



ANNUAL REPORT 2012


swissmedic

CONTENTS

Foreword by Christine Beerli	6
Foreword by Jürg H. Schnetzer	8
Activities during the year	10
Developments in the Authorisation sector in 2012	12
Swissmedic is 10 years old	16
Outlook for 2013	20
Facts and figures	22

 Reports

MARKET ACCESS // MARKETING AUTHORISATIONS

Authorisation overview	24
------------------------	----

AUTHORISATION OF HUMAN MEDICINAL PRODUCTS

First marketing authorisations	26
Human medicinal products with a new active pharmaceutical ingredient	26
Human Medicines Expert Committee	28
Extensions and discontinuations	28
Variations requiring approval and variations requiring notification	29
The fast-track authorisation procedure	29

SPECIAL CATEGORIES OF HUMAN MEDICINAL PRODUCTS

Orphan Drugs	30
Paediatric medicinal products	31
New processes	31
Transplant products	31
Herbal medicinal products	32
Complementary medicinal products	32
Asian medicinal products	33

AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS

Authorisation	33
Veterinary medicinal products with a new active pharmaceutical ingredient	34
Veterinary Medicines Expert Committee	34
Extensions and discontinuations	34
Variations requiring approval and variations requiring notification	35
Minor Use – Minor Species	35
Appeals procedure with regard to the authorisation of medicinal products	35
Table of performance indicators for human and veterinary medicinal products	37

MARKET ACCESS // LICENSING**LICENSING OF MEDICINAL AND TRANSPLANT PRODUCTS**

Establishment licences for medicinal products	38
Special licences	38
Certificates	39
Control of the flow of narcotics	39
Clinical trials	40

INSPECTIONS

GMP and GDP inspections	41
GCP inspections	42
GLP inspections	42
Inspections for third parties	43
inspections by foreign authorities in Switzerland	43
Monitoring of the blood transfusion service	44
Official Medicines Control Laboratory	44
Appeals against decisions in connection with licences	45

MARKET SURVEILLANCE**MARKET SURVEILLANCE OF MEDICINAL PRODUCTS**

Vigilance of medicinal products	46
Pharmacovigilance	46
Haemovigilance	47
Vigilance of veterinary medicinal products	48
Risk management	48
Risk mitigation measures	50
Market monitoring of medicines	50
Measures against illegal medicinal products	51
Control of advertising	52
Appeals	53

MARKET SURVEILLANCE OF MEDICINAL DEVICES

Integration within the European system	55
Placing on the market	55
Clinical investigations of medical devices	56
Vigilance of medical devices	57
Market monitoring of medical devices	58
Appeals	58

STANDARDS**LEGAL MATTERS**

Legislation	59
Pharmacopoeia	60

TECHNICAL STANDARDS

Technical standards for medical devices	61
---	----

PENAL LAW

General development	62
Investigative measures	63
Decisions / Judgements	64

STAKEHOLDER MANAGEMENT

INFORMATION

General enquiries	65
Press relations	66
Publications	66
Events	67
Lectures	67
Transparency	68

COLLABORATION

National collaboration	68
Participation by Swissmedic in external further training initiatives	69
International collaboration	69

TELEMATICS / INFORMATION TECHNOLOGY

IT management	71
Solution development	71
IT operations, use, maintenance and ongoing improvements	72

ORGANISATION

Swissmedic Agency Council	73
Members of the Swissmedic Human Medicines Expert Committee	73
Members of the Swissmedic Veterinary Medicines Expert Committee	73
Auditor	73
Our staff	74

Facts

Income statement	76
Product accounting	77
Products funded mainly by the Confederation	78
Balance sheet	79
Imprint	81

“THE PROBLEM CHILD BECOMES TOP OF THE CLASS: SWISSMEDIC IS A CONSTANTLY LEARNING ORGANISATION”

Swissmedic celebrated its ten years of existence 2012 and marked it by holding a symposium in Interlaken. The event provided us with the opportunity to carry out a situational analysis and an in-depth exchange with our stakeholders and partners from Switzerland and abroad. I will come back to this later.

ENTRY INTO FORCE OF THE REVISED ORDINANCE ON FEES FOR THERAPEUTIC PRODUCTS

After an intensive exchange with all the interested circles, which we have been taking into consideration from the outset, it was possible to complete work on the revised Ordinance on Fees in 2012. Following its publication in the Official Compilation of Federal legislation, the Ordinance entered into force on 1 January 2013. Despite the fact that the procedure had been announced, some firms contested the lack of transitional provisions for pending applications. By closely monitoring the number of applications that would have fallen under the new Ordinance on Fees if there had been a delay on the part of the Agency, however, Swissmedic was able to keep these to an absolute minimum.

It was possible to complete the preparatory work regarding the procedure with prior notification, foreseen in the new Ordinance, according to plan. As of 1 January 2013, the prior notification of applications is possible. Such applications are processed in 20% less time, but with a fee supplement of 100%.

REVISION OF THE THERAPEUTIC PRODUCTS ACT

The Therapeutic Products Act, which constitutes the legal basis for Swissmedic's work, is currently under revision. This work is led by the Federal Office of Public Health. In 2012, Swissmedic provided know-how and considerable input for the project. The draft adopted by the Federal Council on 7 November 2012 will be the subject of parliamentary consultation in 2013. Swissmedic will of course follow the consultation with great interest.

HEADCOUNT INCREASED BY 25 FULL-TIME POSTS

In December 2011, and after an in-depth examination of the efficiency of the processes and of the deployment of resources, the Agency Council decided on a final increase to the head count of 25 full-time posts. It was possible to fill all these posts in 2012. Twelve of the new members of staff were hired for the Authorisation sector. Between 2009 and 2012, the Agency Council has authorised 75 additional full-time posts, bringing Swissmedic's headcount to 360 posts. This measure is accompanied by the clear expectation that by the end of 2014, all applications will be processed and the relevant decisions taken within the time limits.

NEW HEAD OF THE AUTHORISATION SECTOR

On 1 May 2012, Dr Esa Heinonen took up the position of Head of the Authorisation sector at Swissmedic. Dr Heinonen has long-standing experience in the area of research and development for medicinal products, and prior to his recruitment by Swissmedic worked as head of Authorisations for the Finnish authorities (FIMEA).



The Agency Council: leading Swissmedic to success through strategic objectives.

The Agency Council welcomes the appointment of a medical expert with experience in industry and with the authorities, and is convinced that Dr Heinonen will tackle the complex challenges with great success.

INFRASTRUCTURE PROJECTS ON TRACK

The planned building work on the laboratories and offices on Freiburgstrasse 139 in Bern Ausserholligen is currently advancing well in terms of schedule, costs and construction work. These premises will house both laboratories plus all the employees in the Licensing division.

The strategic projects within the IT road map are also on track. The implementation of this initiative required considerable effort, but proved that Swissmedic is also capable of successfully executing complex infrastructure projects.

TRANSPARENCY WITH REGARD TO CONFLICTS OF INTEREST

Since January 2012, Swissmedic has been publishing both the Codex for the expert groups and the provisions regarding conflicts of interest for external experts in the Medicines Expert Committees on its website. This guarantees the greatest possible transparency, and particularly since the experts only provide recommendations: decisions are always taken by Swissmedic staff.

ANNIVERSARY WITH A FOCUS ON INTERNATIONAL RELATIONS

As already indicated earlier in this foreword, Swissmedic did not celebrate its ten years of existence in the form of festivities, but by organising an International Regulatory Symposium in Interlaken on 20 and 21 September 2012. Nearly 350 participants from Switzerland and abroad followed the presentations and podium discussions. The event, which included renowned speakers from partner authorities throughout the world, was a clear sign of Swissmedic's solid international networking and also improved the Agency's image within Switzerland. Federal Councillor Alain Berset, who opened the Symposium, spoke of Swissmedic as a "problem child" that had developed to become the "top of the class", and one that aimed at positive further development on a solid basis.

I am personally convinced – and also conveyed this message to participants at the Seminar – that standing still means moving backwards. My wish for the next ten years is therefore for Swissmedic to remain a learning organisation or – for areas where it has not yet achieved this – for it to become one.

Christine Beerli
Chairwoman of the Agency Council

IN THE THERAPEUTIC PRODUCTS SECTOR, THE DYNAMICS OF RESEARCH AND DEVELOPMENT AND THOSE OF THE MARKET GIVE RISE TO REMARKABLE INNOVATIONS WITH REGARD TO PRODUCTS AND PROCESSES: PRODUCTS ARE MODIFIED, INDICATIONS ARE ADDED, ALTERNATIVE PRODUCTS OR GENERICS ARE DEVELOPED, AND PRODUCT RANGES ARE EXTENDED. COMPANY PROFILES CHANGE, NEW TECHNOLOGIES EMERGE, IN- AND OUT-LICENSING TAKES PLACE, SITES AND SUPPLIERS CHANGE, AND SPINOFFS AND MERGERS ARE CONCLUDED – AND ALL OF THESE ARE PHENOMENA IN THE SECTOR WE SUPERVISE AND THAT CONCERN US.



Ten years after the Swiss Agency for Therapeutic Products was founded, Swissmedic provided service for 1,079 firms and 8,502 authorised medicinal products in 2012. This does not include medical devices and in-vitro diagnostics, since a different system exists for these, via bilateral agreements, and that attributes a clear role to the Agency in an environment characterised by the pace of innovation and a wide variety of products.

ENCOURAGING RESULTS FROM THE CUSTOMER SURVEY

During the first half of the year, around 3,000 individuals were invited to answer questions within the framework of a cus-

tomers survey on Swissmedic. The response rate of 32% was good, and the overall satisfaction with the Agency's work – at 66 out of a maximum of 100 points – is encouraging for a regulatory health authority. Improvements were proposed and are being addressed.

SPEEDING UP THE PROCEDURES

In order to get to grips with its workload, Swissmedic needs to deploy its resources intelligently, work efficiently, and to use IT in order to help shoulder the burden in a targeted way. The constructive exchange with industry has made it possible to clarify the necessity for an increase in fees: a move that aims to make safe, high quality and effective therapeutic products available rapidly to patients and to experts. Capacity building and ensuring its financing are aspects that permit Swissmedic to accelerate processes within its daily work, and to master ever more complex tasks. Binding milestones and time limits permit applicants to stay on their schedule and to co-ordinate follow-up questions from the Agency internally. On Swissmedic's side, it is possible to plan peer reviews and expert input in advance, and to attribute questions to the competent scientific employees. With high-quality, complete applications and binding planning schedules, it is easier to complete processing within time limits.

“THE CUSTOMER SATISFACTION SURVEY CARRIED OUT IN 2012 IS ENCOURAGING AND STIMULATING”

TARGETED IT SOLUTIONS

The implementation of the IT road map is currently on track in terms of timing and financing. These internal developments – together with optimising planning and governance – also serve to enhance transparency and to respond to the needs of the industry: SAP-ERP (Enterprise Resource Planning) has been rolled out, the specialised database is being migrated to a new platform, the web-based application for the licensing of narcotics is up and running, and the case management system for the Authorisation and Licensing sectors is being established. In addition, and as a follow-up to a judgement by the Federal Administrative Court in June 2011, the Agency has initiated a project to guarantee the complete publication of medicinal product information. The AIPS solution now makes information for healthcare professionals and patient information freely accessible for consultation via a search platform, and is free of charge. Firms can thus comply with the mandatory requirements to make the officially approved texts available to those entitled to do so: they upload their texts to AIPS and release them for electronic publication. Within the framework of a further project, the technical basis has been created that will in future permit the exchange of reports on adverse drug reactions between Swissmedic and market operators.

WEIGHING UP BENEFITS AND RESIDUAL RISKS

Regular exchange with patient and consumer organisations permits us to align the business interests of industry with the expectations of these bodies. Side effects are also linked to the effects of medicinal products – a fact that has long been known

but awareness of it is only rekindled as a result of dramatic events. To show residual risks in scientific or statistical terms is one thing, but to present them to either experts or – in the case of over-the-counter products – to patients, in a comprehensible way that ensures conscious risk management, is another, and is a far from trivial matter. Interest, and particularly in the case of innovative medicinal products or new indications, is often focused on benefit, and the health authority must stress the need to take the risks into account. Here, discussion with representatives of patients and consumer associations is particularly important and valuable: both innovation and enhanced awareness of residual risks constitute benefits for patients.

ENHANCED SAFETY

The risk of confusion related to medication in connection with naming and packaging elements is a known risk worldwide. By revising the corresponding Ordinances, Swissmedic's internationally supported practice is now anchored in legislation, in the interests of experts and patients alike.

The need for a structural improvement of food control on a Federal and Cantonal level has been recognised, and the corresponding measures have been taken. Swissmedic is actively involved in this issue with the Federal Office of Public Health (FOPH) and the Federal Veterinary Office (FVO). The Veterinary Medicinal Products Ordinance will be adapted in order to simplify the responsibilities of Swissmedic and the FVO with regard to the enforcement of controls and measures throughout the production chain for foods of animal origin.

INTENSIVE INTERNATIONAL COLLABORATION

Building up and intensifying international collaboration continued in 2012. It was possible to conclude agreements with the Paul Ehrlich-Institut in Germany, and the Brazilian Health Authorities (ANVISA). In addition, Switzerland became the first country to be placed by the European Union (EU) on the list of third countries that are exempted from the new, additional requirements relating to the import of active pharmaceutical ingredients and medicinal products. Since October 2012, the Mexican authority has unilaterally recognised authorisations that Swissmedic has granted for innovative medicinal products. This is also a mark of the quality and reputation of the Swiss Agency for Therapeutic Products.

Jürg H. Schnetzer
Director Executive, Swissmedic



ACTIVITIES DURING THE YEAR

A STUDY CONFIRMS SWISSMEDIC'S INTERNATIONAL COMPETITIVENESS

The speed and care with which an authority carries out an authorisation procedure is crucial for the industry and patients alike. In this respect, Swissmedic is measured above all against the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). The first results from a study, commissioned by the Agency Council and carried out by the Centre for Innovation in Regulatory Science (CIRS) in London, confirms Swissmedic's worldwide competitiveness among regulatory health authorities. Although the customary procedures for new medicinal products take somewhat longer at Swissmedic, its so-called "fast-track" procedure is competitive. The fast-track procedure is used to assess authorisations for new active pharmaceutical ingredients to treat life-threatening diseases for which no effective treatment possibilities are yet available.

NEW PHARMACOPOEA HELVETICA 11 ONLINE

The revised version of the Pharmacopoea Helvetica entered into force on 1 July 2012, and is now also available online. The Swiss pharmacopoeia defines the requirements regarding the quality of medicinal products, pharmaceutical excipients and some medical devices. In addition to a newly structured general section, the pharmacopoeia now includes all the schematic illustrations of thin-layer chromatography, presented in a uniform way. In addition, the general section also includes a translation table of all monograph titles from the European pharmacopoeia (Ph. Eur.) in German, Latin, French, Italian and English.

www.phhelv.ch

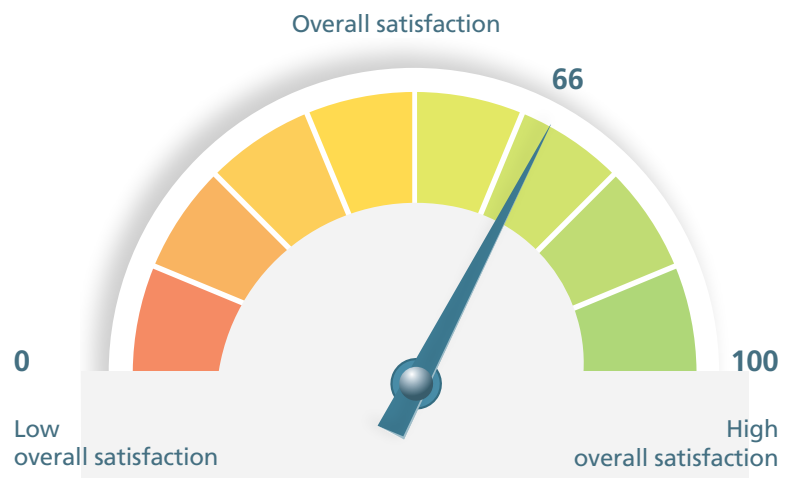




CUSTOMER SATISFACTION IS GOOD

The 2012 customer survey among Swissmedic's stakeholders demonstrated that overall satisfaction is good. It was rated at 66 points out of 100.

The therapeutic products industry and the Federal authorities were satisfied with Swissmedic, whereas the level of satisfaction was somewhat lower among the associations and organisations. There is a need for action in areas that were assessed critically and that were considered to have a major influence. According to this, the topics that have the highest influence on customer satisfaction were Swissmedic's service quality (69), complaints / problem handling (60), communication (67), issues management (66) and organisation. Swissmedic will analyse these topics and define the corresponding measures.



ASSISTANCE FOR INSPECTIONS IN WESTERN SWITZERLAND

As a result of a long-standing lack of inspectors for Good Manufacturing Practice (GMP) in the Regional Medicines Inspectorate of Western Switzerland (ISOPTH), it was not possible to inspect all firms in this region within the time limit foreseen. Swissmedic therefore took over certain GMP inspections to be carried out by the ISOPTH that could not be postponed. International acceptance of Swiss inspection practice was maintained, as also confirmed by an equivalence evaluation within the framework of the existing Mutual Recognition Agreement (MRA) with Health Canada in August.

PHARMACOVIGILANCE GATEWAY NOW OPERATIONAL

Reports of adverse drug reactions (ADRs) can in future be exchanged in electronic form between pharmaceutical firms and Swissmedic. The system became operational in December 2012, with five pilot companies; the gradual expansion to other firms is planned in 2013. The new electronic exchange of ADR reports via the Gateway shortens the time for forwarding the reports, avoids the duplication of entries and increases the consistency of the reports.

CLOSER COLLABORATION WITH GERMANY AND BRAZIL

Swissmedic has signed an agreement regarding closer collaboration with the Brazilian Health Authority ANVISA. Brazil is the fourth largest market for medicinal products and is becoming an increasingly significant production location. In May, the Swiss Agency for Therapeutic Products and the German Paul-Ehrlich Institut (PEI) agreed to closer collaboration in the area of biological medicinal products. With these agreements, Swissmedic is achieving the objective, stated in the 2011-2014 service mandate from the Federal Council, of further expanding international collaboration and in particular with the EU.

SWITZERLAND IS THE FIRST COUNTRY ON THE EU LIST FOR ACTIVE PHARMACEUTICAL INGREDIENTS

As of 2 July 2013, active pharmaceutical ingredients for medicinal products in the European Union may only be imported if they are accompanied by a written confirmation from the authorities of the country of origin. This measure is intended to help prevent counterfeit medicinal products from reaching the legal delivery chain. No such confirmation is required if the country of origin is placed on a list of third countries by the EU Commission. On 22 November 2012, Switzerland was the first country to be included in this list – a confirmation of the high level of therapeutic product control in the country.

OPTIMUM USE OF RESOURCES: DEVELOPMENTS IN THE AUTHORISATION SECTOR IN 2012

ONE OF THE KEY OBJECTIVES OF THE AUTHORISATION SECTOR IS TO SPEED UP THE AUTHORISATION PROCEDURES WITHOUT AFFECTING THEIR QUALITY.

IN THE PAST, IT WAS NOT POSSIBLE TO RESPECT THE TIME LIMITS, NOTABLY FOR NEW AUTHORISATIONS WITH VOLUMINOUS DOCUMENTATION. THE YEAR 2012 WAS MARKED BY THE MEASURES TAKEN TO CONTINUE IMPROVING THE EFFICIENCY OF THE AUTHORISATION PROCEDURES.



NEW SUBMISSIONS DIVISION

At the beginning of 2012, the reception of new applications for authorisation and for variations in the Authorisation sector was transferred to a new Submissions division (Infrastructure sector). One of the reasons for doing so was the constantly rising number of applications submitted in electronic form, for which the validation processes demand an increasing amount of IT knowledge. The Case Management team familiarised the new team with this task. In the new process, the Submissions division forwards the documents to Case Management after the processing required on reception is completed. Case Management then establishes the rough planning for the various applications and forwards them to the competent specialised divisions.

PROJECT PRIME

In connection with the IT PRIME project, the specialised database will be migrated to a new platform, and a business management system will be implemented. In addition, a new planning tool to replace the previously used PS Next system will be developed. This database presently includes the administrative data for all authorised medicines and those for which applications are being processed. The project is a highly complex one, and is the key component in implementing the Swissmedic IT road map. Case Management and other divisions within the Authorisation sector are providing an important contribution to this new IT system that will be operational in 2013.

ADDITIONAL RESOURCES WITH A VIEW TO IMPROVING RESPECT FOR TIME LIMITS

The difficulties related to respecting the time limits were partially due to insufficient resources, and also partially a result of the processes for processing applications. During the development of a medicinal product – which takes place over 15 to 20 years – a massive quantity of data is produced. The Authorisation sector must then evaluate it all, plus the stance on the part of the firm, within 330 days. The fact that it

was possible to create twelve new positions in the sector in 2012, and mostly in the Clinical Review division, was therefore extremely important. By the end of 2012, all the employment contracts for these positions had been signed, with most of the new staff members in place and in the familiarisation phase.

NEW SENIOR STAFF MEMBERS

Changes have taken place in both the Authorisation sector and its management, with a new head of the sector and new heads of the Clinical Review and Complementary and Herbal Medicines divisions.



THE AUTHORISATION SECTOR

The Authorisation sector is responsible for ensuring that therapeutic products available in Switzerland are of high quality, safe and effective.

OPTIMISATION OF THE ORGANISATION IN THE AUTHORISATION SECTOR

The Clinical Review division has been reorganised as a result of the additional human resources. There are now four units, and each is responsible for clearly defined treatment areas. Collaboration between the Clinical Review and Case Management divisions has also been improved.

PROCESS OPTIMISATION

Today, the main focus is to use the limited resources in the Authorisation sector sensibly and efficiently. It is important that the reviewers analyse challenging applications immediately after they are received with regard to the review capacities they will require over the coming months. Within a unit or a division, the work will be allocated according to this capacity planning. Another key issue is for reviewers from the various divisions to meet regularly in order to discuss the scientifically complex points within an application. An exchange of best practices with regard to resource management takes place between the divisions. At times, an external expert from the Human or Veterinary Medicines Expert Committee (HMEC, VMEC) is tasked with carrying out part of the scientific assessment. The HMEC and VMEC constitute important forums for the Authorisation sector, since they bring in valuable input with regard to preclinical and clinical aspects, plus informative appraisals of the benefit – risk balance of new medicinal products.

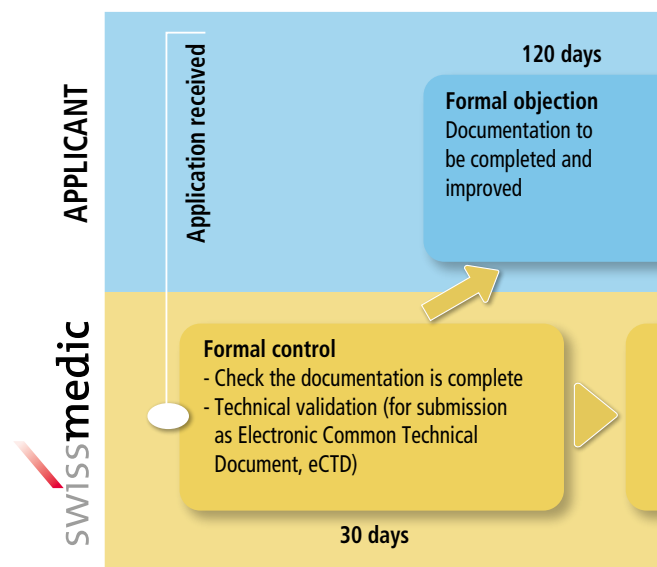
Taking into consideration assessments of known active pharmaceutical ingredients by other authorities, in accordance with Article 13 of the Therapeutic Products Act, is an aspect that has been intensified and the internal process has been rationalised.

COLLABORATION IN THE “INTERNATIONAL REGULATORS CONSORTIUM”

Collaboration with the authorities from Australia, Canada and Singapore with regard to the authorisation of generics, known active pharmaceutical ingredients, and medicinal products with new active pharmaceutical ingredients has been stepped up. The medium-term objective of this collaboration is to rely more heavily on the assessments of these authorities, or even to split the assessment activities between authorities.

PROCEDURE WITH PRIOR NOTIFICATION

The revised Ordinance on Fees now includes the possibility of a “Procedure with prior notification”, whose design was discussed on numerous occasions during the year with the relevant associations from the pharmaceutical industry. It makes it possible for an applicant to inform Swissmedic, five to eight months in advance, of the planned submission of an application. Swissmedic then processes the application in a time 20% shorter than for the normal authorisation procedure – with a fee supplement of 100%. The new procedure will be applied to new active pharmaceutical ingredients and new applications. A two-year pilot phase will begin early in 2013.



Total length of procedure for Swissmedic:	330 days
Total length of procedure for the applicant:	300 days
Total length of the processing of the application*:	630 days

OBJECTIVES

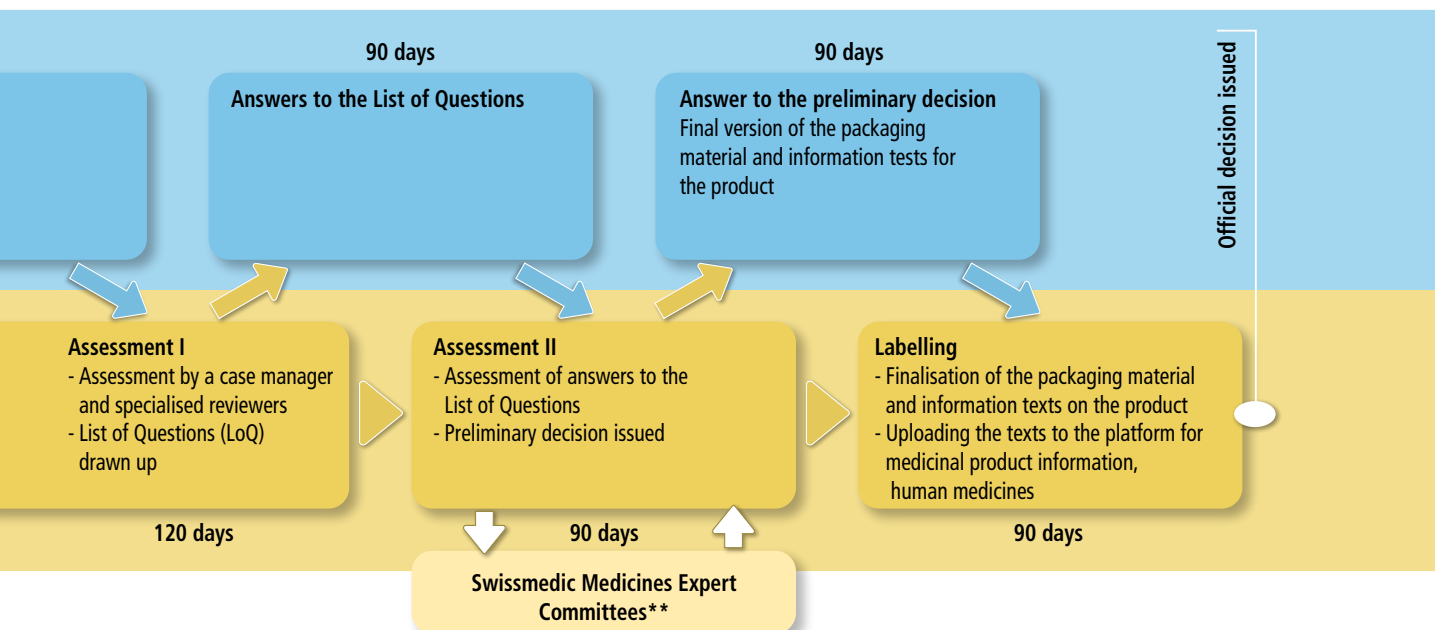
Respecting the deadlines for 99% of all applications is among the key strategic objectives of the Authorisation sector up to the end of 2014. In 2012, 92% of all applications were processed on time, so the objective appears to be a realistic one. For complex applications in particular, considerable challenges nevertheless remain (76% of deadlines met for innovative medicinal products). At the same time, the Authorisation sector must ensure that the high quality of Swissmedic's work does not suffer. This means that staff members must have sufficient time to keep their knowledge up to date but also to increase it, because science progresses constantly. The most important resources within the Authorisation sector are its professional, competent and motivated staff.

NEW HEAD OF THE AUTHORISATION SECTOR: ESA HEINONEN

Dr Esa Heinonen is from Finland. He held leading positions in the Finnish pharmaceutical firm Orion Pharma for many years, including as Senior Vice President Research & Development.

In May 2009 he moved to the Finnish Medicines Authority (FIMEA), where he ultimately led one of the authorisation divisions. Since 2012, Esa Heinonen has been the head of Swissmedic's Authorisation sector and a member of its management team.

Authorisation process by type of time limit: first authorisation and major variations



* Other time limits apply to other categories and for the fast-track procedure

** Generally speaking intervention only for first authorisations of medicinal products containing a new active pharmaceutical ingredient and additional indications.

SWISSMEDIC IS 10 YEARS OLD

IN SEPTEMBER 2012, SWISSMEDIC CELEBRATED ITS TEN YEARS OF EXISTENCE WITH AN INTERNATIONAL SYMPOSIUM IN INTERLAKEN.

ADDRESSES BY HIGH-PROFILE EXPERTS FROM SWITZERLAND AND ABROAD, PLUS TWO PODIUM DISCUSSIONS, PROVIDED THE AROUND 350 PARTICIPANTS WITH AN INFORMATIVE INSIGHT INTO CURRENT TOPICS RELATING TO THE CONTROL OF THERAPEUTIC PRODUCTS AND INTERNATIONAL DEVELOPMENTS IN REGULATORY AFFAIRS.

Federal Councillor Alain Berset, Agency Council Chairwoman Christine Beerli and Swissmedic's Director Jürg H. Schnetzer opened the Symposium. Councillor Berset underlined the importance of Swissmedic being independent and competent. He referred to the "teething troubles" that had challenged Swissmedic shortly after its foundation, noting that in recent years it had successfully overcome them. The Agency – on its creation in 2002 – was



called upon not only to implement the newly enacted legislation that brought together the Cantonal, inter-Cantonal and Federal regulations – but also faced the task of turning two previous organisations (the Therapeutic Products division of the Federal Office of Public Health and the Inter-Cantonal Office for the Control of Medicines) into a new entity with its own culture.

The work on building up the Agency was intensive, and there was no lack of criticism on the part of the public, since the new procedures faltered somewhat in the early days. It was quickly realised, however, that more staff were needed in order to operate smoothly, since a multitude of new tasks lay ahead: for example expanding international collaboration, building up the expert division on penal law, or implementing the new Ordinance on Veterinary Medicines.





SOME KEY MILESTONES IN THE AGENCY'S HISTORY:

2002

- The Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act) came into force on 1 January 2002.
- Swissmedic, the new Swiss regulatory authority for authorisation and control of medicinal products and medical devices began its work.
- The Mutual Recognition Agreement (MRA) with the EU on the elimination of technical barriers to trade came into force on 1 June 2002. It provides for the mutual recognition of conformity assessments for most industrial products, including medical devices.

2003

- The control of therapeutic products, with the key sectors of Authorisation, Market Surveillance and Inspections was agreed upon with partners, and refined.
- The first Memorandum of Understanding/Confidentiality Commitment was concluded with the US Food and Drug Administration (FDA) in September 2003.

2004

- A database to record adverse drug reactions became operational.
- Over one million residents living close to nuclear power stations were provided with potassium iodide tablets (project management by Swissmedic). This was the world's largest campaign to date for the preventive protection of the population in the case of a radiation leak.





2005

- Swissmedic moved into its new offices on the Hallerstrasse in Bern.
- Creation of the new, central Market Monitoring division, to handle procedures in the area of illegal trade and infringements of the provisions relating to advertising.
- Market surveillance was reinforced by the publication, on the Internet, of recalls of medical devices.

2006

- Swissmedic carried out a process and organisational analysis in order to form the basis for a reorganisation aimed at addressing public criticism. Building up a process-oriented organisation led to a new management structure.
- The last implementing Ordinances to the Therapeutic Products Act came into force on 1 October 2006.
- Agreements on the exchange of information in the area of therapeutic products were concluded with Australia and Canada.

2007

- As a result of the reorganisation, Market Surveillance was centralised and reinforced; the Authorisation sector was restructured.
- Work on creating a quality management system was started.

2008

- Swissmedic took part in the first, partial revision of the Therapeutic Products Act, whose objective was to alleviate the problem regarding the supply of medicinal products in the hospitals.
- Holding of the 13th International Conference of Drug Regulatory Authorities (ICDRA), in conjunction with the WHO. Over 300 participants from regulatory authorities in around 100 countries took part.
- An agreement was concluded with the Health Sciences Authority in Singapore on the exchange of information in the therapeutic products sector.

2009

- Introduction of an electronic vigilance reporting system for pandemic vaccines.
- An agreement regarding the exchange of information on H1N1 pandemic medications was concluded with the European Medicines Agency (EMA).

2010

- The first submission of applications in fully electronic form became possible (electronic Common Technical Document, eCTD).
- The procedure for the authorisation of medicinal products already authorised abroad by comparable authorities was simplified.
- Creation of a Complementary and Herbal Products division and a Veterinary Medicinal Products division in the Authorisation sector.



- The Task Force initiated by the Agency Council to reduce the backlog of applications completed its work successfully by the end of the year.
- Decision to modernise the IT infrastructure. The target architecture was defined, and an IT road map was drawn up.

2011

- Implementation of a planning tool for authorisation applications.
- Swissmedic took part in a major national campaign against illegal medicinal products under the aegis of STOP PIRACY.

2012

- See the present annual report...

Over the years, Swissmedic has clearly positioned itself, and successfully risen to the challenges that have arisen in the recent past. The objective of executing its mandate within the time limits imposed, and of maintaining high quality, is something that the Agency takes very seriously. The challenge remains – ensuring that patients can have trust in therapeutic products.

10 YEARS OF PHARMACOVIGILANCE

The National Pharmacovigilance Network (Regional Pharmacovigilance Centres at the University Hospitals and the Centro di Farmacovigilanza in Lugano) was established in June 2001, even before Swissmedic began its work. Since 2002, the National Pharmacovigilance Centre evaluates reports of adverse drug reactions reported via the network or by firms.

The number of reports received has more than doubled since the current concept of pharmacovigilance has existed in Switzerland. In addition to reports from users in Switzerland, international signals are also recorded and evaluated in order to monitor the safety of medicines. Since medicinal products are today distributed and used worldwide, the significance of international co-operation is increasing.

The WHO, the EU and national organisations operate various work platforms and databases. Since 2004, Swissmedic has therefore been linked to the system developed jointly with the International Pharmacovigilance Centre of the World Health Organization (Uppsala Monitoring Centre, UMC), which now consists of over eight million reports. In 2006, a member of the Swissmedic Pharmacovigilance division carried out a mission in Tanzania, on the invitation of the WHO, which consisted of providing advice to the authorities on building up pharmacovigilance in the country.

In 2007, a competence centre was established with the Safety of Medicines division in which all topics related to the risks of medicinal products are brought together. In November 2008, with the creation of the Pharmacovigilance Newsletter (PV Newsletter), the foundations were laid for regular reporting to specialised circles.

OUTLOOK FOR 2013



NEW SWISSMEDIC PUBLICATION PLATFORM FOR INFORMATION ON MEDICINAL PRODUCTS

As of 3 January 2013, Swissmedic is providing a new platform for the publication of information on medicinal products, for all authorised human medicines. It is mandatory, as of this date, for authorisation holders of human medicines to publish the texts of their product information (information for healthcare professionals and patient information) electronically, via the Swissmedic AIPS publication platform. This comprehensive electronic directory of information on medicinal products, which can be used by specialists and the public alike, is essential in order to guarantee the safety of medicines. The AIPS search platform is free of charge and freely accessible at: www.swissmedicinfo.ch

REGULAR REVISION OF THE THERAPEUTIC PRODUCTS ACT IN PARLIAMENT: PHASE TWO

The Federal Council is endeavouring, with the proposed amendments to the Therapeutic Products Act, to improve the population's access to medicinal products. In particular, market access for complementary and herbal medicinal products will be facilitated, and a larger range of medicinal products suitable for children will be made available. In addition, the provisions regarding rebates and bonuses and those on self-medication will be revised. The consultation process for the draft, to take place at the beginning of 2013, has been initiated by the competent Parliamentary Commission. The revised law is expected to come into force as of 1 January 2016.



SWISSMEDIC'S IT-ROADMAP IS ON TRACK

Swissmedic's IT road map defines its intentions with regard to information technology, and how these will be implemented. After the successful rollout of the business management system (performance measurement, controlling, invoicing) in 2012, the replacement of the core systems in the areas of business administration, planning and the specialised database by various integrated SAP system components is now taking place. This permits seamless, improved process control and forms the basis for further IT projects, notably to start the introduction of the electronic document management system.

NEW ORDINANCE ON FEES LEVIED BY THE SWISS AGENCY FOR THERAPEUTIC PRODUCTS, IN FORCE SINCE 1 JANUARY 2013

On 2 December 2011, the Agency Council approved the revised Ordinance on fees levied by the Swiss Agency for Therapeutic Products that entered into force on 1 January

2013. With the input of the pharmaceutical industry, Swissmedic established the details for the new procedure with prior notification and stated the attribution of applications more precisely.

NEW WEBSITE DESIGN

Swissmedic's website, now five years old, is being updated. The new design takes into account both the results of the 2012 customer survey and technical developments. It will target a broad public, and adapted with a view to changed visual habits and increased demands on the part of users with regard to easier navigation and clarity of the content.



FACTS and FIGURES

BUSINESS STATISTICS AS AT END 2012

Firms with a Swissmedic licence

The licences below were attributed to a total of 1,079 firms.

Manufacture of medicinal products:	
Manufacture of medicinal products (with a licence for wholesale distribution)	250
Manufacture of medicinal products (without a licence for wholesale distribution)	103
Wholesale distribution of medicinal products:	
Import of medicinal products	511
Wholesale trade of medicinal products	795
Export of medicinal products	402
Foreign trade with medicinal products	324
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	43
Blood transfusion services or hospitals with a Swissmedic licence for handling blood or blood products (blood transfusion activities)	38
Controlled substances	
Establishment licence for handling controlled substances	348
Laboratories with FOPH recognition	
Microbiological and serological laboratories inspected by Swissmedic	94

NUMBER OF AUTHORISATIONS BY TYPE OF PRODUCT AS AT END 2012

Human medicinal products (original, generic, co-marketing medicinal products)	5,069
Phytopharmaceuticals	734
Homeopathics	697
TCM medicinal products	5
Anthroposophics	237
Ayurvedic medicinal products	1
Tibetan medicinal products	6
Bacterial and yeast products	29
Vaccines	76
Blood products	94
Radiopharmaceuticals	33
Biotechnologicals	339
Veterinary medicinal products	690
Allergens	487
Transplant products	1
Generators	4

NUMBER OF AUTHORISATIONS BY DISPENSING CATEGORY AS AT END 2012

Dispensing category / authorised medicinal products

A Dispensed once only on medical or veterinary prescription	1,826
B Dispensed on medical or veterinary prescription	3,807
B/C Dispensed on medical or veterinary prescription / after expert advice from medical personnel	35
B/D Dispensed on medical or veterinary prescription / after expert advice	38
C Dispensed after expert advice from medical personnel	601
C/D Dispensed after expert advice from medical personnel / Dispensed after expert advice	23
D Dispensed after expert advice	1,946
E Dispensed without expert advice	175
No dispensing category (firm base dossiers)	51
Total	8,502

HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINAL PRODUCTS WITHOUT INDICATION AUTHORISED AS AT END 2012 (NOTIFICATION PROCEDURE)

Single remedies	11,519
Complex remedies	1,052

SWISSMEDIC AS AN AGENCY

Staff headcount year end	429
Full-time positions at year end	357
Total women	56.9%
Total men	43.1%
Staff working part time (part time is defined as working up to 89% of full-time post)	38.9%
Average age of staff members	46.2
Women	44.5
Men	47.9
Language distribution:	
German	87.6%
French	10.2%
Italian	1.5%
Rhaeto-Romanic	0.7%
Staff turnover rate	5.5%

MARKET access

MARKETING AUTHORISATION

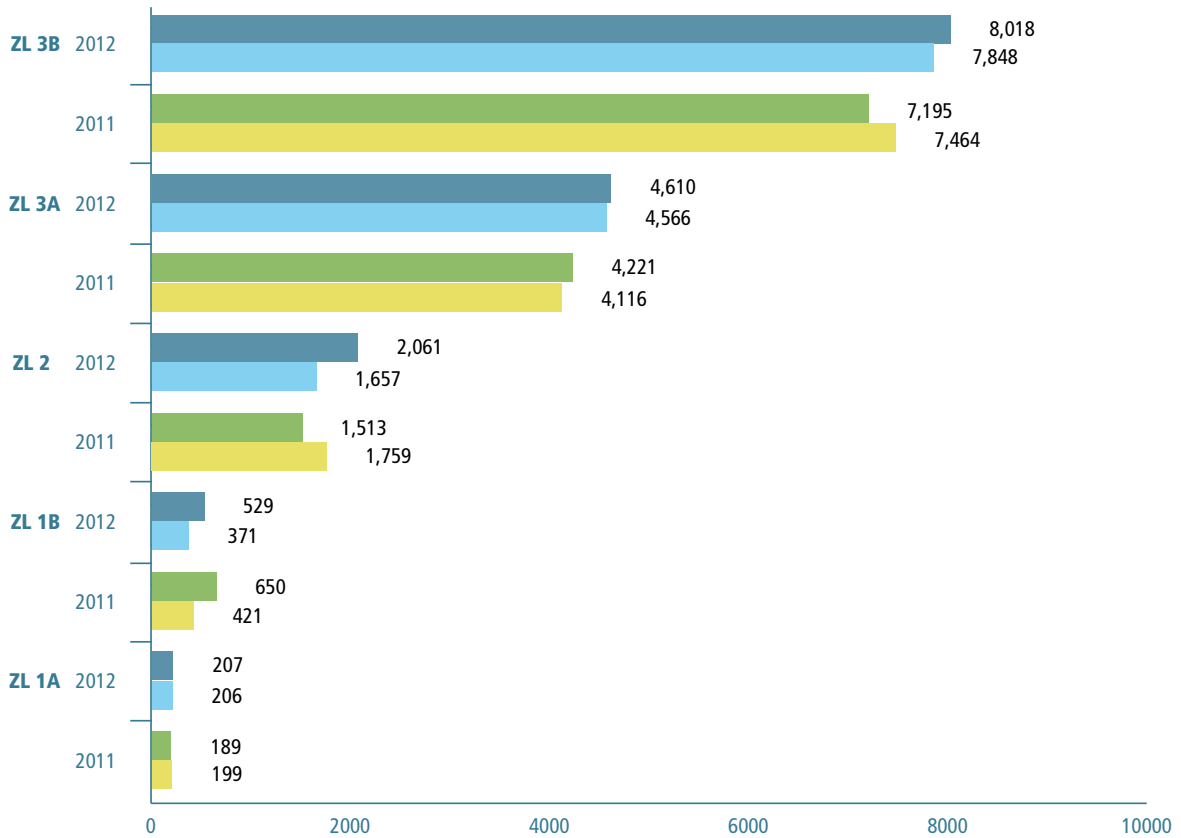
AUTHORISATION OVERVIEW

The Marketing Authorisation sector is involved in all phases of a medicinal products life cycle. As early as during the development phase of a medicinal product, firms can obtain scientific advice with regard to the various aspects of a development programme. The main task of the Marketing Authorisation sector consists of examining and approving marketing authorisation applications for all medicinal products to be placed on the domestic market. By doing so, the sector ensures that all medicinal products available to the Swiss population are of high quality, safe and effective. This also includes constantly evaluating new information on the characteristics of a product throughout its entire life cycle.

Activities

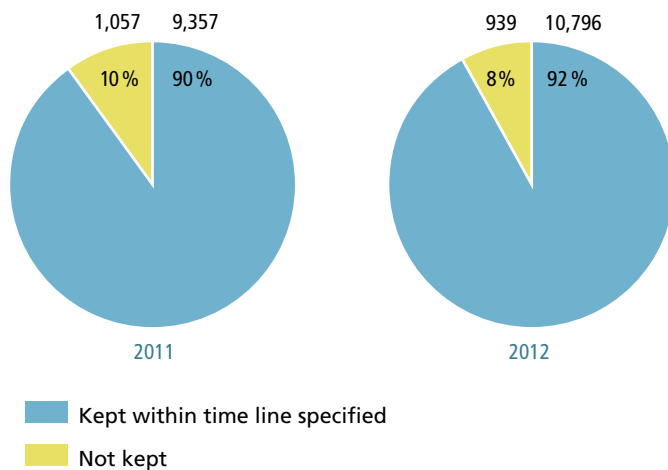
- Among the greatest challenges facing the sector is to keep the time lines prescribed for the various authorisation process in 99% of the cases. In 2012, an internal analysis of the sector was carried out in order to identify the areas that are handled with a view to improving respect for timelines, to achieving the objective by the end of 2014, and to define the corresponding measures. The outcome of the analysis revealed the following key objectives:
 - Optimisation of planning: PSNext, the new planning tool, is fully operational and as experience with it is gained, planning is based on increasingly more realistic assumptions with regard to the resources to be deployed.
 - Optimisation of the processes within Clinical Review: Organisation, responsibilities and standard operating procedures have been adapted.
 - Optimisation of the processes within Case Management: Measures were taken to improve the quality of the regulatory report, and the scope of the Case Managers' tasks was broadened.
 - Simplification of the application of Article 13 of the Therapeutic Products Act: The corresponding Administrative Ordinance was revised and discussed with the respective stakeholder groups.
 - The specialists of the Human Medicines Expert Committee (HMEC) are brought in to a greater extent. The Codex for the members of the Swissmedic Medicines Expert Committees (SMEC) with regard to conflicts of interest was revised.
- In 2012, 2.4% more marketing authorisation applications were submitted to Swissmedic than in 2011.
- In 2012, 35 Scientific Advice Meetings, 24 Presubmission Meetings and 42 Clarification Meetings were held.

Number of marketing authorisation applications received and completed, by type of application



- | | |
|--|--|
| <ul style="list-style-type: none"> 2012 Completion by type of application 2012 Reception by type of application 2011 Completion by type of application 2011 Reception by type of application | <p>Type of application:</p> <ul style="list-style-type: none"> ZL 3B Administrative variations ZL 3A Scientific variations ZL 2 Extensions / Discontinuations ZL 1B First authorisations for non-innovative medicinal products ZL 1A First authorisations for innovative medicinal products |
|--|--|

An analysis of all completed applications in 2012 reveals that the time lines were kept to a significantly better extent than in 2011. The main reasons for this improvement were increased resources and optimised procedures.



AUTHORISATION OF HUMAN MEDICINAL PRODUCTS*

FIRST MARKETING AUTHORISATIONS

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

Activities

- In 2012, 190 applications were submitted for first authorisations of innovative medicinal products and major variations thereto; 185 of them were completed.
- In 2012, 27 medicinal products with a new active pharmaceutical ingredient were authorised for the first time. Four of them were completed in the fast-track procedure.
- Regarding authorisation applications for non-innovative medicinal products, 491 were completed, including 102 for co-marketing products.
- No applications for the parallel import of a medicinal product were received in 2012.
- Regarding applications to take Article 13 of the Therapeutic Products Act (TPA) into account, 120 were completed, of which 98 were processed under Article 13. A total of 88 were approved.
- Respect for time limits compared with 2011 improved for all application types, including for resource-intensive first applications (for ZL 1A, 64% vs. 73% and for 1B, 69% vs. 75%).

HUMAN MEDICINAL PRODUCTS WITH A NEW ACTIVE PHARMACEUTICAL INGREDIENT AUTHORISED IN 2012

	ACTIVE PHARMACEUTICAL INGREDIENTS	PRODUCT NAME	APPLICATION
Alimentary tract	Linagliptinum	Trajenta®, film-coated tablets	Diabetes mellitus type 2 (DMT2) monotherapy or with metformin, sulfonylureas, thiazolidindiones or metformin plus sulfonylureas combined
Blood	Ferumoxytol	Rienso®, solution for intravenous injection	Iron deficiency in adults with a chronic kidney disease, if an adequate oral intake of iron is not sufficiently effective or is not possible
	Catridecacogum	NovoThirteen®, injectable	Bleeding prophylaxis in patients as of age 6 with a congenital lack of factor XIII subunit A and relevant risk of bleeding
	Dabigatranum etexilatatum	Pradaxa®, capsules	Prevention against strokes and systemic embolisms in patients with a non-valvular atrial fibrillation with one or several risk factors
Heart and circulation	Pitavastatinum-Calcium	Livazo®, film-coated tablets	Primary hypercholesterolaemia, including heterozygous familial hypercholesterolaemia or for combined (mixed) dyslipidaemia
	Acidum Fenofibratum	Trilipix®, retard capsules	Severe hypertriglyceridemia, mixed hyperlipidaemia
	Azilsartanum medoxomilum	Edarbi®, tablets	Treatment of essential hypertension in adults

* The performance indicators regarding marketing authorisation are displayed on page 37.

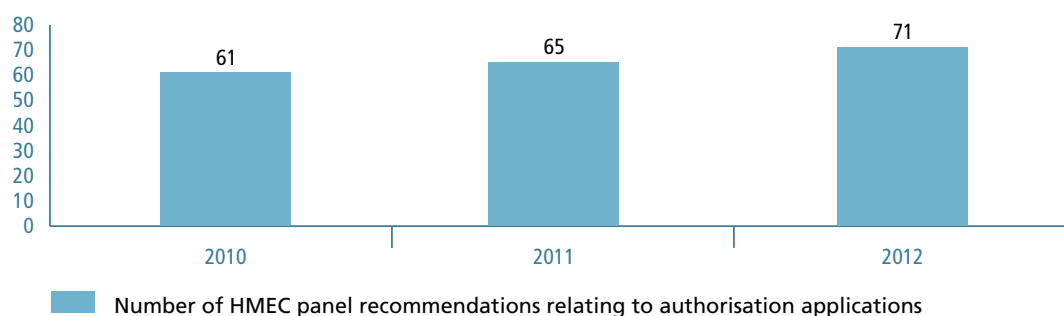
Contraception	Nomegestrol acetate	Zoely [®] , film-coated tablets	Oral contraception for women as of age 18
	Ulipristal acetate	ellaOne [®] , tablets	Emergency contraception for women age ≥18, within 120 hours (5 days)
Urogenital system modulators	Dapoxetine	PRILIGY [®] , film-coated tablets	Premature ejaculation
Endocrinal disorders	Pasireotide	Signifor [®] , solution for injection	Morbus Cushing, if all non-pharmaceutical therapies in accordance with currently valid standards have been exhausted
Antimicrobials	Micafungin	Mycamine [®] , powder for solution for infusion	Candidaemia, oesophageal candidiasis, as of age 16; invasive candidiasis from 1 month to age 16; Mycamine should only be used if other systemic antifungals such as Azole or other echinocandins cannot be used
Malignant tumors	Crizotinib	Xalkori [®] , capsules	Second line treatment for locoregional or metastatic ALK positive non-small cell lung carcinoma
	Axitinib	Inlyta [®] , film-coated tablets	Advanced renal cell carcinoma after failure of previous systemic therapy
	Vandetanib	Caprelsa [®] , film-coated tablets	Unresectable, rapidly progressing and symptomatically metastasised medullary thyroid carcinoma
	Pertuzumab	Perjeta [®] , concentrate for solution for infusion	In combination with Herceptin and Docetaxel for HER2-positive metastatic or locally recurrent, unresectable breast cancer
	Decitabine	Dacogen [®] , lyophilisate	Acute myeloid leukaemia, if intensive chemotherapy and / or stem cell transplant are not possible
	Ruxolitinib	Jakavi [®] , tablets	Intermediate myelofibrosis or high-risk in primary fibrosis or as a complication of a polycythaemia vera or essential thrombocythaemia
Immune system	Belimumab	Benlysta [®] , powder for solution for infusion	Active, autoantibody-positive systemic lupus erythematosus
Nervous system	Amifampridine	Firdapse [®] , tablets	Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults
	Perampanel	Fycompa [®] , film-coated tablets	Add-on therapy for focal epilepsy seizures with or without secondary generalisation, as of age 12
	Dexmedetomidine	Dexdor [®] , concentrate for infusions	For the sedation of adult patients in intensive care and who need a sedation depth that still permits awakening by verbal stimulation
Psychiatry	Asenapine	Sycrest [®] , sub-lingual tablets	Treatment of acute, moderate to severe manic episodes for bipolar 1 disorders in adults
Eyes	Aflibercept	Eylea [®] , solution for intravitreal injection	Treatment of exudative (wet) age-related macular degeneration
Transplants	Keratinozyten	Keragraf [®] , epidermal autologous equivalent	Skin transplant for chronic, refractory ulcers
Complementary and herbal medicine	Glechomae hederaceae extractum spissum ethanolicum	Gallith [®] , capsules	Traditionally used as a herbal medicine for supportive treatment of functional disorders to the biliary tract in the framework of the formation of gall stones (cholesterol stones)
	Camelliae sinensis extractum siccum raffinatum	Veregen [®] 10%, ointment	Condylomata acuminata in immunocompetent patients as of age 18

HUMAN MEDICINES EXPERT COMMITTEE (HMEC)

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

Activities

- During the course of its 12 meetings, the advisory HMEC panel issued 71 recommendations regarding marketing authorisation applications. The majority of them concerned new authorisations or additional indications for medicinal products.
- In addition, 13 expert reports relating to full assessments and 55 partial expert reports were provided by the HMEC experts.
- In December 2012, all HMEC members were re-elected for the period in office 1 January 2013 to 31 December 2016.



EXTENSIONS AND DISCONTINUATIONS

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

Activities

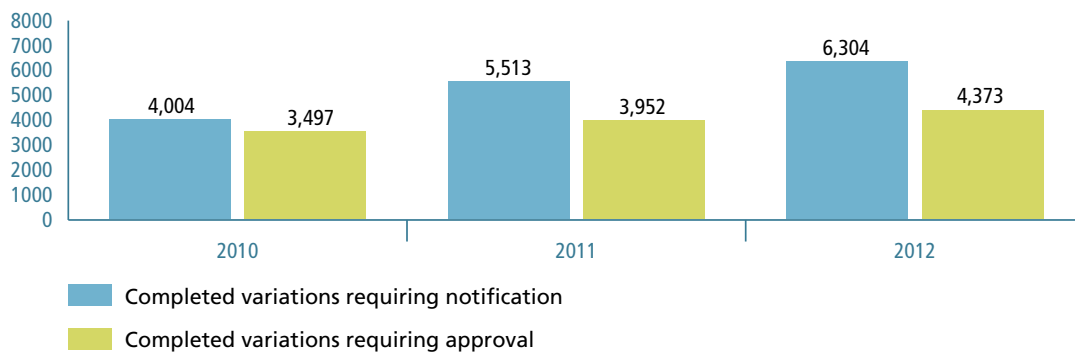
- In 2012, 1,229 applications of extensions of marketing authorisations were submitted; 1,352 applications were completed.
- In 2012, 262 applications for the discontinuation of a product and 24 applications for a discontinuation of a sequence of a product were submitted; 512 applications for the discontinuation of a product and 24 for the discontinuation of a sequence were completed.

VARIATIONS REQUIRING APPROVAL AND VARIATIONS REQUIRING NOTIFICATION

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

Activities

- In 2012, 6,218 variations requiring notification were submitted; 6,304 notifications were completed.
- Regarding variations requiring approval, 4,368 applications were submitted; 4,373 were completed.



THE FAST-TRACK AUTHORISATION PROCEDURE

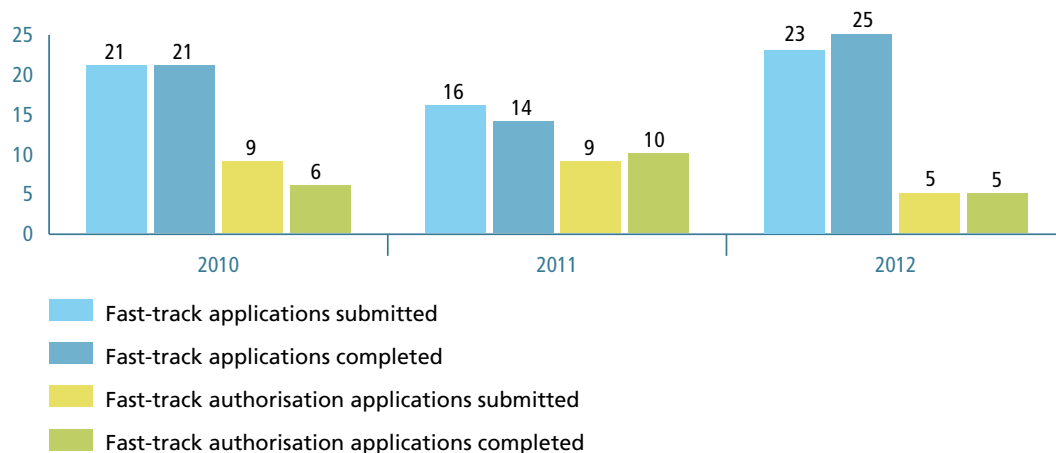
Applications for fast-track marketing authorisation procedures can be submitted for human medicinal products with new active pharmaceutical ingredients, additional indications, new pharmaceutical forms, or known active pharmaceutical ingredients. Three conditions must all be fulfilled:

- expected successful treatment in the case of severe diseases,
- lack of other possible treatments with medicinal products,
- the use of the medicinal product indicates a significant therapeutic benefit.

After a positive assessment of these conditions on the part of Swissmedic, the request for the fast-track procedure is approved and the application is processed in accordance with the fast-track procedure. For Swissmedic, the time limit for processing the authorisation applications is reduced from 330 to 140 days.

Activities

- In 2012, 23 requests for applying the fast-track procedure were submitted, and 25 fast-track applications were completed.
- In 2012, 5 authorisation applications using the fast-track procedure were submitted and completed.



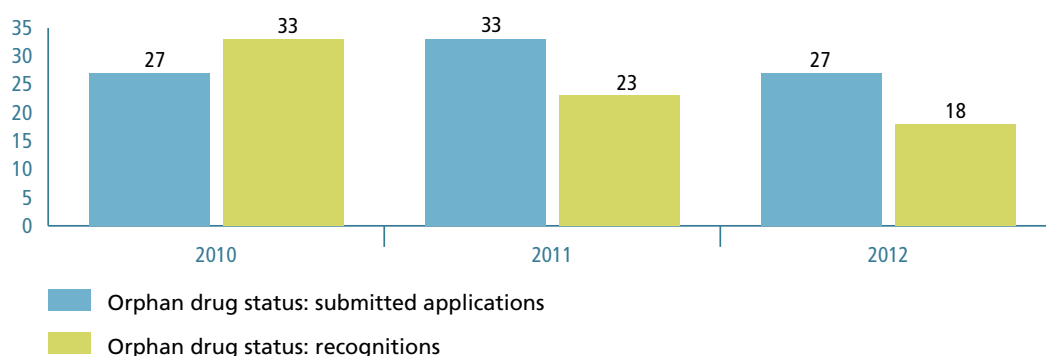
SPECIAL CATEGORIES OF HUMAN MEDICINAL PRODUCTS

ORPHAN DRUGS

Swissmedic recognises the status as a medicinal product for a rare disease (orphan drug) on application. The applicant must prove that the medicinal product is used for the diagnosis, prevention or treatment of a rare, life-threatening or chronically debilitating disease that affects at most 5 out of 10,000 people. Most applications are based on the recognition of the status in another country with comparable medicinal control, and in particular by the European Medicines Agency (EMA) or the US Food and Drug Administration (FDA). A distinction is made between the recognition of orphan drug status and the – usually subsequent – authorisation of a medicinal product as an orphan drug. The authorisation procedure for orphan drugs is exempt from processing fees.

Activities

- In 2012, 27 applications were submitted for the recognition of the orphan drug status. This status was granted for 18 products.
- Two products were authorised as orphan drugs. Additional orphan indications were approved for three previously authorised orphan drugs.



PAEDIATRIC MEDICINAL PRODUCTS

Since the entry into force of the EU Regulation EC 1902/2006 and the Food and Drugs Administration Amendment Act (FDAAA), it has been mandatory for pharmaceutical firms to submit their paediatric investigation plans (PIPs) to the authorities and to develop their medicinal products for use by children in accordance with these plans. The Swissmedic Paediatrics Working Group is responsible for the consistent handling of this specific group of medicinal product.

Activities

- Swissmedic was represented by their Paediatrics Working Group in the WHO Paediatric medicines Regulators' Network (PmRN).
- On the occasion of the creation of a Chair of Paediatric Pharmacology in Basel, a Swissmedic expert gave an address at the Swiss Clinical Trial Organisation within the framework of the GCP seminar for paediatricians.
- The Working Group is regularly consulted with regard to marketing authorisation applications for paediatric medicinal products.

NEW PROCESSES

Swissmedic also grants authorisations for special manufacturing processes. This is necessary when a comprehensive appraisal of the quality of the end product is not possible or can only be achieved by guaranteeing the safety of the manufacturing procedure. This process is typically used for labile blood products and transplant products.

Activities

- After an inactivation system for the treatment of thrombocytes was introduced throughout Switzerland in 2011, some blood transfusion services have now registered their interest in a similar system for the treatment of plasma for transfusions. Specific validation instructions that must be fulfilled in order for simplified authorisation to be possible have been drafted and approved. The first applications are expected early in 2013.
- The authorisation of an inactivation system for the treatment of plasma for transfusion, but that has not, however, been used in Switzerland to date, has initially been extended for a limited period of time.

TRANSPLANT PRODUCTS

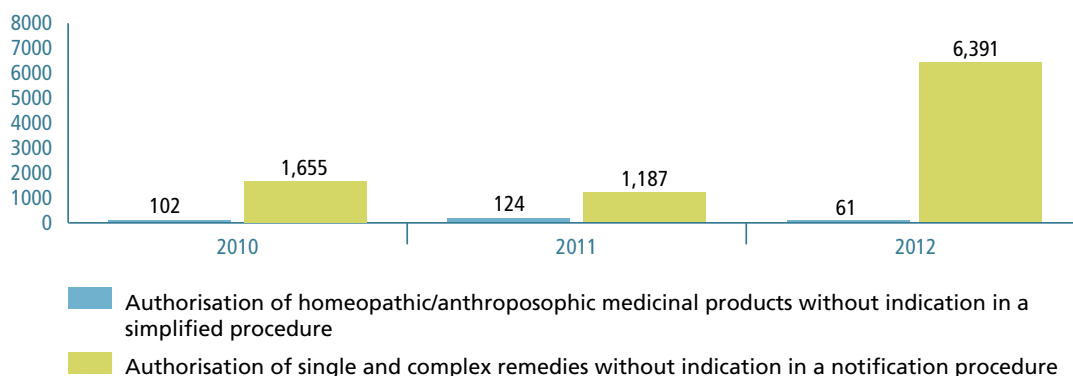
Products from somatic cell therapy, tissue cultures and ex vivo gene therapy are, in accordance with the Transplantation Act, equivalent to medicinal products and thus also subject to the Therapeutic Products Act. On behalf of the Federal Office of Public Health, inspections are carried out at firms and institutions working with cells, tissues and organs. During them, investigations are carried out relating to compliance with the legal provisions of the Transplantation Act and regarding whether it can be guaranteed that cells, tissues and organs are handled appropriately, in accordance with the standards specified in the Transplantation Act.

Activities

- Keragraf® was the first transplant product to be granted marketing authorisation in Switzerland.
- Of the 16 applications for authorisation submitted since the Transplantation Act came into force in 2007, only three were still being processed at the end of 2012.
- In 2012, Swissmedic held a total of 13 Scientific Advice Meetings, Presubmission Meetings and Clarification Meetings with the applicants regarding transplant products.

COMPLEMENTARY, HERBAL AND ASIAN MEDICINAL PRODUCTS

For these product groups, Swissmedic ensures that the main authorisation requirements are respected. Basically, a simplified authorisation procedure is possible for all categories of complementary and herbal medicines, in accordance with the general provisions of the Ordinance on Complementary and Herbal Medicines. Quality, safety and tolerability must be guaranteed in each case.



HERBAL MEDICINAL PRODUCTS

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

Activities

- In 2012, two herbal medicines with a new active ingredient were authorised.
- 23 applications for non-innovative first authorisation of herbal medicines were completed, of which 14 concerned applications for co-marketing products.
- In 2012, one application according to Article 13, was completed.
- The instructions for the authorisation of cough and throat drops and pastilles in dispensing category E was extended and published as an Administrative Ordinance.

COMPLEMENTARY MEDICINAL PRODUCTS

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

Activities

- In 2012, six applications for the first authorisation of non-innovative homeopathic or anthroposophic medicinal products with an indication were completed.
- In 2012, 6,391 products without an indication were newly authorised: this consisted of 6,224 single products and 167 combined products. New basic dossiers were approved for four firms as the basis for the notification procedure.
- In 2012, 105 applications for a simplified marketing authorisation procedure with a reduced dossier were completed; 61 products were authorised via this procedure and 44 applications were rejected.
- The list of homeopathic and anthroposophic substances (HAS list), is used as the basis for authorisation without an indication, with reduced dossier or via the notification procedure. The list was updated: 93 substances were added.
- A new release of the HOMANT software for the notification procedure was introduced, with functions implemented that include, for example, the input of manufacturing procedures, and the processing of support cases or of extensions via the notification procedure.

ASIAN MEDICINAL PRODUCTS

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

Activities

- The development of the HOMANT-Asia data capture software was completed. This software permits applicants to submit notifications electronically. In addition, an extension of Swissmedic’s internal HOMANT processing software for Asian medicinal products was completed.
- Collaboration with the Swiss Centre for Applied Human Toxicology (SCAHT) of the University of Basel, with the objective of broadening knowledge of the substances in the list of documented traditional Asian substances (TAS list) and adjusting the list accordingly. The TAS list constitutes the basis for the notification procedure.

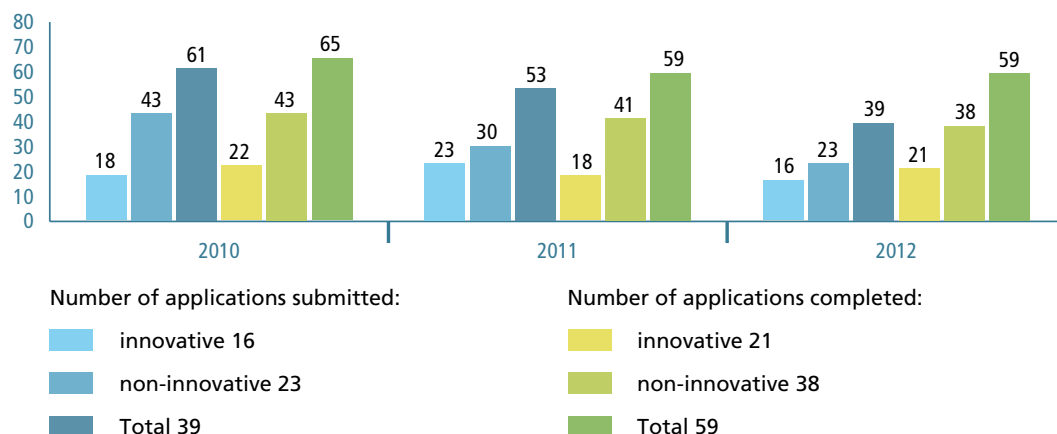
AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS

AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS

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

Activities

- In 2012, 16 applications for innovative first authorisations and major variations were submitted; 21 applications were completed.
- Of these 16 applications, 6 concerned the first authorisation of a medicinal product with a new active pharmaceutical ingredient.
- In 2012, 6 medicinal products with a new active pharmaceutical ingredient were authorised for the first time.
- In order to improve the way in which the division is integrated within the international context of veterinary medicinal product regulators, an exchange programme was established with the Veterinary Medicines Department of the Irish Medicines Board in 2012.



VETERINARY MEDICINAL PRODUCTS WITH A NEW ACTIVE PHARMACEUTICAL INGREDIENT AUTHORISED IN 2012

ATCVET CODE	WIRKSTOFFE	PRODUCT NAME	APPLICATION
Nervous system	Pergolidum	Prascend ad us. vet., tablets	Dopamine agonist for horses
	Tiletaminum	Zoletil ad us. vet., solution for injection	Anaesthetic for zoo and wild animals
Antiparasitics	Indoxacarbum	Activyl spot-on ad us. vet., spot-on solution	Ectoparasitic for dogs and cats
Antimicrobials	Orbifloxacinum, Mometasoni furoas et Posaconazolium	Posatex ad us. vet., ear drops	For the treatment of acute otitis externa and acute worsening of a chronic otitis in dogs, associated with strains of bacteria susceptible to Orbifloxacin and yeast susceptible to Posaconazol, notably <i>Malassezia pachydermatis</i>
	Pradofloxacinum	Veraflox ad us. vet., tablets	Antimicrobial (Gyrase /Topoisomerase IV-inhibitor) for the systemic treatment of cats and dogs
Musculoskeletal system	Natrii pentosani polysulfas	Anarthron ad us. vet., solution for injection	Solution for injection for dogs, for the treatment of non-infectious joint diseases

VETERINARY MEDICINES EXPERT COMMITTEE (VMEC)

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

Activities

- In 2012, the authorisation applications or additional indications for 26 products were evaluated at five meetings.
- The development of resistance to antibiotics and discussions regarding measures for the careful use of antibiotics and their targeted use in veterinary medicine remains a key focal point within the scientific assessments carried out by the VMEC.
- In December 2012, all VMEC members were re-elected for the period in office from 1 January 2013 to 31 December 2016.

EXTENSIONS AND DISCONTINUATIONS

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

Activities

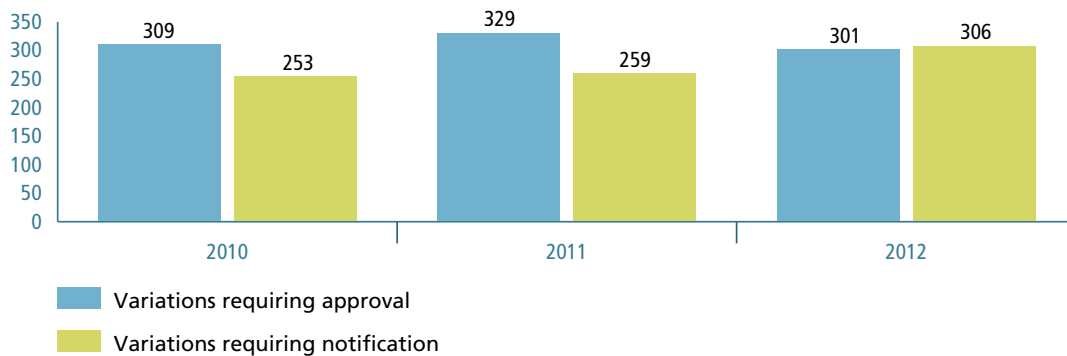
- In 2012, the authorisation was extended for 164 products.

VARIATIONS REQUIRING APPROVAL AND VARIATIONS REQUIRING NOTIFICATION

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

Activities

- In 2012, 301 variations requiring approval and 306 variations requiring notification were processed.



MINOR USE – MINOR SPECIES (MUMS)

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

Activities

- Treating diseases of the bee is a high priority. In 2012 it was possible to overcome gaps in the range of medicinal products for bees.

APPEALS PROCEDURE WITH REGARD TO THE AUTHORISATION OF MEDICINAL PRODUCTS

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

Activities

- In 2012, four appeals were lodged with the Federal Administrative Court against official decisions taken by the Agency in connection with product authorisations. In one case, the appeal was dismissed and in all of the others the judgement is still outstanding.
- Of the proceedings still pending before the Federal Administrative Court or the Federal Supreme Court, a judgement has been passed on six. One appeal was rejected by the Federal Supreme Court, and three were rejected by the Federal Administrative Court. One appeal was not processed, and one was dismissed.

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

More human resources

The 12 new positions for the sector, granted at the end of 2011, were filled; they contribute towards improving the response time and efficiency of processing the applications.

Process optimisation

At the beginning of 2012, a comprehensive analysis was carried out regarding what type of process optimisation would be necessary in order to keep the prescribed time lines for the various categories of marketing authorisation applications. In total, 20 measures were identified; some of these concerned the processes and the organisation of certain divisions (Case Management and Clinical Review), others concerned the sector as a whole. It was already possible to implement some of the measures in the 3rd and 4th quarter of 2012, such as various organisational changes, clarification and optimisation of the use of the resource planning tool, a simplification of the internal workflows for managing cases in accordance with Article 13 and adjustments to the HMEC Codex.

Authorisation procedure with a prior notification

The introduction of the new authorisation procedure with a prior notification was prepared. Within the framework of this procedure, a firm informs Swissmedic five to eight months in advance of the planned submission of a new application. Swissmedic assesses these applications within a time limit that is 20% shorter than is usually the case for the marketing authorisation procedure.

Creation of the Submissions division

The Submissions division was established on 1 January 2012 with the objective of handling the reception process of applications in a uniform, consistent and timely way. It is an organisational unit within the Infrastructure sector. The tasks of the division include registering the business cases, and the technical validation and the formal control of the incoming paper and eCTD applications for the Authorisation, Licensing and Market Surveillance sectors. During 2012, the staff and organisation of the division was built up, and the processes involved were optimised or new ones were developed with the aim of enhanced efficiency.

First authorisation of a transplant product in Switzerland

On 25 October 2012, Keragraf® was the first so-called transplant product to be authorised by Swissmedic. It concerned a skin substitute made from cultivated autologous epidermal cells. Keragraf® is indicated for the treatment of refractory venous or arterio-venous leg ulcers in adults that do not heal after at least three months of optimum standard therapy and for which a skin transplant is therefore a consideration. This first authorisation of a transplant product was granted by Swissmedic after a comprehensive benefit – risk balance evaluation, taking into consideration the characteristics of this new product category.

TABLE OF PERFORMANCE INDICATORS FOR HUMAN AND VETERINARY MEDICINAL PRODUCTS

The key figures for respecting time limits encompass all medicinal products, i.e. both human and veterinary products.

Performance indicator	Target	Result	
		2012	2012
		First half year, cumulative	Second half year, cumulative
Marketing Authorisation procedures (all application categories), the proportion completed within the prescribed time lines	92%	90%	94%
First marketing authorisations of innovative medicinal products (ZL1A); the proportion completed within the prescribed time lines	80%	68%	76%
First marketing authorisations of non-innovative medicinal products (ZL1B); the proportion completed within the prescribed time lines	80%	74%	74%
Extension / discontinuations of marketing authorisations (ZL2); the proportion completed within the prescribed time lines	90%	78%	98%
Scientific variations (ZL3A); the proportion completed within the prescribed time lines	90%	94%	93%
Administrative variations (ZL3B); the proportion completed within the prescribed time lines	90%	96%	96%

The objective of keeping the time lines was met for all completed applications and most application sub categories. A clearly positive development took place during the second half of 2012. The results show an improvement compared with the previous year.

LICENSING

LICENSING OF MEDICINAL AND TRANSPLANT PRODUCTS

ESTABLISHMENT LICENCES FOR MEDICINAL PRODUCTS

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

Activities

- At the end of 2012, 1,079 companies held an establishment licence for the manufacture, wholesale, import, export and trade in foreign countries of medicinal and transplant products. Some of these companies carry out several of the activities mentioned.
- In 2012, 732 establishment licences were issued for the first time, extended or amended.

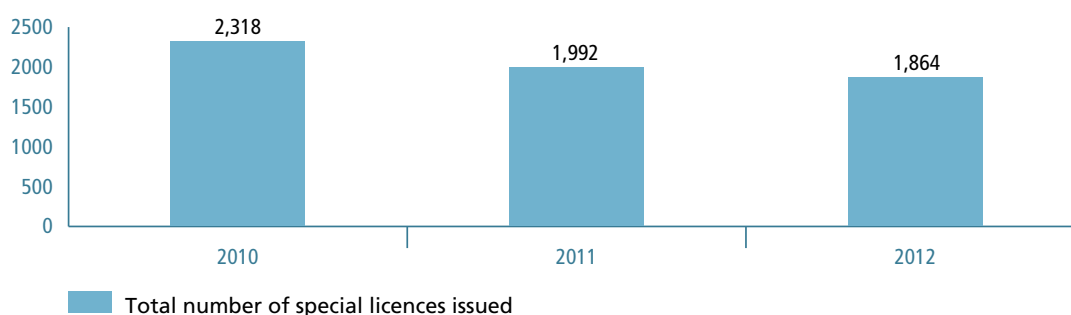
Performance indicator	Target	Result
Establishment licences; proportion of procedures that were completed within six months	95%	91%

SPECIAL LICENCES FOR MEDICINAL AND TRANSPLANT PRODUCTS

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

Activities

- Three-quarters of the special licences issued for human medicinal products came from Cantons with a university hospital. Approximately 40% of the special licences were for radiopharmaceuticals, in particular for diagnostic purposes.
- The number of special licences has again decreased, and among other reasons following the authorisation of a radiopharmaceutical medicinal product in October 2012.
- As a result of the partial lifting of the mandatory requirement for licences following the modification of the Establishment Licences Ordinance (ELO), which entered into force in October 2010, the number of licences issued in 2012 was once again below 2,000.



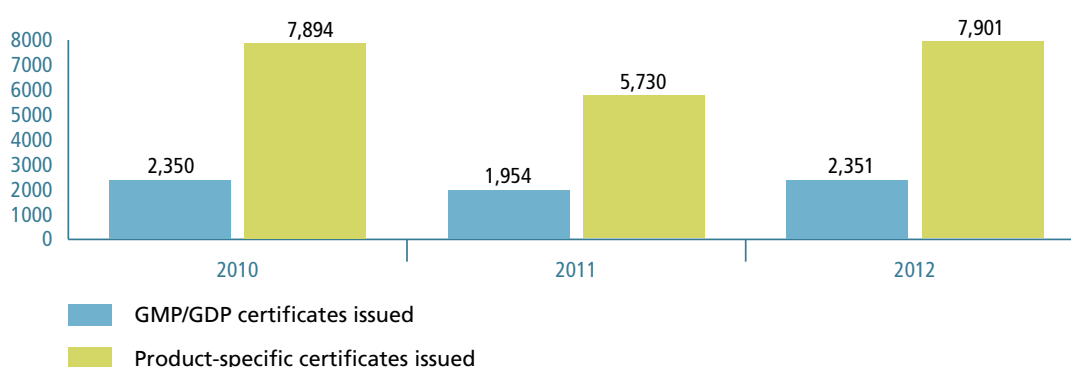
Performance indicator	Target	Result
Special licences; proportion of procedures that were completed within 24 hours	95%	99%

CERTIFICATES FOR MEDICINAL AND TRANSPLANT PRODUCTS

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

Activities

- In 2012, 2,351 certificates were issued for Good Manufacturing Practice (GMP) and for Good Distribution Practice (GDP).
- In 2012, 7,901 product-specific certificates were issued.



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

CONTROL OF THE FLOW OF NARCOTICS

Swissmedic issues establishment licences to firms and individuals who manufacture, procure, broker, import, export, dispense or trade in controlled substances. The import and export of controlled substances must be licensed in advance by Swissmedic. The Agency must be notified of domestic deliveries of narcotics in "Lists A and D" in accordance with 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 2012, 348 firms were in possession of an establishment licence for handling controlled substances. A total of 173 applications for modifications, renewals or for the start of operations were processed.
- Swissmedic has issued around 7,311 import or export licences to firms for international trade.
- In total, Swissmedic was notified of 942,611 domestic narcotics deliveries.

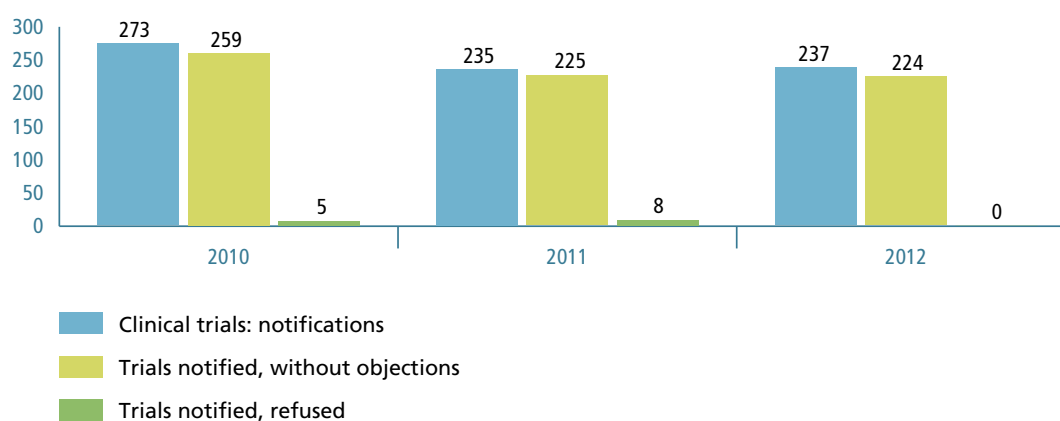
Performance indicator	Target	Result
Import and export licences for controlled substances, proportion of procedures that were completed within 10 working days	95%	95%

CLINICAL TRIALS WITH MEDICINAL AND TRANSPLANT PRODUCTS

Clinical trials are used for the systematic gathering of information on medicinal products when used on humans. Swissmedic carries out controls to determine whether appropriate measures are taken to preserve the health and the personal rights of the test subjects and patients, the quality and safety of the test product, and the correctness of data and results. Clinical trials may only be carried out in Switzerland if they have been approved by a Cantonal Ethics Committee, and if Swissmedic is notified and raises no objections within 30 days (notification procedure). During the trials, adverse reactions and amendments must always be reported to the Ethics Committees and/or to Swissmedic.

Activities

- In 2012, Swissmedic was notified of 237 clinical trials with medicinal products; 224 clinical trials were approved, of which 72 were approved only after resolution of objections. Seven dossiers were returned because of incompleteness. No clinical trials were refused.
- An increase in notifications/authorisations for clinical trials with transplant products and gene therapy was noted.
- In 2012, Swissmedic continued its collaboration with the Federal Office of Public Health (FOPH) and the Swiss Association of Ethics Committees for Clinical Trials (AGEK), with the aim of simplifying the transition to the new Human Research Act (HRA) and the related ordinances (OHR-1, OHR-2, HRA-Org) at the end of 2013.
- The staff of the Clinical Trials division contributed to various external training courses.



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

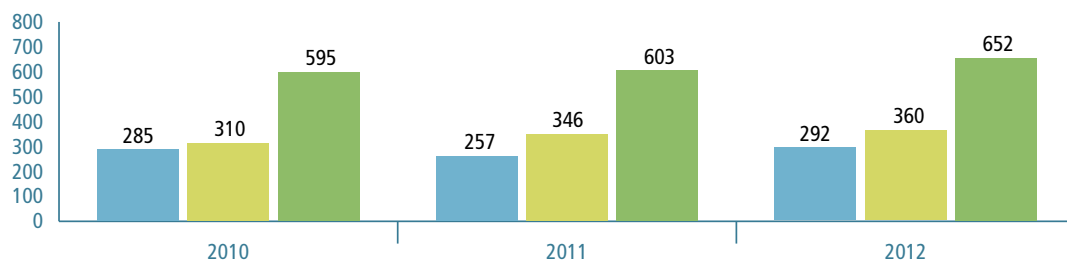
INSPECTIONS

GMP AND GDP INSPECTIONS

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

Activities

- A total of 652 GMP/GDP inspections were carried out of manufacturers and wholesale firms, of which were carried out 82 by the Swissmedic inspectorate and 570 by the regional inspectorates.
- In almost 40% of cases, the inspections carried out by the Swissmedic inspectorate concerned blood transfusion services and in 11% they concerned the control of transplant products.
- The Swiss Federal Audit Office evaluated as one of the key points during their audit of the business year 2011 the risks adhering to the Swiss inspection system, and optimisation measures were then implemented.
- In order to address the lack of staff in the Regional Medicines Inspectorate of Western Switzerland (ISOPTh), Swissmedic carried out 20 GMP inspections that fell within the remit of the ISPOTh during the first six months of the year.
- Swissmedic and the regional inspectorates again took part in inspections by partner organisations abroad in 2012, and in four evaluations of partner authorities within the framework of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Swissmedic inspectors took part in the following inspections abroad:
 - Three inspections of manufacturers of active pharmaceutical ingredients in India, together with the European Directorate for the Quality of Medicines & HealthCare (EDQM).
 - One inspection of a manufacturer of advanced cell therapy medicinal products, carried out jointly by Swissmedic and the Health Sciences Authority (HSA) within the framework of the consortium.



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

- Manufacturers
- Wholesale firms
- Total

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

GCP INSPECTIONS

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

Activities

- Swissmedic carried out 21 GCP inspections within the framework of clinical trials with medicinal products.
- In addition, Swissmedic carried out two GCP inspections in the area of advanced therapy medicinal products (ATMPs). One of them concerned an inspection of a clinical trial with transplant products and one inspection was of a previously approved in vivo gene therapy trial.

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

GLP INSPECTIONS

With the exception of pharmacodynamic investigations, nonclinical studies are to be performed in accordance with Good Laboratory Practice (GLP) for notification or authorisation procedures. The GLP compliance monitoring unit at Swissmedic carries out activities (inspections or study audits) in cooperation with the corresponding GLP units at the Federal Office for the Environment (FOEN) and the Federal Office of Public Health (FOPH) within the framework of the GLP compliance monitoring programme.

Activities

- Within the scope of its GLP monitoring activities regarding GLP compliance of nonclinical studies of medicinal products, Swissmedic carried out ten routine inspections in 2012.
- A new test facility was inspected for the first time in 2012 and was enrolled in the monitoring programme. A further application for GLP certification is pending. Two test facilities left the programme in 2012.
- A joint GCP/GLP inspection to cover bioanalytics of plasma samples from clinical trials was carried out in collaboration with the GCP inspectorate of the Clinical Trials Division.

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

INSPECTIONS FOR THIRD PARTIES

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

Activities

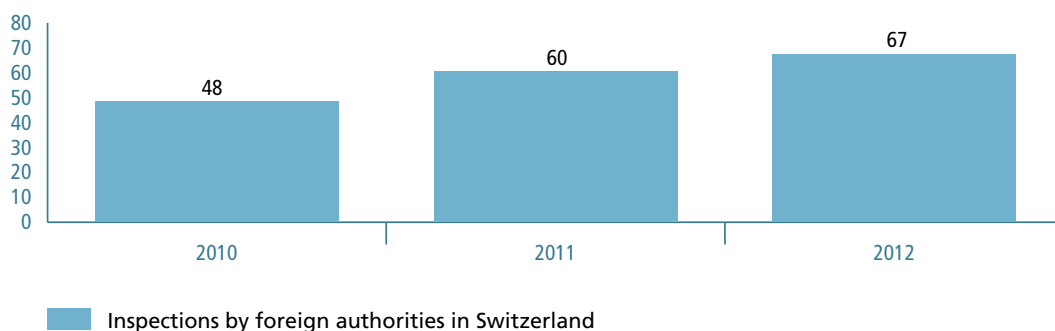
- Swissmedic carried out a total of 31 inspection procedures for the FOPH in 2012.
- The framework contract that forms the basis for the collaboration with the FOPH and the various modular contracts were renewed at the end of the year for a further four and two years respectively. The exception to this is the modular contract for implementation tasks in the area of heroin-based treatments, which became invalid as a result of the revised Ordinance on Narcotics.

INSPECTIONS BY FOREIGN AUTHORITIES IN SWITZERLAND

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

Activities

- Foreign authorities carried out 62 GMP inspections in Swiss pharmaceutical companies. The inspecting authorities were from the USA, with 30 inspections, Brazil with 12, Korea with 9, Turkey with 4, Saudi Arabia with 2, and Russia, Ukraine, Kazakhstan, Yemen and Oman with 1 inspection each. These inspections were accompanied by inspectors from Swissmedic or from the regional inspectorates.
- Swissmedic also accompanied 5 GCP inspections on the part of foreign authorities. The inspecting authorities were the USA and Italy with 2 GCP inspections each, and England with 1 inspection.



MONITORING OF THE BLOOD TRANSFUSION SERVICE

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

Activities

- A small outbreak of Q fever occurred in the Canton of Vaud, affecting 14 persons. The source of the infection was identified as a flock of sheep. The SRC Blood transfusion service was requested by Swissmedic to take the appropriate measures in order to guarantee the safety of blood donations. As a result, all donations in the region were tested for Q fever pathogens for a period of six weeks. This made it possible to exclude, to the greatest possible extent, the risk of transmission to patients via nucleic acid amplification technology.
- This season also saw widespread West Nile virus infections in some regions of Europe. In order to prevent the risk of transmission by blood donors who had visited the regions concerned, the SRC Blood transfusion service published regular decisions to adapt the donor suitability assessment.

OFFICIAL MEDICINES CONTROL LABORATORY (OMCL)

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

Activities

- The number of analytical work other than batch releases increased considerably.
- The extension of the Laboratory Information and Management System in 2012 now makes it possible to archive and manage batch documents electronically.
- Within the framework of the project for the construction of a new laboratory and office building at Freiburgstrasse 139, all the specifications required for the laboratory equipment were drawn up at the laboratory.
- Numerous effective analytical methods were developed (for example to identify the presence of Botulinumtoxin A) and many existing methods were significantly improved (for example GC/MS screening now 40% faster).

Analysis conclusions for new marketing authorisations and market control

	2010	2011	2012
Authorisation procedure: number of medicinal products examined	73	4	26
Market surveillance: number of medicinal products examined	931	1,304	1,676
Total	1,004	1,308	1,702

Batch assessments and plasma pool analysis

	2010		2011		2012	
	Blood products	Vaccines	Blood products	Vaccines	Blood products	Vaccines
Batch assessments (CH, EU and WHO)	433	128	484	162	544	88
Notifications	269	165	290	176	310	160
Plasma pool analysis	1,350	–	1,642	–	1,563	–
Product analysis as WHO reference laboratory WHO	–	7	–	28	–	35

Performance indicator	Target	Result
Batch releases; proportion of assessments within the prescribed time limit	100%	99%

APPEALS AGAINST DECISIONS IN CONNECTION WITH LICENCES

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

Activities

- In 2012, appeals were lodged with the Federal Administrative Court against five official decisions taken by the Agency in connection with establishment licences. In two cases, the court decided to dismiss the appeal. For the other proceedings, the judgement is still outstanding.
- Of the proceedings that had already been pending before the Federal Administrative Court of the Federal Supreme Court, two appeals were rejected.

SPECIAL ACTIVITIES AND EVENTS: LICENSING OF MEDICINAL PRODUCTS**New laboratory building**

New laboratory and office premises for the Licensing sector are being built at Freiburgstrasse 139 in Bern. There will be two storeys of modern office space. The other two floors will hold secure, cutting-edge laboratories with a total surface area of 800 m². The construction work is progressing according to plan, and will be in line with the budget approved by the Agency Council. The Licensing sector will move into the new workspaces by the end of September 2013.

New MESA database to record the flow of controlled substances

Since 1 January 2013, the new Ordinance on the Control of Narcotics requires the full registration of all domestic deliveries of narcotics and psychotropic substances. For this reason, the previous electronic reporting systems BEKO and ABEKO have been replaced by the new MESA system. This was completed by the end of 2012 and was successfully implemented, according to plan, on 1 January 2013. Comprehensive information and training material is available on the Swissmedic website.

MARKET SURVEILLANCE

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

MARKET SURVEILLANCE OF MEDICINAL PRODUCTS

VIGILANCE OF MEDICINAL PRODUCTS

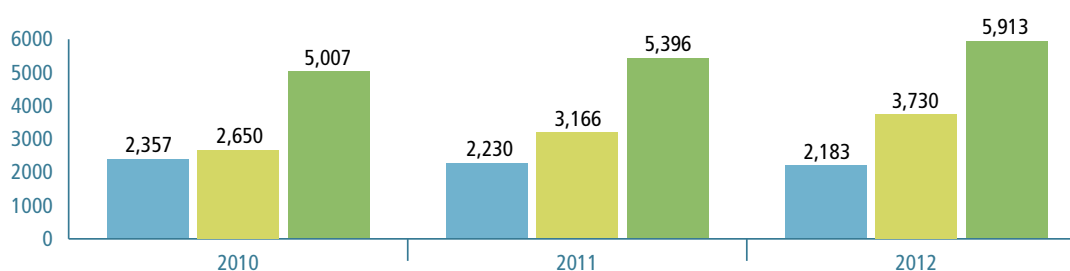
Swissmedic records safety signals associated with medicinal products, vaccines, labile blood products and veterinary medicines based on reports of adverse drug reactions (ADRs) from within Switzerland. If the evaluation indicates a new risk, Swissmedic initiates the necessary measures.

PHARMACOVIGILANCE

Within the framework of the pharmacovigilance network, reports on adverse drug reactions are evaluated and recorded in the national database, by six regional pharmacovigilance centres (RPVCs) on behalf of Swissmedic. The reporting health professionals receive appropriate feedback. Further reports on adverse drug reactions from within Switzerland are sent to Swissmedic by the pharmaceutical companies.

Activities

- In 2012, Swissmedic received and evaluated 5,913 reports of adverse drug reactions from the six RPVCs and from industry. Compared with the previous year, the reporting frequency increased by 10%, which is the result of a further increase in the number of reports sent by the pharmaceutical companies.
- Given the high reporting rate in Switzerland in international comparison, and its constant growth since the system has existed, emphasis was placed on the further improvement of the quality of the reports. The topic "What is a good report?" was the subject of a workshop at the specialised conference organised for the firms, was addressed at a meeting with the RPVCs, and an article on the topic for professionals was published in the Vigilance News.
- The project for the electronic exchange of ADR reports between firms and Swissmedic (gateway) was successfully completed. It is now intended that the gateway will be used by as many companies as possible.



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

- Regional Pharmacovigilance Centres
- Pharmaceutical companies
- Total

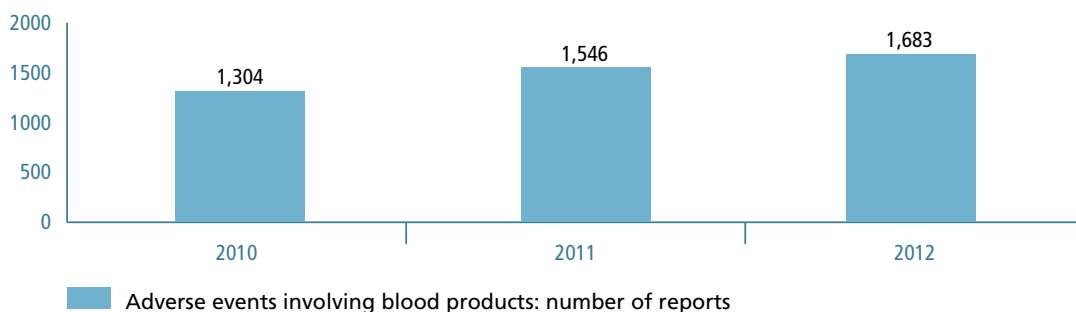
Performance indicator	Target	Result
Serious adverse drug reactions: evaluation and transmission of the reports to the companies within 15 calendar days	95%	98%

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 products to patients. Emphasis is placed on identifying errors in the system. For that reason, so-called “near miss” events are also recorded, referring to situations when an error is detected and corrected prior to the transfusion. The evaluation of haemovigilance reports provides a picture of the current risks related to transfusion, can indicate the cause of preventable transfusion incidents, and reveals areas where corrective measures are necessary and possible. The objective of haemovigilance at Swissmedic is to improve the safety of transfusion therapy.

Activities

- In 2012, a total of 1,683 reports were received and evaluated.
- Switzerland is among the first countries worldwide to implement the procedure for pathogen inactivation of platelets. Within haemovigilance, emphasis was placed on reporting about the new data and the successful nationwide implementation, including at the Swisstransfusion Congress, at three international scientific conferences and during a WHO expert committee meeting.
- Two workshops were held to provide training for haemovigilance officers.
- The results and findings from the previous year’s report were also published in 2012, in the Annual Haemovigilance Report: www.swissmedic.ch/marktueberwachung/00159/00160/00437/index.html?lang=en.
- The Blood Regulators Network (BRN) has published the “Assessment criteria for blood regulatory systems” on the WHO website. Swissmedic, as a member of the BRN, made a considerable contribution to this catalogue of criteria www.who.int/bloodproducts/brn/en/.



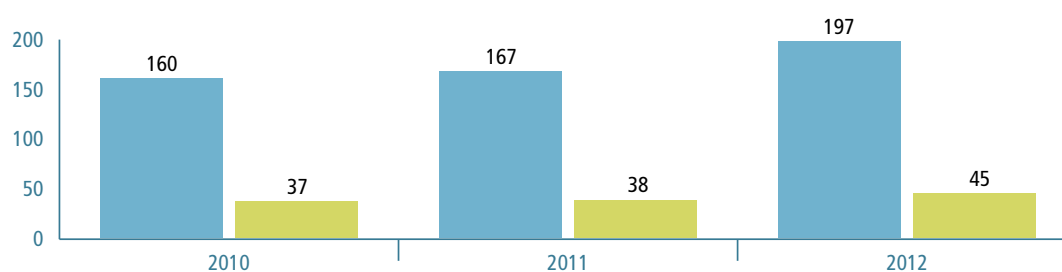
Performance indicator	Target	Result
Report on new findings	1	1
Training courses for haemovigilance officers	2	2

VIGILANCE OF VETERINARY MEDICINAL PRODUCTS

Swissmedic works with the Institute of Veterinary Pharmacology at the University of Zurich for the collection and evaluation of reports on adverse reactions to veterinary medicinal products. Reports on vaccines for animals do not fall within the area of competence of Swissmedic, and are recorded by the Federal Veterinary Office.

Activities

- The number of adverse reactions to veterinary medicinal products increased by 18% compared with the previous year, to reach a total of 197. The Swiss Toxicological Information Centre (STIZ) in Zurich submitted 45 reports.
- The distribution of the reports remained stable in terms of species and products. Domestic animals were the largest category. A total of 11 signals were generated from the 197 reports.



Adverse reactions to veterinary medicinal products

■ Number of reports
■ of which transmitted by STIZ

Performance indicator	Target	Result
Report on new findings	1	1

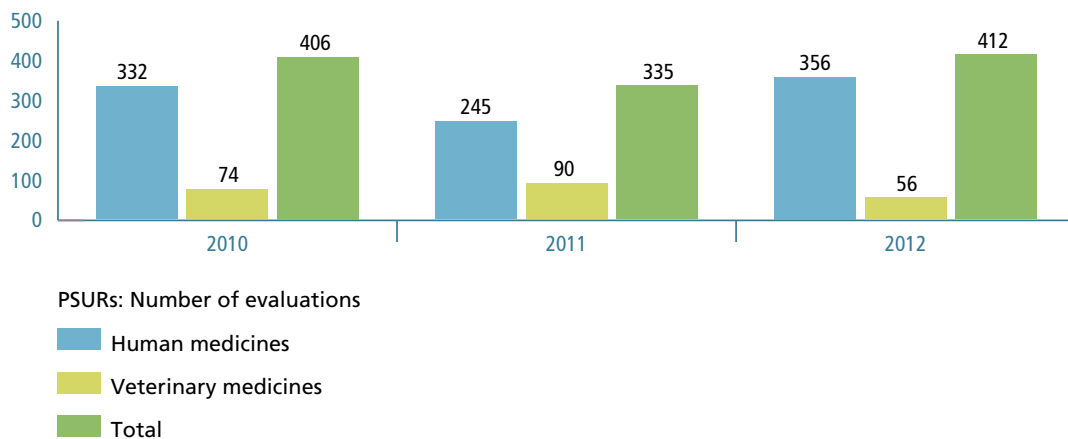
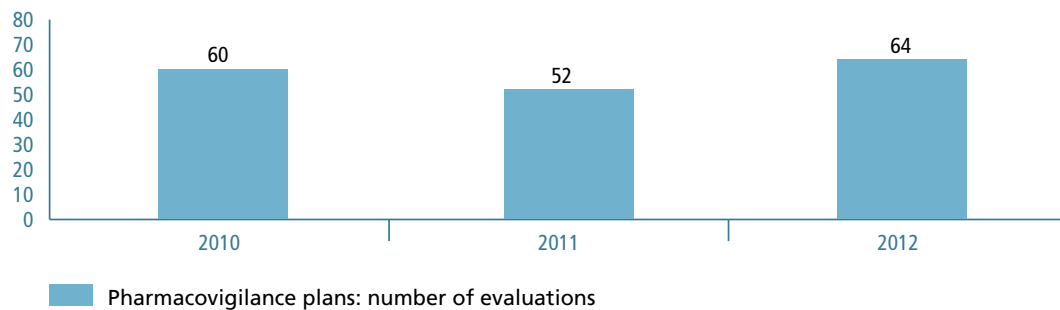
RISK MANAGEMENT

Swissmedic's tasks also include the evaluation of international data on the safety of medicines. When applying for authorisation of a new medicinal product, companies have to submit a pharmacovigilance plan in accordance with the guidelines by the International Conference on Harmonisation (ICH). In the plan, the marketing authorisation holder takes a stance regarding the possible risks associated with the new medicinal product and demonstrates how they will be prevented, followed up, and how any lack of information will be corrected. Swissmedic also evaluates the Periodic Safety Update Reports (PSURs) that must be submitted regularly by the firms, as well as safety signals from national and international sources.

Activities

- The evaluation of pharmacovigilance plans continues to be one of the key tasks within the safety of medicines. In total, 64 first submissions and updates were assessed; 20 responses by companies to the list of questions - submitted to them by Swissmedic - were evaluated.

- In total, 356 PSURs on human medicinal products were assessed. The introduction of a short assessment process with systematic prioritisation made it possible to reduce the assessment time. Of the PSURs, 56 concerned veterinary medicinal products, for which the majority are subject to mandatory PSUR submission.
- Swissmedic processed 120 safety signals on medicinal products, of which 61 originated in Switzerland and 59 were from international sources. Most of the signals required more in-depth evaluation, meaning that despite a decrease in the number compared with 2011, the overall resources deployed remained the same.
- The section Risk Management was provided with additional staff (1 Case Manager) and is now lead by the new appointed Head of Risk Management.
- Together with the Licensing sector, three pharmacovigilance inspections were carried out, of which two were the result of questions on the pharmacovigilance and risk management systems of the firms concerned and that were raised by Swissmedic during the evaluation. One was to accompany inspections carried out by foreign authorities.



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

RISK MITIGATION MEASURES

It is mandatory for companies, even after a medicinal product is authorised, to apply for a change of the product information in case of any new information, particularly relating to the safety of medicines. If Swissmedic becomes aware of a new risk and the responsible company does not take action and initiate risk mitigation measures, Swissmedic takes the corrective measures ex officio. The texts of the circulars to experts (Direct Healthcare Professional Communications, DHPC) and the intended recipients thereof are examined and approved by Swissmedic. They are then published on the Swissmedic website. If appropriate, Swissmedic also provides information, under its own responsibility, on risks related to medicinal products.

Activities

- Swissmedic initiated four review procedures as a result of new safety signals. In many cases, risk mitigation measures could be implemented without initiating a review procedure. Twelve review procedures were completed, including the harmonisation of the product information for products containing methylphenidate.
- In 25 cases, authorisation holders sent a Direct Healthcare Professional Communication (DHPC) to healthcare professionals on their own initiative or as instructed by Swissmedic, to inform them of new risks related to medicinal products.
- Major risks related to medicinal products concerned the use of the blood pressure medication Aliskiren (increased cardiovascular complications in diabetics or in combination with ACE inhibitors or sartans), the question of increased mortality with the plasma expander HES (hydroxyethyl starch) in patients with sepsis (mainly associated with renal complications) and significant new interactions with the antiviral medication Boceprevir with a series of other active pharmaceutical ingredients. Signals from Switzerland, about which Swissmedic provided information, concerned overdoses of methotrexate in patients with rheumatoid arthritis as a result of incorrect use, once more the risk of thromboembolism under hormonal contraceptives, and the risks of iron infusion for pregnant women.

Performance indicator	Target	Result
Number of procedures completed (including review procedures)	25	25

MARKET MONITORING OF MEDICINES

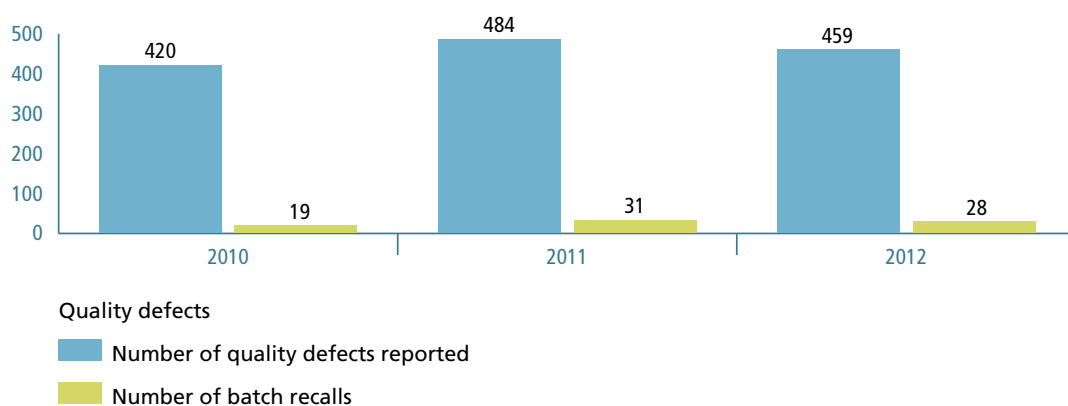
Quality defects and batch recalls

Swissmedic records quality defects in medicinal products and decides on the measures required. A quality defect that is reported is evaluated, prioritised and processed. Depending on the risk potential of the defect in question, a batch recall or a circular to healthcare professionals is necessary. A further important component of market monitoring is that of international information exchange and the examination of foreign reports with regard to their significance for the Swiss market.

Activities

- In 2012, a total of 459 reports on quality defects were submitted. Of them, 344 came from within Switzerland, and 115 were from foreign partner authorities. Switzerland was concerned by 324 of the 459 reports received, and measures were taken with regard to 127 of them. Four reports were classified as urgent.
- 28 batch recalls were issued, and two products had to be recalled at patient level because of the high risk.
- During the last quarter of 2012, influenza vaccines constituted a particular focus. White particles were discovered in various batches from one manufacturer. Since it was at first not possible to establish the reason for the particles with certainty, nor whether Swiss batches were concerned by the problem, Swissmedic imposed a provisional halt to its use. Investigations by the manufacturer and analysis at Swissmedic' laboratory (OMCL) were able to prove, independently of one another, that the particles were harmless aggregates of the normal ingredients. The batches of vaccine foreseen for Switzerland were moreover free of particles and were again released for use.

- For another influenza vaccine, deliveries were delayed because two batches failed the sterility test during the release check. After extensive analysis of the root cause and a benefit – risk balance, certain batches of this product could nevertheless be delivered. As a result of this, and of the extraordinary import of foreign supplies, a sufficient quantity of vaccines could be placed on the market in time for the influenza vaccination.
- Manufacturing or quality problems led to a temporary shortage of oncological medicinal products and of important antibiotics. Recently, there has been a greater tendency towards supply shortages, often as a result of production problems.
- Since quality problems and supply shortages are becoming increasingly complex and are taking on more international dimensions, the Swissmedic Market Monitoring of Medicines division organised an international workshop on this topic in November 2012.



MEASURES AGAINST ILLEGAL MEDICINAL PRODUCTS

Swissmedic is tasked with warning the public about the possible dangers of illegal medicinal products: it does so, for instance, by means of publishing information on the Swissmedic website or by issuing press releases. In order to reduce risks, it is particularly important to inform healthcare professionals and the public about new findings without delay, to foster the regular exchange with product users, and to maintain good national and international networking. Swissmedic receives reports on illegal products, activities, and imports of medicinal products (particularly on illegal trading), assesses them, and if necessary initiates corrective measures. Imported medicinal products are controlled in conjunction with the customs authorities.

Activities

- In 2012, Swissmedic received 329 reports on illegal activities related to medicinal products. Of them, 83 concerned illegal distribution.
- In 46 cases, the evaluation revealed cases of retail trade or illegal products for which legislation on therapeutic products was not applicable. The cases were therefore forwarded to the Cantons for further action.
- Of 111 reports concerning counterfeit medicinal products, Switzerland was only affected by 17.
- Within the framework of the action week Pangea V, around 750 imports of medicinal products were examined at the Zurich-Mülligen postal sorting centre in co-operation with the customs authorities: more than half of them proved to be illegal.
- The customs authorities forwarded 1,070 suspicious shipments to Swissmedic. In 1,004 cases it was necessary to initiate administrative proceedings.

- In 2012, it was possible to take down 17 Swiss Internet sites that advertised or sold illegal medicinal products.
- The stakeholder meeting “Enforcement related to illegal medicinal products in 2011” took place in March 2012. At the forefront were discussions on the exchange of information between designated contact persons within the authorities and other stakeholders in the fight against illegal medicinal products, and trends in illegal trading during the previous year.

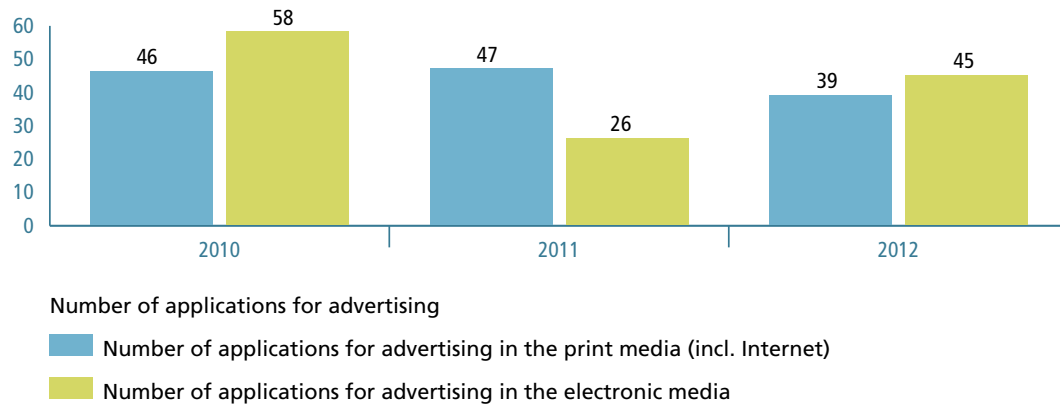
	2010	2011	2012
Illegal distribution (responsibility of Swissmedic)	75	69	83
Illegal retail trade (responsibility of the Cantons)	50	27	36
Illegal cosmetics and dietary supplements (responsibility of the Cantons)	23	18	10
Counterfeit medicinal products	122	118	111
Suspicious medicinal products: no. of checks	30	34	36

CONTROL OF ADVERTISING

Swissmedic controls and monitors the advertising of medicinal products. Advertising for which a control by the Agency is mandatory is evaluated and approved. In addition, Swissmedic follows up information regarding infringements of advertising legislation and decides whether administrative proceedings need to be initiated, or in which cases legal compliancy can be re-established by means of an official objection. To promote the transfer of knowledge, Swissmedic informs interested stakeholders of the currently valid legal basis for the advertising of medicinal products.

Activities

- In total, 84 applications for prior control were submitted. Of them, 39 concerned printed advertising, 4 were related to Internet sites (that are covered by the regulations governing the printed media), and the other 45 applications concerned advertising on electronic media such as television commercials or e-boards.
- A total of 45 advertisements for advertising that targeted the public or healthcare professionals were submitted to Swissmedic. In 13 cases, administrative proceedings were initiated. In 10 of them, an official objection was issued.
- During the year, responses were provided regarding 22 complex enquiries regarding various advertising topics.
- For cases of prior control, Swissmedic issues the first preliminary decision in less than 20 days on average. For highly voluminous documentation – for example when assessing websites or the simultaneous submission of several applications – it was not always possible to respect the target time limit of 4 weeks. A fairly large number of applications for the prior control of advertising revealed significant shortcomings with regard to compliance with the legislation on advertising and therefore required comprehensive assessment. In 20% of the prior controls, it was therefore not possible to respect the target time limit of 4 weeks.
- A well-attended further training event focused on sample packs in advertising for healthcare professionals and the public.
- Based on a court ruling, Swissmedic was able to public guidelines for the use of the term “Botox” in advertising, so that – for example – no unauthorised public advertising by physicians for medicinal products with botulin toxin is allowed on Internet sites. These guidelines were published in Swiss Medical Journal.
- The publication “Advertising material in veterinary practices” was drawn up in collaboration with the Association of Swiss Veterinarians.



Performance indicator	Target	Result
Prior control of advertising; preliminary decision within four weeks of receipt of application	100%	80%

The following performances indicators concern all activities of the Market Surveillance

Performance indicator	Target	Result
First activities within 10 days for priority 1 reports	100%	100%
First activities within 30 days for priority 2 reports and within 90 days for priority 3 reports	90%	97%
Number of presentations, publications and circulars to raise awareness among stakeholders	12	33

APPEALS

Appeals against decisions taken by Swissmedic with regard to the marketing of medicinal products may be lodged with the Federal Administrative Court within 30 days. That Court's judgement may in turn be contested before the Federal Supreme Court.

Activities

- In 2012, appeals were lodged with the Federal Administrative Court against nine decisions by the Agency in connection with the market monitoring of medicines. Most of them concerned illegal imports of medicinal products and illegal advertising. Three appeals were not admitted and in the other cases, the judgement is still outstanding.
- Of the appeals pending before the Federal Administrative Court or the Federal Supreme Court, judgements were passed on twelve. The Federal Supreme Court approved one appeal, meaning that a judgement by the Federal Administrative Court was partially overruled; it concerned the legal requirements for the transmission of rebates in accordance with Art. 33 TPA. One case was rejected, four others were not admitted and two were dismissed.

SPECIAL ACTIVITIES AND EVENTS: MARKET MONITORING OF MEDICINES

Specialised conference on the safety of medicines

On 23 April 2012, Swissmedic held a specialised conference on the safety of medicines. It was an opportunity for Swiss physicians in clinical practice and experts from the medicinal products industry and the supervisory authority to exchange experiences. The key topics were good pharmacovigilance practice on the one hand and risk management and communication when carrying out a market withdrawal on the other. The participants unanimously believed that facts should trigger an event, and that good communication with the authorities from the outset was important with regard to limiting damage. Thanks to targeted information, patients and healthcare professionals alike can learn to identify unusual symptoms so that any side effect can be identified, treated and reported more rapidly.

Introduction of a system for the publishing of medicinal product information (AIPS)

Following a decision on the part of the Federal Administrative Court on 17 June 2011, Swissmedic could no longer make it mandatory for firms to publish information on medicinal products on a directory belonging to a private provider. This resulted in the publication of the information being dispersed over various directories; some of the information was only published on the firms' Internet sites. Since a comprehensive directory of all information for healthcare professionals and patient information is extremely important with regard to ensuring the safety of medicines, Swissmedic decided to develop a publication platform at its own expense in 2012. As a result of a WTO tender, HCI solutions AG was selected to implement and operate AIPS. After intensive development work and numerous tests, which also included input from the industry, the platform began operation on 1 January 2013. The authorisation holders responsible for the publication of the correct texts were required to check that the texts were up to date and to update them and complete them if necessary. With AIPS, Swissmedic provides the guarantee that both healthcare professionals and the public can consult all the information necessary for the safe use of authorised medicinal products in a single directory.

International experts' meeting on quality problems

The globalisation of the manufacturing and distribution of medicinal products, which has been increasing for many years, is leading to a further rise in the number of complex quality defects with an international dimension. In November 2012, Swissmedic held an experts' meeting to exchange experiences on the processing of quality defects and on supply shortages. It was attended by representatives of the authorities from 18 countries and a representative of the European Medicines Agency (EMA). When assessing risks, it is also increasingly necessary to take possible supply shortages into consideration. Swissmedic makes use of international networking to improve risk management and to define the appropriate corrective measures. These include the immediate withdrawal of a medicinal product from the market or additional controls for market release, i.e. prior to use. The meeting was the first of its kind and the reactions to it were extremely positive.

MARKET SURVEILLANCE OF MEDICAL DEVICES

The manufacturer carries out its own conformity assessment procedure for its products, under its own responsibility. In the case of higher-risk products, an officially designated notified body for conformity assessment also examines the product. The procedure leads to the CE marking of the products. Swissmedic is responsible for the monitoring of medical devices that are already available on the market and for the notified bodies. Swissmedic also monitors clinical investigations of medical devices that are not yet authorised for the market. Medical devices encompass an extremely large range of products, including implants such as hip prostheses and heart pacemakers, in-vitro diagnostics such as HIV tests, or products for the general public such as contact lenses.

INTEGRATION WITHIN THE EUROPEAN SYSTEM

With regard to medical devices, Swissmedic is integrated within a European system. Switzerland has concluded agreements on the mutual recognition of conformity assessments for medical devices with EU Member States, EFTA states and Turkey. This European system provides the authorities of the contracting states with a shared database (EUDAMED) for the purposes of market surveillance and as an information system. CE-marked medical devices are considered as being compliant and may be distributed in all contracting states. Swissmedic has taken part in the meetings of high-level bodies in this respect, i.e. the Central Management Committee and the Competent Authorities Meeting. The Agency has moreover been an active participant in the Medical Devices Expert Group and its working groups: Vigilance, Borderline and Classification, In Vitro Diagnostic Technical Group, Compliance and Enforcement Group, Clinical Investigation and Evaluation, EUDAMED, Notified Bodies Operations Group (NBOG) and New and Emerging Technologies (NET).

PLACING ON THE MARKET

Manufacturers of medical devices with specific risks must call upon in officially recognised notified bodies for the conformity assessment. Swissmedic monitors the Swiss notified bodies in co-operation with the Swiss accreditation centres, designates them, receives their communications regarding certificates issued, and records them in EUDAMED. Swissmedic also takes part in quality assurance methods carried out by the designating authorities in Europe. Notification is mandatory for certain medical devices, and for these, Swissmedic receives the notification, carries out random checks regarding their classification, issues instructions regarding any necessary corrections, and records the notification in EUDAMED, the European database. In addition, Swissmedic issues export certificates and certificates of origin for medical devices on request by the Swiss firms concerned.

Activities

- A total of 283 notifications for class I medical devices were recorded, e.g. for reusable surgical instruments, adhesive plasters, and rolling walkers.
- On 1 May 2011, the expanded EUDAMED European database became operational. It means that some of the notifications for in-vitro medical devices (IVDs) were no longer handled by Swissmedic. This led to a further decrease in IVD notifications compared with previous years: in 2012, 180 such notifications were recorded.
- In 66 cases, Swissmedic rejected notifications of medical devices from firms because of incorrect classification or lack of competence.
- 30 EU enquiries on delimitation questions regarding the classification of devices were initiated or answered by Swissmedic.
- 2,552 export certificates were issued.

	2010	2011	2012
Class I notifications	302	465	283
IVD notifications (Switzerland)*	2,473	595	180
Notifications rejected	40	19	66
EU enquiries	37	35	30
Export certificates	1,918	2,120	2,552

* As a result of the change to the regulations in 2011, the figure for 2012 cannot be fully compared to that for previous years.

CLINICAL INVESTIGATIONS OF MEDICAL DEVICES

Swissmedic monitors clinical investigations of medical devices for human use if the products or the intended use in Switzerland are not yet permitted. Notification to Swissmedic is mandatory for intended investigations of such products, and the notifications are reviewed. During the clinical investigations, Swissmedic monitors incidents for which notification is mandatory, such as serious adverse events and reports on the safety of the subjects taking part in the investigation. Swissmedic is authorised to inspect investigators, sponsors and clinical research institutions throughout Switzerland, and records notifications and measures from Switzerland in EUDAMED. Swissmedic moreover takes part in the drafting of international guidelines.

Activities

- 30 notifications for new investigations of medical devices not yet permitted for the market were evaluated.
- A total of 764 notifications relating to already accepted clinical investigations were processed.
- Swissmedic carried out in-depth reviews of three ongoing pre-market investigations. In particular, the actions taken by sponsors in the case of serious events were examined, as was the suitability of the procedures for handling such events.
- On 3 October 2012, Swissmedic organised a workshop on the evaluation by the authorities of intended investigations, in conjunction with European authorities. The key topics were: the review of first-in-man studies, reviews of pivotal studies, and the EUDAMED database.

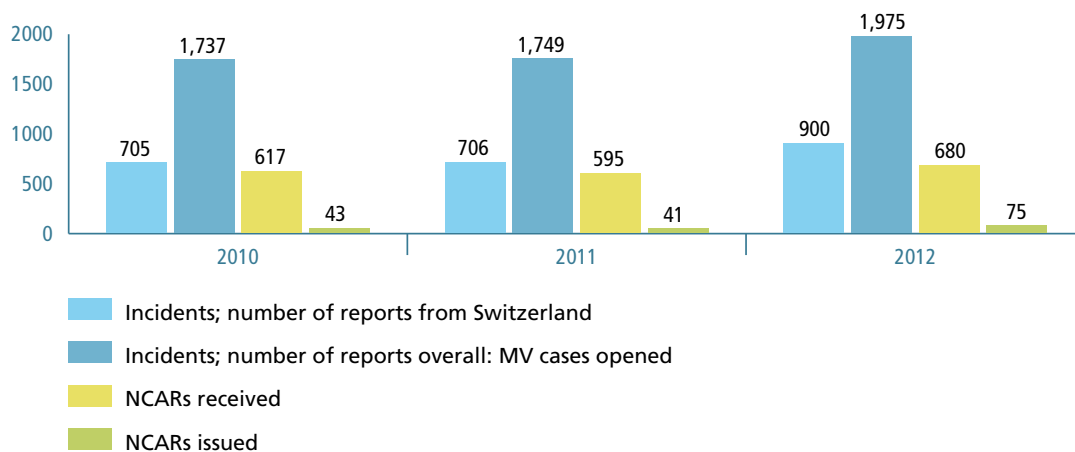
Performance indicator	Target	Result
Notifications of clinical investigations; proportion of notifications that were assessed with 30 days	100%	100%

VIGILANCE OF MEDICAL DEVICES (MATERIOVIGILANCE, MV)

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

Activities

- A total of 1,975 materiovigilance cases were processed, of which 900 occurred in Switzerland.
- In 629 cases, the implementation of field safety corrective action measures was monitored in Switzerland: a number that was identical to that for the previous year.
- 75 reports on defects in medical devices (NCARs) were issued for foreign authorities. In return, Swissmedic received 680 NCARS from European partner authorities.
- A conference was once again organised in 2012 for materiovigilance contact persons from hospitals under the motto “From practice – for practitioners”. In order to promote the exchange of knowledge between the contact persons, and in addition to presentations on the legal background, some workshops on topics of general interest were included on the programme.



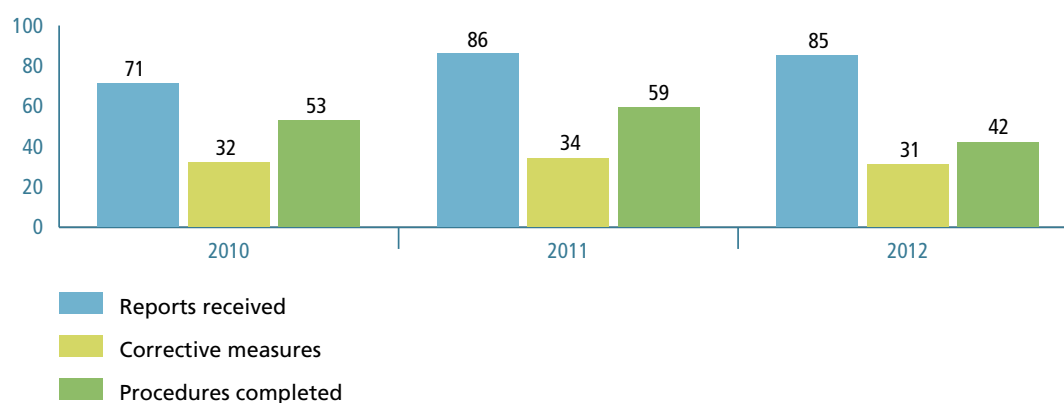
Performance indicator	Target	Result
Reports requiring immediate action; first measures taken within 10 days	100%	100%

MARKET MONITORING OF MEDICAL DEVICES: SUSPICION REPORTS AND MEASURES TAKEN

In order to guarantee a high level of safety for patients, efficient state-organised controls are of decisive importance. Distributors of medical devices in Switzerland must guarantee the conformity of the products and, on request, be able to prove it. Swissmedic receives suspicion reports, initiates the necessary corrective measures and monitors their implementation. Swissmedic works closely with the Cantonal authorities in this respect. Measures are frequently taken in consultation with international partner authorities.

Activities

- 85 reports on devices where an infringement of conformity was suspected were received by Swissmedic. In 57 cases, a market monitoring procedure was opened.
- Corrective measures were imposed in 31 opened cases, such as adjustments to the product descriptions or halting distribution.
- 42 procedures were completed.



Performance indicator	Target	Result
First activities for priority 1 cases within 10 days	100%	100%
First activities for priority 2 cases within 30 days and for priority 3 cases within 90 days	90%	96%

APPEALS

Appeals against decisions taken with regard to the market monitoring of medical devices may be lodged with the Federal Administrative Court within 30 days. That Court's judgement may in turn be contested before the Federal Supreme Court.

Activities

- In 2012, no appeals were lodged against decisions taken by the Agency in connection with the market monitoring of medical devices.
- No proceedings are pending before the Federal Administrative Court or the Federal Supreme Court.

SPECIAL ACTIVITIES AND EVENTS: MARKET MONITORING OF MEDICAL DEVICES

More export certificates once again

The demand for export certificates continued to grow in 2012. Thanks to the optimisation of internal procedures, it was possible to issue the certificates more rapidly.

Close co-operation on monitoring with the EU

In connection with cases of counterfeit breast implants and excessive metal abrasion in hip implants, the EU Commission called for more intensive national monitoring of the notification bodies. Swissmedic took an active part in preparing the necessary joint inspections.

STANDARDS

LEGAL MATTERS

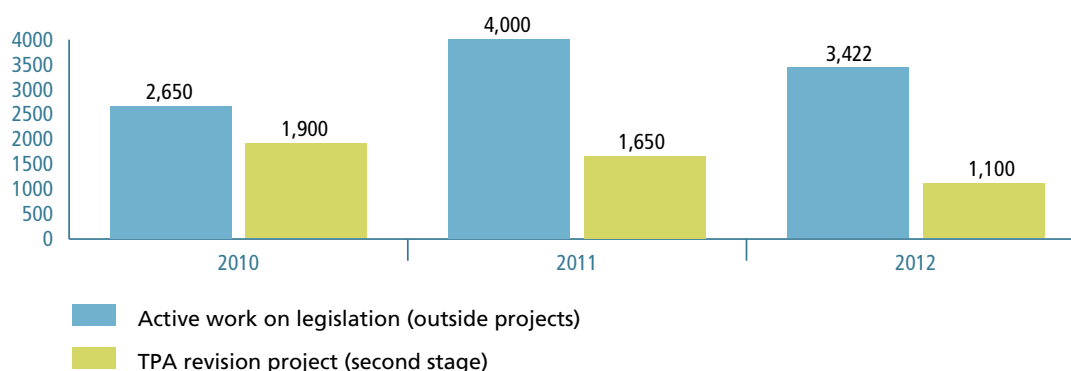
LEGISLATION

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

Activities

- On 7 November 2012, the Federal Council issued the message pertaining to the ordinary revision of the Therapeutic Products Act (second stage) to Parliament, signalling the beginning of the parliamentary consultation process regarding this comprehensive revision project. Swissmedic will take part in the work within the framework of the common project work with the Federal Office of Public Health, which will be the lead for drafting the legislation.
- The partial revision of the TPA (first stage), which was brought forward, entered into force, together with the corresponding ordinances of the Federal Council, on 1 October 2010. In order to align the existing Agency Council ordinances with the higher-ranking law and to comply with the requirements for a clearer naming of medicinal products, the Agency Council initiated a partial revision of the Ordinance on the Authorisation of Medicinal Products (VAM) and the Ordinance on the Simplified Authorisation of Medicinal Products and the Authorisation of Medicinal Products by means of the Notification Procedure (VAZV). The modifications come into force on 1 January 2013.

Human resources deployed to legislation
Hours worked (rounded to 50)



PHARMACOPOEIA

The pharmacopoeia that is valid in Switzerland consists of the European Pharmacopoeia (*Pharmacopoea Europea, Ph. Eur.*) and the Swiss Pharmacopoeia (*Pharmacopoea Helvetica, Ph. Helv.*). It contains risk-appropriate quality requirements for common, known medicinal products and pharmaceutical excipients and for certain medical devices. The requirements are drawn up in the light of current science and technology and are legally binding. The pharmacopoeia contributes significantly towards ensuring that all patients have access to therapeutic products of an equally high quality. It therefore constitutes a prerequisite for safe and effective therapeutic products. Swissmedic takes part in the elaboration of the *Ph. Eur.* on the basis of a treaty, and through the *Ph. Helv.*, it publishes supplementary prescriptions that are important on a national level.

Activities

- In 2012, Swissmedic – together with Swiss experts from industry, universities and authorities – devoted a total of 11.3 man years to specialised work in this area. 132 specialists were involved in the relevant works, with 69% being carried out by the Swiss Agency for Therapeutic Products, whose Pharmacopoeia division is Switzerland's National Pharmacopoeia Authority.
- Switzerland made a significant contribution to the preparation of the three supplements 7.3, 7.4 and 7.5 of the 7th edition of the *Ph. Eur.*, which entered into force in 2012, and to its translation into German.
- On 1 January 2012, an urgent amendment of the *Ph. Eur.* monograph "Human normal immunoglobulin for intravenous administration" was implemented. The purpose of the change was to recognise and remove impurities that had been identified and that constituted a threat to health, thus guaranteeing appropriate controls of raw materials and products and – not least – providing an important contribution towards the fight against counterfeit medicines.
- From 29 February to 2 March 2012, the WHO in Geneva organised the "International Meeting of World Pharmacopoeias". Swissmedic, like 22 other countries, presented its country-specific pharmacopoeia. The event also included discussion regarding the necessity and possibilities of further developing a pharmacopoeia in a constantly changing and increasingly globalised environment.

- The “Annual Meeting of National Pharmacopoeia Secretariats” was held in Berne on 14 and 15 May 2012. The meeting, organised by Swissmedic, offered participants the desired platform for an open exchange of opinions and experiences of key topics and on the further development of the pharmacopoeia.
- The 11th edition of the Ph. Helv. entered into force on 1 July 2012. In this new edition, and with the input of the Swiss Pharmacopoeia Commission, the general chapters plus various specific monographs were adapted to the state-of-the-art for science and technology. In addition, the structure of the general part was revised to improve its clarity. The work can still be obtained in printed form. The electronic version of the Ph. Helv., which was included with the Ph. Helv. on CD-ROM so far, was however replaced by access to a web-based online version, thus making it more user-friendly.

TECHNISCHE NORMEN

TECHNICAL STANDARDS

If a medical device complies with the valid harmonised standards published in Europe, they are considered to be in conformity. Swissmedic publishes an annual list of these harmonised standards in the Federal Gazette, and is involved in various national standards committees and technical committees. These latter analyse the effects of new or revised international standards on medical devices with regard to Switzerland, and issues comments on them where needed.

Activities

- In 2012, Swissmedic was active in four national standards committees.
- In the area of electro-medical equipment, for example, over 133 norms were agreed upon in two committee sessions.
- The Agency examines proposals regarding international standards for medical devices, takes a stance on them and represents its interests when taking part in the relevant discussions.

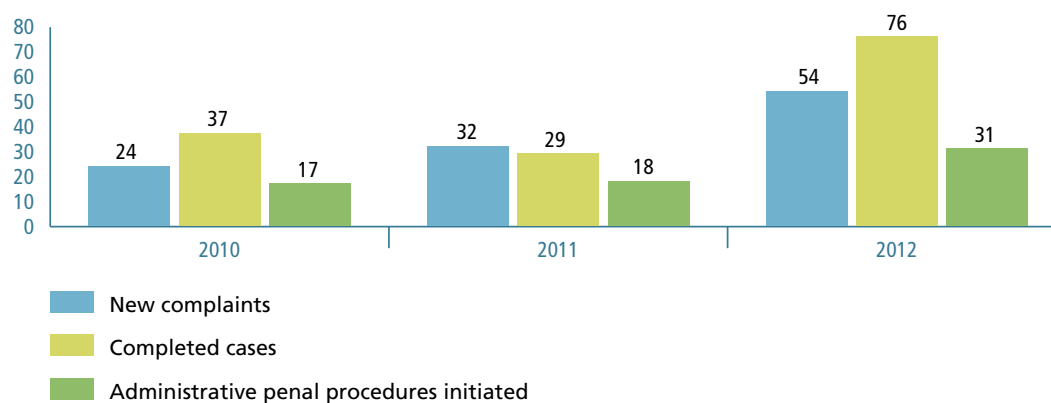
Penal Law

GENERAL DEVELOPMENT

Swissmedic is competent to conduct a significant part of criminal proceedings in connection with violations of the Therapeutic Products Act: the Agency is entitled to carry out investigations and (where fines or financial penalties are involved), to impose sanctions. Swissmedic represents the prosecution before tribunals and appellate courts.

Activities

- 54 new complaints were filed, 31 administrative penal procedures were opened, and 76 cases were closed.
- After the hiring of two additional members of staff for the Penal Law division during the first quarter of 2012, it was possible to process and complete pending cases. These additional resources also permitted the division to reduce the time taken to process new complaints and to improve the quality of the investigations.
- At the same time, it was possible to divide the work more evenly over the Agency's various areas of responsibility. Emphasis could be placed on work related to medical devices and to clinical trials, for example. In addition, the balance improved between complex cases and less significant ones, which latter nevertheless contribute strongly towards prevention when penal proceedings are initiated.
- Regarding legislation, work with a view to ratifying the Medicrime Convention continued. With the implementation of the convention, the ratifying parties will have the necessary common working basis to fight activities that even in less widespread cases almost always have international ramifications (such as import, trading abroad).

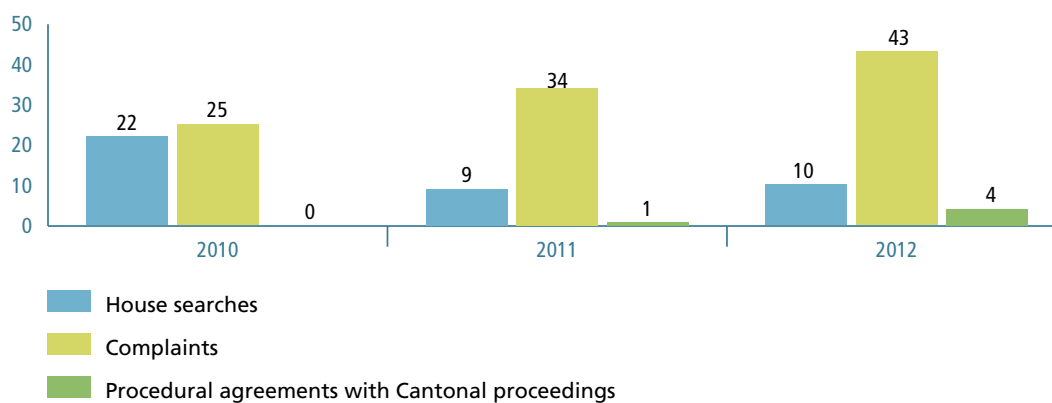


INVESTIGATIVE MEASURES

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

Activities

- In total, 10 house searches and 43 hearings were conducted.
- One complaint to the Federal Penal Court regarding the blocking of a bank account was dismissed.
- In the area of international legal assistance in penal matters, Swissmedic processed four applications submitted by Germany and France, and submitted three requests for legal assistance to Germany and Austria.
- In four cases processed by Swissmedic, there was a procedural association with Cantonal proceedings as a result of links between the cases. This possibility, foreseen under administrative penal law, leads to the optimisation of investigational measures in concrete cases. Most such cases concern imports or illegal dispensing.

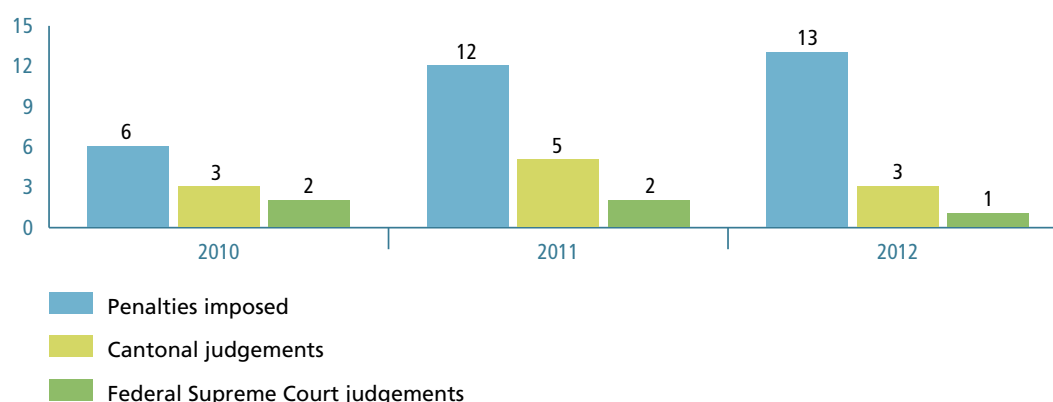


DECISIONS / JUDGEMENTS

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

Activities

- 13 penalties were imposed. Of them, 10 concerned cases of illegal trading in medicinal products (above all imports), one concerned the granting of unauthorised material benefits (Art. 33, TPA) and 2 concerned unauthorised advertising for products based on botulinum toxin.
- Three judgements by Cantonal authorities following two proceedings initiated by Swissmedic were issued. One case concerned trading in products claimed to heal severe diseases and that generated a turnover of more than three million Swiss francs. The judgement was confirmed by the Cantonal Court as the second instance. The other case concerned extensive trading in illegal medicinal products with the use of addresses and names of fictitious entities. The court of first instance acquitted the defendants. The Criminal Court (second instance) reversed this decision and sentenced the defendants, who may now appeal to the Federal Supreme Court. In addition, Swissmedic assisted the Cantonal Prosecutor's Office and took part in several Cantonal proceedings by submitting an appeal, in co-operation with the Federal Prosecutor's office (as legally prescribed in such cases). In two out of five cases, Swissmedic and the Federal Prosecutor's office were successful, and in the three others the judgement of the court in question is still outstanding. In another Cantonal case where penal proceedings were initiated, and during which Swissmedic and the Federal Prosecutor's Office had successfully opposed the planned termination of the proceedings by the Cantonal Prosecutor's Office, the defendant was subsequently sentenced and the appeal against the judgement was rejected by the Federal Supreme Court.
- In application of Art. 33, TPA, the Federal Supreme Court stated, in a judgement it issued, that the penalty foreseen by the legislator in the case of violations against Art. 3, para. 2, TPA (accepting material benefits) was in contradiction with the "principle of certainty" stated in Art. 1 of the Penal Code ("nulla poena sine lege certa"). This decision underlines the importance of the proposed modifications to the law on this issue within the framework of the ongoing revision of the TPA. In the same judgement, the Federal Supreme Court followed the arguments of the Agency, and referred to its previous jurisprudence, which is highly contested within case law: it decided that a statute of limitation can be halted not only by a judgement by the first instance but also by an acquittal.



STAKEHOLDER MANAGEMENT

INFORMATION

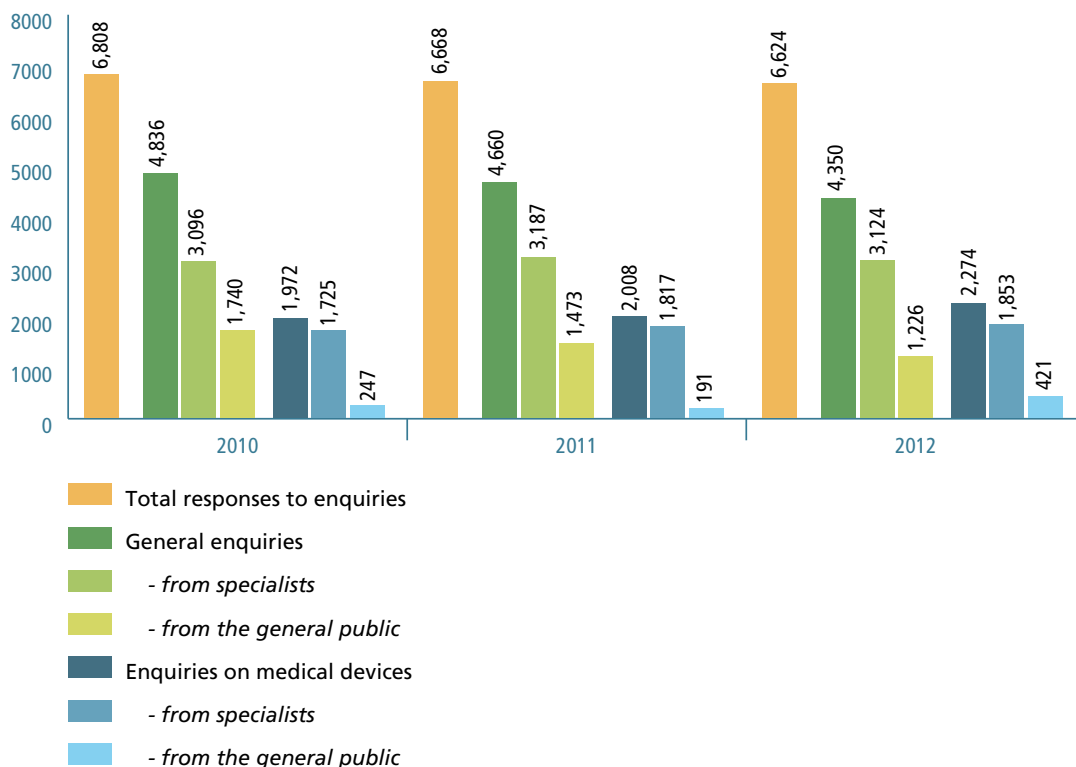
Swissmedic provides fast, specific information on new findings concerning therapeutic products that could constitute health hazards. In addition to safety-relevant information, new authorisation decisions or major changes to information on medicinal products are of considerable interest.

GENERAL ENQUIRIES

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

Activities

- In 2012, Swissmedic responded to 6,624 general enquiries. This constitutes a slight decline in comparison with the previous year.
- One-third of the enquiries concerned medical devices, on an extremely broad spectrum of issues. They concerned questions ranging from the legal basis to specific enquiries about high-tech products.
- 97% of all enquiries received a response within ten calendar days.
- The majority of enquiries concerned the interruption to supplies of the influenza vaccines Agrippal and Fluad in October, and the new publication system for medicinal product information (AIPS), developed by Swissmedic in 2012 and in operation since January 2013.
- A large number of enquiries in 2012 also concerned topics surrounding authorisation, such as first applicant protection, submissions for generics, the use of the authorisation forms, and the procedure for importing medicinal products.



Performance indicator	Target	Result
General enquiries: response provided within 10 days	95%	97%

PRESS RELATIONS

Patients and consumers wish to receive information on the benefits and risks of medicinal products and medical devices in a form that is serious, competent and easy to understand. This is where Swissmedic's press relations work comes in: to ensure that Swissmedic provides rapid, factual information. Doing so enables the Agency to create transparency towards the public and to make an important contribution to the health and safety of humans and animals.

Activities

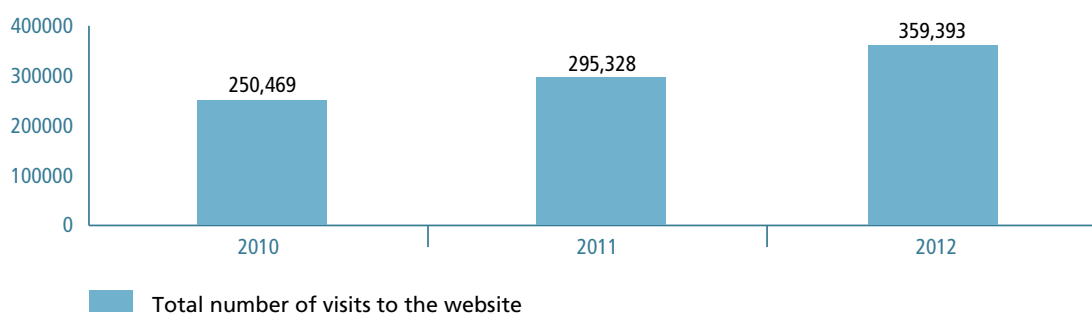
- In 2012, Swissmedic answered around 660 enquiries from journalists, meaning an increase of 140 compared with the previous year.
- During 2012, and via the official Swiss "News Service Bund", Swissmedic issued eight press releases that all attracted considerable attention. They concerned subjects such as Operation Pangea (international action week on counterfeit medicines on the Internet), the recall of Anapen emergency injectors, the halt to the distribution of certain influenza vaccines and an extension of the narcotics list "e", with regard to designer drugs.
- Other major topics handled by press relations work in 2012 included the defective PIP breast implants, counterfeit Avastin in the USA with ramifications in Switzerland, supply shortages of cancer medicines, and the financing of Swissmedic.
- Press relations work in connection with the International Regulatory Symposium held in September, in Interlaken, was particularly intensive.

PUBLICATIONS

In addition to its official monthly publication, the *Swissmedic Journal*, and its annual report, Swissmedic also publishes other types of information. This includes a newsletter, reports, guidelines, and articles regarding current topics, available on the Agency's website.

Activities

- The total number of visits to the Swissmedic website grew by nearly 20% compared with the previous year, reaching a total of nearly 360,000.
- A peak occurred at the end of October 2012, with an average of over 5,500 visits per day. This was during the preventive halt to deliveries of Novartis influenza vaccines.
- The number of visitors who access one or more sections of the website daily also rose during 2012.
- In addition to the current communications regarding safety-relevant topics, the lists of all authorised products, the electronic version of the *Swissmedic Journal* (Swissmedic's official publication), plus up-to-date information on the new system for publishing information on medicinal products on the Internet are particularly popular topics.



EVENTS

Every year, Swissmedic organises a number of events, information sessions and workshops. All of them are intended to improve co-operation with stakeholders and to disseminate the information provided. Most specialised presentations are prepared and given by Swissmedic staff, although depending on the topic, guest speakers from other authorities or from industry are invited.

Activities

- In 2012, Swissmedic organised 19 information events.
- The high point among the year's events was the "Swissmedic International Regulatory Symposium" held in Interlaken on 20 and 21 September to mark the ten years of Swissmedic's existence.
- In 2012, Swissmedic also hosted the National Pharmacopoeia Authority Meeting. A total of 31 participants from the 22 competent European pharmacopoeia authorities travelled to Berne for this edition of the annual exchange of experiences.
- For the first time, Swissmedic organised an international meeting for members of the authorities with a view to exchanging experiences on quality defects. A total of 44 participants from 18 countries attended.
- Other events concerned the areas of the advertising of medicinal products, haemovigilance, risk management, and veterinary medicines. The event organised for the launch of the electronic ADR report system and its gateway was the final one during a year that saw many interesting, educational opportunities.

LECTURES

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

Activities

- A total of 139 addresses were given at external and internal events. Their number remains constant over the last three years.
- The events concerned are not commercial, public congresses or conferences, but those intended for experts from the pharmaceutical and regulatory environment.

TRANSPARENCY

The Transparency Act, which entered into force on 1 July 2006, and the corresponding Ordinance, grant every individual the general right to access official documents. This includes documents concerning public mandates and that are drawn up or received by Swissmedic after 1 July 2006. An application to consult such documents need not be justified. The right of access may be restricted or refused in order to protect overriding public or private interests.

Activities

- In 2012, Swissmedic received 17 requests to consult documents under the Transparency Act.



COLLABORATION

Collaboration between Swissmedic and its various stakeholders is defined in the concept for national and international collaboration. The concept defines the inclusion of the 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, and that preserves and fosters mutual understanding.

NATIONAL COLLABORATION

National network

Collaboration on a national level is a fundamental aspect that permits Swissmedic to achieve the objectives specified in its legal mandate, the service mandate and the service agreement. Guaranteeing the safety of therapeutic products is of the utmost priority in the said objectives. The following stakeholder groups comprise Swissmedic's national network:

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

Activities

- The annual meeting with the Cantonal Pharmacists took place on 2 March 2012. At this event, the three co-ordination groups for the areas of law, market monitoring and medical devices that had met during the year presented their results and current topics.
- In March, August and December 2012 Swissmedic organised Regulatory Round Table meetings for representatives of the industry associations.
- Bilateral discussions with representatives of the pharmaceutical associations and representatives of associations from the healthcare sector took place throughout the year.
- A Swissmedic afternoon information session was again held in 2012, in close collaboration with the Middle European Organisation for Regulatory Affairs (MEGRA). At this event, Swissmedic representatives provided responses to questions submitted in advance on current topics in connection with the therapeutic products sector. Emphasis was placed on the Authorisation sector, with questions on the Instructions for Generics or the application of other administrative ordinances.
- In December 2012, representatives of patient and consumer organisations were invited by Swissmedic to the annual strategic exchange.

PARTICIPATION BY SWISSMEDIC IN EXTERNAL FURTHER TRAINING INITIATIVES

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

Activities

- In 2012, Swissmedic once again took an active part in the MEGRA further training course "StartUp Schweiz" and provided speakers for each module.
- Swissmedic provided support for Module 5, Regulatory Affairs, of the Masters programme "Medicinal and Industrial Pharmaceutical Sciences 2011" by the University of Zurich, with presentations by specialists.
- The seminar that was newly designed with the University of Neuchâtel in 2011 was successfully held for the second time. The topic was the regulation of therapeutic products, with emphasis on legislation on therapeutic products.
- Swissmedic experts took part in further training initiatives organised by third parties in the form of individual addresses. For example, the tasks and responsibilities of Swissmedic were presented, and the requirements and processes related to authorisation were explained.

INTERNATIONAL COLLABORATION

Collaboration among authorisation and supervisory authorities and with international organisations active in the field of medicinal products and medical devices is of great importance for the stakeholders, for Switzerland as a location, and for Swissmedic. Exchanging information is of tremendous importance in the entire process of the authorisation of medicinal products, market surveillance, and within the process of preparing new legislation on all aspects of therapeutic products. For example, this collaboration with authorities from other countries and with international institutions makes it possible to identify risks at an early stage and to initiate co-ordinated measures.

International network

In recent years, Swissmedic has consistently continued its strategy of networking with partner authorities and has now concluded information exchange agreements with virtually all internationally recognised therapeutic products authorities of a comparable standard. This includes those from the USA, Canada, Australia, Singapore, New Zealand, Japan and Ireland. Using and intensifying the existing collaboration and working towards further forms of co-operation, with clear goals, is an important strategic objective.

Activities

- Swissmedic continued its bilateral and multilateral exchange within the framework of the existing agreements, and particularly with the partner authorities of Australia, Singapore and Canada, the members of the so-called Consortium.
- The International Conference on Harmonisation Steering Committee and its expert groups met in Fukuoka, Japan on 2 – 8 June 2012 and from 10 – 15 November 2012 in San Diego, USA. In this Committee, Swissmedic represents the EFTA States and has observer status. It also plays an active part in various expert working groups.
- The International Conference of Drug Regulatory Authorities (ICDRA) took place in Tallinn, Estonia from 23 – 26 October 2012. Swissmedic took an active part, with several expert presentations on topics such as Swissmedic's collaboration with patient and consumer organisations and its risk-based approach.
- In October 2012, and after prior, in-depth discussions with Swissmedic, the Mexican Medicines Authority COFEPRIS published an agreement for its unilateral recognition of Swissmedic authorisations for innovative medicinal products.
- With regard to the monitoring of medical devices, the EU Commission urged all national authorities to strengthen their market monitoring activities. Swissmedic made a commitment to stronger controls of the notified bodies for conformity assessments. Since mid-2012, monthly international telephone conferences have been taken in order to discuss materiovigilance cases, with a view to identifying new safety problems more quickly and to initiate corrective measures.

SPECIAL ACTIVITIES AND EVENTS: STAKEHOLDER MANAGEMENT

Swissmedic International Regulatory Symposium

The Swissmedic International Regulatory Symposium was held on 20 - 21 September 2012 to mark Swissmedic's ten years of existence. Over 300 participants from Switzerland and abroad followed the addresses and podium discussions. The topic for the first day was "Safe, effective therapeutic products: how does the system function today and how will it function in the future?" The second day: "No therapeutic product is without risks: what does this mean for those affected?"

Customer survey

Within the framework of a customer survey carried out in April 2012, various stakeholders in Swissmedic assessed the agency positively, with a score of 66 points out of 100. In areas where there is a need for action, Swissmedic defined the appropriate measures and included them in its communication concept for 2012. They will be implemented in 2013/2014.

Implementation of the Falsified Medicines Directive in the EU: Inclusion of Switzerland in the list of Third Countries

On 22 November 2012, the EU Commission included Switzerland as the first country on the list of third countries, thus exempting it from the Commission's new requirements relating to the importing of active pharmaceutical ingredients for medicinal products to the EU.

Agreement with Germany's Paul-Ehrlich-Institut

At the beginning of May 2012, Swissmedic and the Paul-Ehrlich-Institut in Germany signed an agreement whereby collaboration between the two entities regarding biological medicinal products will be facilitated and fostered. This, after the agreement with the Irish authorities, is the second bilateral co-operation agreement with an EU national authority.

Agreement with the Brazilian partner authority

The Heads of Agencies Summit took place in Manaus, Brazil, from 26 – 29 November 2012. On this occasion, Swissmedic and the Brazilian Health Surveillance Agency ANVISA signed an agreement on closer co-operation in the area of therapeutic products.

TELEMATICS / INFORMATION TECHNOLOGY

IT MANAGEMENT

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

Activities

- As a result of the new Information Technology Ordinance (BlnfV) that entered into force early in 2012, Swissmedic revised its sub-strategy for the sourcing of IT in 2012. Since Swissmedic's largest sourcing partner for IT, the Federal Office of Information Technology, Systems and Telecommunications (FOITT), has restructured its range of services and its focus, Swissmedic is now no longer procuring various services from the FOITT. In 2012, various IT service providers for development, maintenance and support services were evaluated for the first time by means of public calls for tender, and integrated within the Swissmedic IT processes.
- In 2012, the internal organisation of IT was adapted to changed needs in connection with implementing the IT road map and the constantly growing portfolio of operational applications that has arisen from it.

SOLUTION DEVELOPMENT

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

Activities

- The projects to be developed in line with the 2012 road map were successfully completed. The following specialised applications became operational according to plan:
 - *Narcotics control*: the new, specialised application (MESA DB) permits the Internet-based reporting and evaluation of deliveries of controlled substances (narcotics and now also psychotropic substances). *Narcotics control*: licences for cross-border deliveries of controlled substances (import / export) can now be processed more rapidly thanks to the Internet-based specialised application NDS-WEB (National Drug Control System).
 - *Safety of medicines*: For Swiss authorisation holders (firms and primary reporters) with their own E2B-compatible drug safety systems, Swissmedic now provides an electronic gateway for the submission of individual case safety reports. The pilot phase began with five authorisation holders.
 - *Internal quality assurance*: A new documentation system provides support for the creation and linking of internal and external model documents in order to reduce the resources needed.
- Project PRIME will be the future backbone for Swissmedic's business activities. It replaces the outdated core application with a solution that is viable for the future, based on SAP products. The project, which began in 2013, is progressing according to plan and will become operational in 2013.

IT OPERATIONS, USE, MAINTENANCE AND ONGOING IMPROVEMENTS

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

Activities

- With the growing number of Swissmedic eGovernment solutions, the external partners require an increasing degree of support. Swissmedic responded to this need by providing an IT Service Centre (ISCS). The development was completed according to plan at the end of 2012. During the first half of 2013, the services will for the most part be provided internally, but as of the second half of the year the ISCS will also make external partners available.
- It was possible to maintain the excellent stability of the new SAP / ERP platform introduced on 1 January 2012 for finance and accounting and to develop it further, as well as to prepare for the new Ordinance on Fees that is in force as of 2013.
- With over 50 small projects, numerous contributions were made to maintaining the IT structure at a high level and to adapting the specialised applications to changes of the legal basis and the needs of process optimisation.

ORGANISATION

SWISSMEDIC AGENCY COUNCIL

status December 2012

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 2012

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

Aicher Lothar, Dr. Phil. nat.

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.

Fitz Gerald Reginald Edward, Dr. Phil. nat.

Follath Ferenc, Prof. Dr. med.

Frost Heiner, Dr. med.

De Geyter Christian, Prof. Dr. med.

Genton Blaise, Prof. Dr. med.

Giannopoulou-Politikakis Catherine, PD Dr. med.

Heusser Peter, Prof. Dr. med.

Hüsler Jürg, Prof. Dr. Phil. nat.

Itin Peter Hans, Prof. Dr. med.

Kraenzlin Marius Edgar, Prof. Dr. med.

Lauterburg Bernhard, Prof. Dr. med.

Leniger Tobias, PD Dr. med.

Marbet German Albert, Prof. Dr. med.

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.

Schimmelmann Benno G., Prof. Dr. med.

Schmid Beat, Dr. Phil. nat.

Schmid-Grendelmeier Peter, Prof. Dr. med.

Seger Reinhard A., Prof. Dr. med.

Strik Werner Konrad, Prof. Dr. med.

Thalmann George N., Prof. Dr. med.

Thomi Matthes Brigitte, Dipl. pharm.

Tramèr Martin Richard, Prof. Dr. med.

Weber Klaus, Dr. rer. nat.

Wilks Martin F., Prof. Dr. med.

Yerly Daniel, Dr. Phil. nat.

Zangemeister Uwe, Prof. Dr. Phil. nat.

Zimlich Klaus-Heinrich, Dr. rer. nat.

VETERINARY MEDICINES EXPERT COMMITTEE (VMEC): MEMBERS

status December 2012

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

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.

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

AUDITOR

Swiss Federal Audit Office

OUR STAFF – OUR CAPITAL

status December 2012

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

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

OUR STAFF

Abegglen Julia, Ackermann Thomas, Aeschbacher Monique, Ammann Doris, Amstutz Marco, Antonov Janine, Appenzeller Campana Katrin, Bachmann Beat, Bachmann Gabriela, 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, Bertholet Josiane, Bichsel Bernhard, Bigler Weber Cornelia, Bill Helena, Birthistle Karl Anthony, Bitschnau Monika, Blanco Philippe, Blaser Béatrice, Blaser Simon, Blum Markus, Bögli-Schlüchter Franziska, Bögli-Stuber Katja, Böhlen-Walther Caroline, Bolli Richard, Bolte Claus, Borner Stefan, Boss Doris, Boyle Charles, Brockmann Silke, Brönnimann Rainer, Brunner Stefan, Bucheli Caroline, Büchi Jacqueline, Büchler Monika, Buchs Renato, Buchter Linda, Bühler Urs, Bunn Ulrike Ursula, Bur Kathrin, Burgener Martin, Burgener Roger, Burkhalter Gabriele, Burkhalter Stefan, Burri Anton, Burri Bieri Michael, Bürzle Marc, 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, Dai Wenjuan, 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, Endress Eva-Maria, Engel Marie-Helene, Erne Franz, Erny Samuel, Escandari Markus, Essen Renate, Eyal Eva, Fahrni Ursula, Faller Claudine, Fasel-Rossier Brigitte, Federer-Oetliker Martina, Fehlmann Sabine, Felber Hanspeter, Feldmann Danila, Ferbitz-Scheurer Simone, Filgueira David, Fischer Bernt, Fischer Lisa, Flechtner Olivier, Fleischmann Ines, Francini Nicola, Friedli Franziska, Fuhrer Therese, Gamma-Lauber Madeleine, Gassmann Peter, Gassner Beat, Gaudesius Giedrius, Gautschi Matthias, Gehrig Patrick, Gehrke Christine, Geiser Hansruedi, Gertsch Rolf, Gilgen Michael, Girard Philippe, Glauser Daniel, Gloor Corinne, Gloor Eveline, Gnägi Brigitte, Gnehm Rolf, Gosdschan Tobias, Gottofrey James, Graber Fabrice, Grimm Friederike, Gross Bruno, Grubenmann Bruno, Grüter Eric, Guggisberg Mirjam, Guggisberg Stefan, Gugler Claudia, Gukic Ljubica, Gürtler Rolf, Gut Joseph, Gygax Dominik, Gysin René, Häberli Adrian, Häberli-Airoldi Isabelle, Haberstick Eva, Haenggeli Christine, Hahn Spielmann Véronique, Haldemann Silvia, Haldimann Heidi, Hammel Mario, Häni Brigitte, Häuptli Daniel, Heckenmeyer-Probst Clara, Hediger Ronald, Hein Bader Silvia, Hellstern Oliver, Heneka Bilkis, Henkel Verena, Herren Daniel, Herli Stefan, Hildebrand Pius, Hofmann Jennifer, Hofmann Linda, Hofstetter Christiane, Holdener Rudolf, Horn-Lohrens Ottmar, Hottiger Thomas, Huber Adrian, Huber Cornelia, Huber Elisabeth, Hügli Muriel, Hug-Michel Christine, Hürlimann Maria Gertrud, Iten Silvia, Jaggi Lukas, Jäggi Marco, Jahn Katrin, Jaquet Françoise, Järmann Stephan, Jaus Alexandra, Jentzsch Christoph, Jéquier Martine, Jermann Ronald, Jiskra Marianne, Jobaro Beatrice, Johner Regula, 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, Knöpfli Heinz, Kocher-Guggisberg Beatrice, Koeninger Franziska, Köföncü Evra, Kohler Scarlett, Kolb Franziska, Korschelt Lorenz, Krayenbühl Jean Christian, Kreit Boris, Kreutz Christof, Kühni Martin, Kunz-Greub Marianne, Künzle Werner, Kuster-Weber Iris, Lachat Séverine, Landgraf Cordula, Langos-Mabboux Manuela, Lauer Gabriele, Lavanchy Vincent, 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, Locher Nina, Lory Simon, Lottaz Daniel, Lucas Christine, Luginbühl-Weber Karin, Lüthi Daniel, Lüthi-Wyss Nicole, Lütolf Natalie, Maier Ralph, Manigley Catherine, Manolio Silvana, Marrer Edith, Marti Andreas, Matthes Ingo, Maurer Ruth, Meier Roger, Méroz Jean-Christophe, Meseguer Georges, Messari Annemarie, Messerli Nicole, Meusburger Madeleine, Meyer Andrea, Meyer Rita,

Meyer Simon, Meyer Urs, Minnig Sabine Monique, Mooser Guido, Mosimann Lenzin Ruth, Müller Markus-Peter, Müller-Mook Renate, Munz Thomas, Mutti Sven, Nava Gabriela, Neeser Zaugg Rosmarie, Nick André, Niggli Urs, Nolting Arno, Northoff Hubert, Nussbaum Franziska, Nüssli Simon, Oberli Aurelia, Op den Camp Roeland, Osswald Tschan Marco, Oswald Walter, Paniga Nicoletta, Pavelic Ferretti Danijela, Perret Camille, Perret Irene, Peter Nicole, Petitpierre Claude-Philippe, Pfäffli Chantal, Plüss Ruth, Plüss-Gross Fabienne, Polatti Daniela, Porporini Lucio, Pürro Michel, Putzke Jörg, Ramelli Monica, Ramseier Isabelle, Rätz Katerina, Renaudin Michael, Renftle Wolfgang, Rethage Janine, Reusser Daniel, Richter Thomas, Rieder Barbara, Riedl Jutta, Riesen-Beer Sabine, Robbiani-Meier Corinne, Rogl Schmid Jeannette, Roux Catherine, Ruch Claudia, Rüegeegger Ruth, Rüesch-Kirkwood Morven, Rufenacht Francine, Rumo Anton, Ryf Alfred, Salvisberg Gabriela, Sandrowski-Ramseyer Alice, Sänger Michael, Santos Nicole, Saurer Isabella, Schaffner Nils, Schärer Christian, Schäublin Martina, Scheidegger Anita, Scheidegger Michelle, Scheidegger René, Schläfli Ernst, Schlegel Andreas, Schmid Peter, Schmid Susanne, Schmidkunz Egger Dorit, Schmitt Klaus, Schnetzer Jürg Heinz, 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, Sieg Anna, Siegert Ralf, Sigel Ursula, Skoko Lena, 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, Terkovics Attila Leo, Teuscher Françoise, Thomas Sabine, Thürig Soltermann Eva, Toma Valeriu, Torriani Wymann Kay Isabella, Trapp Christiane, Tschalär Yolanda, Tschirren Markus, Tschümperlin Heidi, Vihertola Mari Kaarina, von Mühlönen Eva, Vozeh Beatrix, Vuilleumier Monika, Wacker Christoph, Wagner Jan, Walter Katharina, Walter-Blaser Louise, Walther Barbara, Wälti Markus, Wälti Rudolf, Waser René, Weber Heidi, Wegmann Barbara, Weiss Markus, Weissmahr Richard, Weitz Manfred, Weix Janine, Weyermann Philipp, Whitehead Frances, Whitehead Margaret, Winkler Lorenz, Winzenried Therese, Wittich Monika, Wittke Bärbel, Wittwer Stefanie, Wüest Patrick, Wüthrich Karin, Wyss Brigitte, Wyss Martin, Wyss Sonja, Wyss-Romanello Sabine, Zaugg Kunz Sandra, Zbinden Kaessner Eva, Zemp Markus, Zenhäusern Gabriela, Ziak Martin, Ziehli Salvisberg Mariette, Zimmermann Esther, Zimmermann Marion, Zurbuchen Andreas, Zurkinden Tanja, Zwahlen Roland.

INCOME STATEMENT 2012

(in KCHF)	2012	2011
Procedural fees and income further to art. 69 TPA	26,598	24,346
Levies on sales	40,138	39,789
Other income	41	58
Federal contribution	15,200	15,624
Other operating income	177	180
Total income	82,154	79,997
Services for third parties	-1,586	-1,668
Personnel	-63,935	-59,195
Rental, maintenance, energy, transport and insurance	-3,274	-3,153
Administration	-5,001	-4,798
IT	-8,999	-8,692
Other expenditure	-425	-294
Amortisation	-3,050	-2,431
Total operating expenditure	-86,270	-80,231
Operating income before financial result	-4,116	-234
Financial income	7	49
Financial expenditure	-246	-245
LOSS FOR THE FINANCIAL YEAR	-4,355	-430

PRODUCT ACCOUNTING 2012

(in KCHF)

Products Products groups	Principal funding of products based on 2011-2014	Expenditure	Procedural fees income	Results
Legal foundations	Federal contributions	-6,692	0	-6,692
Technical standards	Fees	-3,110	0	-3,110
Total Standards products group		-9,802	0	-9,802
Information for the general public	Federal contributions	-5,347	1	-5,346
Information for the therapeutic products branch	Fees	-1,722	167	-1,555
Total Information products group		-7,069	168	-6,901
Marketing authorisation	Fees	-30,497	14,373	-16,124
Licences	Fees	-14,008	9,178	-4,830
Total Market Access products group		-44,505	23,551	-20,954
Vigilance of medicinal products	Fees	-9,107	0	-9,107
Vigilance of medical devices	Federal contributions	-2,905	0	-2,905
Market monitoring of medicinal products	Fees	-7,902	1,489	-6,413
Market monitoring of medical devices	Federal contributions	-1,921	0	-1,921
Total Market Surveillance products group		-21,835	1,489	-20,346
Penal law	Federal contributions	-2,360	801	-1,559
Total Penal Law products group		-2,360	801	-1,559
Services for third parties	Fees	-706	590	-116
Total Services for third parties products group		-706	590	-116
Other operating expenditure		8		8
Total Products		-86,269	26,599	-59,670
Levies on sales				40,138
Federal contributions				15,200
Other income				217
Financial result				-240
Operating income				-4,355

PRODUCTS FUNDED MAINLY BY THE CONFEDERATION 2012

(in KCHF)

Products	Expenditure based on product accounting	Procedural fees income	Result based product accounting
Legal foundations	-6,692	0	-6,692
Information for the general public	-5,347	1	-5,346
Vigilance of medical devices	-2,905	0	-2,905
Market monitoring of medicinal products	-1,921	0	-1,921
Penal law	-2,360	801	-1,559
Total products funded mainly by the Confederation	-19,225	802	-18,423
Total Federal contributions			15,200
Expenditure surplus			-3,223

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 2012

(in KCHF)	Balance sheet at 31.12.2012	Balance sheet at 31.12.2011
Cash and cash equivalents	2,662	2,416
Receivables from sales and services	18,153	16,967
Other receivables	28	28
Active accruals	35	58
Current assets	20,878	19,469
Fixed assets	2,776	2,963
Immovable property	62,068	55,645
Intangible assets	9,534	3,616
Capital assets	74,378	62,224
TOTAL ASSETS	95,256	81,693
Commitments on sales and services	6,627	6,194
Other commitments	3,033	553
Passive accruals and short-term provisions	3,269	3,750
Short-term commitments	12,929	10,497
Firm advances	20,000	10,000
Provisions for loyalty bonuses	2,337	2,122
Provision for pension fund commitments (net)	24,175	18,904
Long-term commitments	46,512	31,026
Endowment capital	14,500	14,500
Reserves	25,670	26,100
Loss	-4,355	-430
Own capital	35,818	40,170
TOTAL LIABILITIES	95,256	81,693

PUBLISHER:

Swissmedic

Swiss Agency for Therapeutic Products

Hallerstrasse 7

P.O. Box

3000 Bern 9

P: +41 31 322 02 11

F: +41 31 322 02 12

www.swissmedic.ch

Hallerstrasse 7

P.O. Box

CH-3000 Bern 9

P: +41 31 322 02 11

F: +41 31 322 02 12

www.swissmedic.ch
