals	58	33
Current assets	19,469	20,267
Fixed assets	2,963	2,653
Immovable property	55,645	54,277
Intangible assets	3,616	556
Capital assets	62,224	57,486
TOTAL ASSETS	81,693	77,753
Commitments on sales and services	6,194	4,371
Other commitments	553	395
Passive accruals and short-term provisions	3,750	3,388
Short-term commitments	10,497	8,154
Firm advances	10,000	10,000
Provisions for loyalty bonuses	2,122	1,939
Provision for pension fund commitments (net)	18,904	17,060
Long-term commitments	31,026	28,999
Endowment capital	14,500	14,500
Reserves	26,100	20,770
Operating income	-430	5,330
Own capital	40,170	40,600
TOTAL LIABILITIES	81,693	77,753

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