SÚKL STATE INSTITUTE FOR DRUG CONTROL

ANNUAL REPORT 2013

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Similarly as in previous years, in 2013, the State Institute for Drug Control (hereinafter referred to as the "Institute") again closely cooperated with the Ministry of Health of the Czech Republic, particularly in the implementation of tasks within the scope of cooperation with the EU as well as in the preparation and subsequent legislative process of adoption of new legal regulations with significant impact on the activities of the Institute. In addition, there has been intensive cooperation with other state authorities such as the Ministry of Foreign Affairs, the Institute for State Control of Veterinary Biologicals and Medicines in Brno, the State Office for Nuclear Safety and the Czech Agriculture and Food Inspection Authority.

The Institute is actively involved in international cooperation in working groups and committees, especially within groups of the EU Council, the European Commission and the European Medicines Agency, the World Health Organization (WHO) or the European Directorate for the Quality of Medicines and Health Care.

In 2013, the project titled "Increasing the Efficiency of Administrative Proceedings of the State Institute for Drug Control" was successfully completed. It is expected to contribute to an increase in the effectiveness of the performance of the Institute, to ensure greater transparency of individual administrative acts and to reduce the administrative burden of regulated entities.

In the area of medicines licensing, more than 500 applications for new marketing authorization of a medicinal product were submitted, and an extension of an existing authorization was applied for in 655 cases. A total of 516 applications were associated with revocation of a marketing authorization. There has been an increase in received applications for parallel imports of medicinal products, while 99 parallel imports were allowed.

The Institute continued to assess borderline products, received applications for authorization/announcement of a clinical trial, issued opinions on specific therapeutic programmes and filed notifications of use of non-authorized products. Intensive pharmacovigilance activities of the Institute continued and more than 2,000 primary reports of suspected adverse reactions to medicines from the Czech Republic were received.

Supervisory activities of the Institute covered the areas of laboratory testing, pharmacies and wholesale distribution, manufacturing of medicines, good clinical and laboratory practices, quality defects, advertising of medicinal products and safety of medical devices. The Institute intensively focused on the field of illegal and counterfeit medicines, issued opinions for the release of medicinal products imported from third countries and opinions for the Police of the Czech Republic and the Customs Administration.

In the area of advertising regulation, the Institute concluded 21 administrative proceedings that resulted in 33 fines of CZK 4.8 million.

According to the Act on Public Health Insurance, the Institute decided on maximum prices and reimbursement of medicinal products and foods for special medical purposes, through administrative proceedings.

Following the amendments to the relevant legislation, the Department of the State Agency for Cannabis for Medical Use was established on 1 January 2013, whose activities consist in granting licenses to grow cannabis for medical use, control of compliance of its cultivation, processing and storage with legislative requirements, ensuring purchases of the grown and harvested cannabis for medical use and its safe storage, transport and distribution, or ensuring its export outside the territory of the Czech Republic.

For professionals as well as for the general public, data about authorized medicinal products, approved specific therapeutic programmes and foods for special medical purposes with all details within the scope of the database of authorized medicinal products were published regularly.

The Institute also fulfilled its reporting obligations, both to the professional and the general public. It adminstered websites – www.sukl.cz, www.olecich.cz and www.nebezpecneleky.cz – including two Facebook profiles. It issued a publication for the general public called infoLISTY seven times and replied to more than 530 questions through the web service "Ask Us" („Zeptejte se"). In 2013, the Institute also intensively cooperated with universities of the third age, public libraries and senior clubs across the Czech Republic, for the members of which the Institute organized informative and educational talks in cooperation with the author of the book Stories of Medicines. Together with the Ministry of Health, it held a press conference on the results of a survey of the Institute titled "The Actual Use of Medicines".


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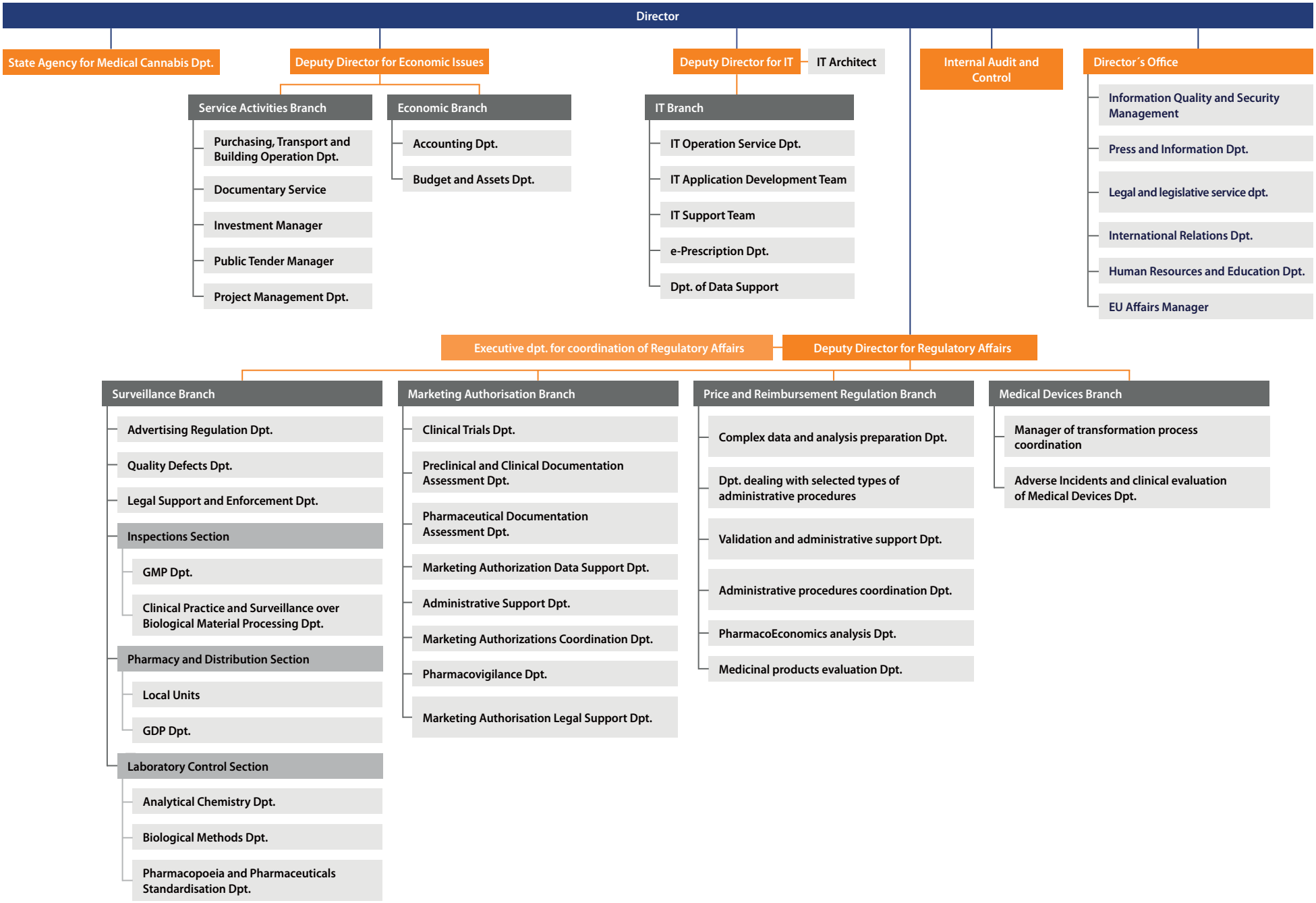
In order to increase the efficiency of the organization of work, the Press Department, Legal and Legislative Department, Department of Human Resources and Education, Department for International relations, Managers from the Division of Quality and Information Safety Management and Manager for European Affairs were removed from the direct managing competence with effect from 1 May 2013 based on an evaluation of the organizational structure of the Institute. The above units were included in a new division of the Director's Office which was managed by the Head of the Director's Office.

The organizational structure of the Institute effective as of 31 December 2013 forms part of this Report. The organizational structure indicating the names of managerial staff is provided on the website of the Institute.


Director
State Agency for Medical Cannabis Dpt.
Deputy Director for Economic Issues
Service Activities Branch
Purchasing, Transport and Building Operation Dpt.
Documentary Service
Investment Manager
Public Tender Manager
Project Management Dpt.
Economic Branch
Accounting Dpt.
Budget and Assets Dpt.
Deputy Director for IT
IT Architect
IT Branch
IT Operation Service Dpt.
IT Application Development Team
IT Support Team
e-Prescription Dpt.
Dpt. of Data Support
Internal Audit and Control
Director´s Office
Information Quality and Security Management
Press and Information Dpt.
Legal and legislative service dpt.
International Relations Dpt.
Human Resources and Education Dpt.
EU Affairs Manager
Executive dpt. for coordination of Regulatory Affairs
Deputy Director for Regulatory Affairs
Surveillance Branch
Advertising Regulation Dpt.
Quality Defects Dpt.
Legal Support and Enforcement Dpt.
Inspections Section
GMP Dpt.
Clinical Practice and Surveillance over Biological Material Processing Dpt.
Pharmacy and Distribution Section
Local Units
GDP Dpt.
Laboratory Control Section
Analytical Chemistry Dpt.
Biological Methods Dpt.
Pharmacopoeia and Pharmaceuticals Standardisation Dpt.
Marketing Authorisation Branch
Clinical Trials Dpt.
Preclinical and Clinical Documentation Assessment Dpt.
Pharmaceutical Documentation Assessment Dpt.
Marketing Authorization Data Support Dpt.
Administrative Support Dpt.
Marketing Authorizations Coordination Dpt.
Pharmacovigilance Dpt.
Marketing Authorisation Legal Support Dpt.
Price and Reimbursement Regulation Branch
Complex data and analysis preparation Dpt.
Dpt. dealing with selected types of administrative procedures
Validation and administrative support Dpt.
Administrative procedures coordination Dpt.
PharmacoEconomics analysis Dpt.
Medicinal products evaluation Dpt.
Medical Devices Branch
Manager of transformation process coordination
Adverse Incidents and clinical evaluation of Medical Devices Dpt.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3.1 Cooperation with the Ministry of Health of the Czech Republic and other state institutions in the Czech Republic

In 2013, the Institute very closely cooperated with the Ministry of Health of the Czech Republic, particularly in the implementation of tasks within the scope of cooperation with the EU, namely in the field of pharmaceuticals and medical devices as well as in the preparation and subsequent legislative process of adoption of new legal regulations with significant impact on the scope of operation of the Institute.

A close cooperation continued in the legislative process concerning the transposition of Directive 2010/84/EU and Directive 2012/26/EU, both these directives amending Directive 2001/83/EU as regards pharmacovigilance. The Institute also participated in the transposition of Directive 2011/62/EU, which amends the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. This cooperation in the legislative field was completed by the issuance of Act No. 70/2013 Coll. and amendments to implementing regulations – amendments to Decree No. 228/2008 Coll., Decree No. 54/2008 Coll., and Decree No. 84/2008 Coll. This completed the process of the transposition of the above Directives.

In addition, the Institute cooperated with the Ministry of Health of the Czech Republic also in the legislative work on the Parliament's draft amendments to the Act on Pharmaceuticals and Act on Dependence-Producing Substances permitting the use of cannabis for medicinal purposes. These works have been completed and Act No. 50/2013 Coll. came into force on 4 March 2013.

During the year, cooperation between the Institute and the Ministry of Health of the Czech Republic as regards preparation of a new act regulating the area of medical devices fully developed. The successful preparation and progress in the legislative process were somewhat delayed due to the dissolution of the Chamber of Deputies of the Parliament; however, in the first weeks of 2014, a draft of the new act and a supporting act were re-submitted to the Chamber of Deputies of the Parliament and nothing stands in the way of the successful completion of the legislative process anymore.

Nevertheless, despite the activities associated with these major tasks, the Institute did not neglect its cooperation in the preparation of other legal regulations governing other areas of relevance to the operation of the Institute.

Legal requirements governing individual areas of professional activities were further explained by the Institute in the guidelines issued thereby. In these guidelines, it made the public familiar with guidelines issued by the European Commission and the European Medicines Agency.

In the course of the last year, particularly cooperation with the Ministry of Foreign Affairs of the Czech Republic and the Ministry of Health of the Czech Republic continued in the preparation of opinions of the Czech Republic on preliminary questions raised by the European Court of Justice related to the sphere of competence of the Institute.

Cooperation with the Institute for the State Control of Veterinary Biologicals and Medicines in Brno and with the State Office for Nuclear Safety continued also in 2013. The Institute's partners for the sphere of market surveillance were the Czech Agriculture and Food Inspection Authority, Czech Trade Inspection and the Czech Customs Administration.

Cooperation in the preparation of standards governing the area of medical devices with the Czech Office for Standards, Metrology, and Testing was going on.

3.2 Cooperation with EU Institutions and Other Foreign Partners

The Institute is actively involved in international cooperation within more than 70 working groups and committees. These concern mainly the working groups of the EU Council, European Commission and its agency – the European Medicines Agency (EMA), but also the bodies of the World Health Organisation (WHO), Council of Europe and its European Directorate for the Quality of Medicines and Health Care (EDQM), or the Organisation for Economic Cooperation and Development (OECD). Last but not least, the Institute is also actively involved in informal groups that bring together experts from various countries specialized in pharmaceuticals, medical devices or tissues and cells. One of these groups is a network of the Heads of Medicines Agencies (HMA) based on voluntary membership, in whose activities the Institute also regularly participates. The constant priorities of the Institute include, in particular, its representation in the EMA scientific committees. In 2013, at the EU level the Institute participated completion of negotiations on the draft regulation on clinical trials, and it also actively contributed to the discussion on legislation regarding medical devices and fees payable to the EMA for pharmacovigilance activities. In 2013, a total of 381 business trips to more than 35 different countries took place. The Institute also hosts at least one international event every year. In November 2013, a meeting of three working groups organized by the Institute in cooperation with EDQM was held in Prague. It was an annual meeting of the European network of inspection laboratories for centrally authorized medicinal products (CAP), a working group on counterfeit medicines (COUN WG) and a working group focusing on the surveillance of the market of medicinal products authorised via the mutual recognition procedure and decentralized procedure.

The link between strategic international issues within the executive support of the Heads of Medicines Agencies HMA, the

Management Board of the European Medicines Agency, the European Commission's Pharmaceutical Committee and others, which was established as a result of introducing the position of the Manager for European Affairs, ensures proper continuity, consistency and timeliness of administration of international issues at the strategic level and commitments of the Czech Republic arising therefrom, in the professional area as well as in terms of drug policy. This step contributes significantly to enhancing the prestige of the Institute and the Czech Republic and to increasing the efficiency of integration into the network of EU regulatory authorities consisting of HMA, EMA and the Commission and at other international forums. Strategic information is in the appropriate extent transferred to the national level through membership in advisory boards of the Government/Ministry of Health of the Czech Republic for the National Antibiotic Program, of the Ministry of Agriculture of the Czech Republic for antimicrobials and other advisory boards as needed by the management of the Institute. Professional cooperation with the field in the area of anti-infectives is implemented through leading the Advisory Council for Anti-Infectives, the successful completion and the publication of the List of Essential Anti-Infectives and its update in 2013.

3.3 Projects

In 2013, the project titled "Increasing the Efficiency of the Administrative Proceedings of the State Institute for Drug Control" co-financed by the European Social Fund under the Operational Programme Human Resources and Employment (HRE) was successfully completed. The implementation of the project outcomes results in increased performance efficiency of the Institute, greater transparency of individual administrative acts and reduction of administrative burden of regulated entities. The positive impact is also reflected in the development of knowledge of employees, especially in the field of information system architecture and project management. As part of the project dealing with the implementation of project management at the Institute, a project management methodology based on the principles of internationally applied methodologies was established. The outcome of the Computerisation of Administrative Proceedings Project are analyses of processes defined by the Institute that are being introduced or have been introduced already but require further development in order to increase user comfort.

4.1 Record System

In 2013, the electronic record system of the Institute registered 54,194 delivered documents and 46,819 sent documents (see Table 1). The priority of official document delivery is delivering using data mailboxes and the Institute thereby continues in the electronic processing of individual areas of its office work (see Table 2).

MARKETING AUTHORIZATION BRANCH

Each proprietary medicinal product is subject to a marketing authorization prior to placing on the Czech market. Within the scope of the marketing authorization procedure, the Marketing Authorization Branch assesses dossiers, in which the future marketing authorization holder evidences the safety, efficacy and quality of the product. Indications, contraindications, product posology, classification for dispensing, as well as package leaflets for patients and proposed labelling of the medicinal product are also subject to assessment. At the time of issuance of the authorization, the marketing authorization holder is informed of the approved summary of the product characteristics, which serves doctors and health care professionals as a key source of information about the medicinal product.

The Institute issues its opinions/decisions where doubts arise as to whether a medicinal product is a medicinal product subject to marketing authorization or an active substance or another, or where applicable, a homeopatic product, either upon request or on its own initiative. The decision of the Institute is essential for the regulatory regimen of the assessed product and for the subsequent process the applicant has to employ prior to placing the product on the Czech market.

Moreover, the Institute issues opinions on applications for specific therapeutic programmes for the Ministry of Health of the Czech Republic. Specific therapeutic programmes allow for the use, distribution, and dispensing of non-authorized medicinal products for human use under certain conditions.

The Department of Clinical Trials assesses applications for authorization/notifications of clinical trials, applications for hospital exemptions, performs surveillance over the conduct of clinical trials, issues opinions for project assessment when trials are not regulated by the Institute, and maintains records on use of non-authorized medicinal products.

The Pharmacovigilance Department is responsible for the surveillance over the risks related to the administration of medicinal products. This surveillance includes particularly the collection and evaluation of information from the reports on suspected adverse reactions filed by health care professionals and patients as well as information obtained in non-interventional post-authorization safety studies.

In 2013, an amendment to the Act on Pharmaceuticals came into effect, which had a major effect on the activities of the Marketing Authorization Branch mainly in the area of pharmacovigilance, the hospital exemption was established and procedural changes in the authorization of medicinal products were made.

Table 1 – Registration of documents going through the Institute in 2011 – 2013

Mail room	2011	2012	2013
Received documents	59,355	61,868	54,194
Dispatch room	**2011**	**2012**	**2013**
Sent documents	46,840	57,607	46,819

Table 2 – Overview of communication channels in 2013

	Mail room, dispatch room	Data messages	E-mail messages	Electronic notice board	Total
Received documents	43,513	4,774	5,907	–	54,194
Sent documents	10,868	29,541	1,803	4,607	46,819

4. Regulatory activities of the Institute

Table 3 – Marketing authorization applications

cont. table 3 see page 19 »

	Submitted in 2013	Decided in total in 2013	Pending applications as of 31 December 2013
Applications for marketing authorization	**499**	**602**	**833**
▪ of which national	40	46	90
▪ of which MRP – RMS	6	7	32
▪ of which DCP - RMS	32	43	41
▪ of which CMS (MRP and DCP)	421	506	670
Switch from national to the MRP/DCP	**0**	**0**	**3**
Renewals of marketing authorization	**582**	**739**	**2,289**
▪ of which national	132	353	1542
▪ of which RMS	41	40	30
▪ of which CMS	409	346	717
National variations to marketing authorization	**4,452**	**4,447**	**932**
▪ of which IA	1,530	1,270	1
▪ of which IB	696	787	4
▪ of which II	867	1,503	558
▪ of which bulk NAR variations (from 4 August 2013)	1,195	723	349
▪ of which PI and labelling	164	164	20
MRP variations to marketing authorization	**4,312**	**4,802**	**1,613**
▪ of which IA	18	44	2
▪ of which IB	130	144	16
▪ of which II	13	71	6
▪ of which PI and labelling	90	100	22
▪ of which bulk MRP variations	4,061	4,443	1,567
Revocation of marketing authorization	**547**	**516**	**15**
Parallel import	**144**	**99**	**64**
Extension of parallel import	**5**	**4**	**1**

» cont. table 3 from page 18

	Submitted in 2013	Decided in total in 2013	Pending applications as of 31 December 2013
Variation to parallel import	**46**	**35**	**10**
Revocation of parallel import	**8**	**8**	**0**

Note: The table does not reflect the numbers of pending applications from the previous period.
Explanatory notes: RMS – Reference Member State, CMS – Concerned Member State, MRP – marketing authorization via mutual recognition procedure, DCP - marketing authorization via decentralised procedure

In 2013, the Commission Regulation (EU) No. 712/2012 also came into effect, which completely changed the system of submission and processing of variations to marketing authorizations for medicinal products authorized by the national procedure (hereinafter referred to as the "national registration") and it unified them with variations to the marketing authorizations for medicinal products authorized using the mutual recognition procedure (MRP) and the decentralized procedure (DCP) (hereinafter referred to as the "MRC/DCP").

4.2 Marketing authorization of medicinal products

Applications for new authorization

In 2013, a total of 535 applications were submitted for scientific assessment following successful validation. Most of them were applications for MRP/DCP authorizations confirming the trend of previous years when the number of applications for national authorizations was gradually decreasing.

Table 4 – Applications for exemption from the sunset clause

	Procedures conducted in 2013
Administrative procedures for granting of an exemption from the sunset clause	**30**
▪ **of which initiated based on an application**	**25**
▪ **of which ex officio initiated administrative procedures**	**5**
▪ granted	9
▪ declined	0
▪ suspended as undue	8
▪ suspended as unjustified	2
▪ suspended for failure to supplement	6
▪ withdrawal of application	4

Note: The table does not reflect the numbers of pending applications from the previous period

In the area of DCP procedures, the number of applications, where the Czech Republic is involved as the Reference Member State, is essential. In 2013, 38 applications were filed for leading the MRP/DCP procedures where the Czech Republic acts as the Reference Member State.

Renewals of marketing authorization

In 2013, a total of 655 applications were submitted for scientific assessment after successful validation. Most of them were applications for renewal of MRP/DCP authorizations, the number of received and validated applications for renewal of national authorizations decreased.

Variations of marketing authorizations

In that year, the Commission Regulation (EU) No. 712/2012 on variations to national authorizations came into force which unified the procedures for submission and processing of applications for variations to the terms of marketing authorizations across the EU. In 2013, there was a slight decrease in the number of received applications for variations to MRP/DCP authorizations and due to the transition to a new system even in the number of received applications for variations to national authorizations.

Parallel import

In 2013, there was an increase in applications received, 99 parallel imports were permitted.

Table 5 – Applications for distinguishing borderline products submitted by legal entities and natural persons in addition to state administration bodies

Pending from the previous period	Applications received in 2013	Number of issued decisions	Number of issued opinions	Of which number of rejections	Of which suspended/ withdrawn	Brought forward to the next year
5	18	10	6	0	1	6

Revocation of marketing authorization

In 2013, 516 applications for revocation of marketing authorization were decided.

Expiry / non-expiry of marketing authorizations

In 2013, the Institute conducted 30 administrative procedures regarding the granting of exemptions from the sunset clause. The Institute received one appeal against the issued decisions which was resolved by reconsideration.

During the year 2013, in 211 marketing authorization numbers the sunset clause was applied under Section 34a of the Act on Pharmaceuticals, and the marketing authorization for these medicinal products expired.

4.3 Borderline products assessment

The assessment of borderline products and issuance of decisions and opinions on product classification were carried out under similar conditions as in 2012. For state administration bodies the Institute issued opinions on 11 products in total.

In 2013, the Institute issued 10 decisions and 6 opinions for distinguishing borderline products submitted by legal entities and natural persons in addition to state administration bodies. In 5 cases the Institute classified the products as medicinal products, in 11 cases the products were not classified as medicinal products. One appeal was filed against one decision issued on request. Consultations on 17 products were carried out in the area of borderline products.

International cooperation (work for CHMP)

In cooperation with the European Medicines Agency (EMA), the Institute joined as a rapporteur and a co-rapporteur in the assessment of 4 centralized authorizations, peer reviews for 3 authorization, variations for two authorizations and renewal for two authorizations. In 2013, the Institute assessed as EU PSUR Reference Member State 7 PSURs within the EU-PSUR Work Sharing procedure (a procedure of the European worksharing in the assessment of PSUR). In addition, it also actively commented on many other centralized procedures and problems with medicines safety.

4.4 Clinical trials on pharmaceuticals

In 2013, negotiations in the European Council regarding the Regulation on Clinical Trials (CTs) continued, in which the Institute participated very intensively, specifically in 18 working meetings in Brussels. Furthermore, the Institute participated in 9 meetings of the CAT working group (Committee for Advanced Therapies), in 6 working meetings of the CTFG group (Clinical Trials Facilitation Group) and in 1 meeting of the Ad hoc group for implementation of Directive 2001/20/EC.

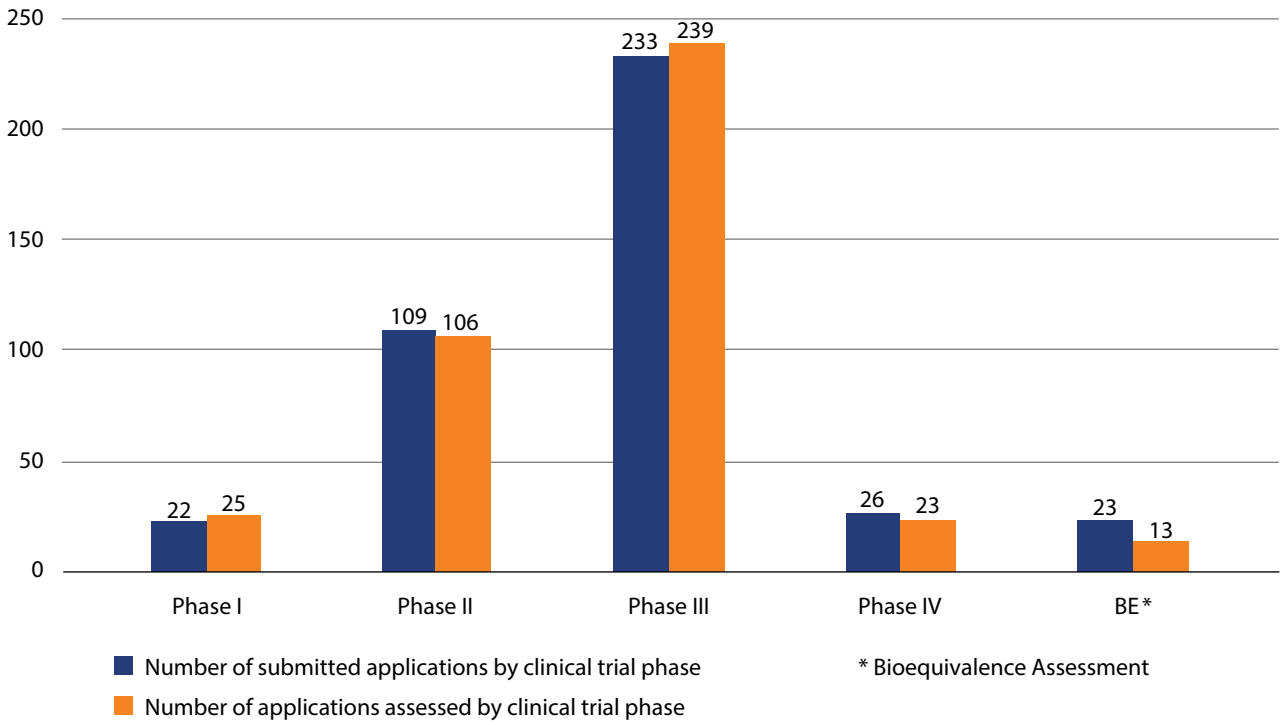
The Institute continued its involvement in the Voluntary Harmonisation Procedure (VHP), which is a voluntary harmonization process of joint assessment of clinical trial documentation managed by the EMA Clinical Trial Facilitation Group. Within the VHP, 36 clinical trials were submitted and assessed in the Czech Republic until mid-2013 which again represented an increase of more than 20 % compared to 2012. Due to the workload of assessors and the duty to ensure assessing of the applications using the national procedure, the participation of the Institute in the VHP was temporarily interrupted.

The total number of applications for authorization/notification of clinical trials submitted in 2013 remained the same

Table 6 – Clinical trials

	Pending from the previous period	Applications received in 2013	Number of decisions issued in 2013	Of which number of rejections	Of which withdrawn
Application for CT authorization	23	121	124	–	7
Notification of CTs	58	292	282	–	22
Notification of amendment to CTs	–	2,402	2,776	–	–

Fig. 1 – Number of applications submitted and assessed in 2013 by clinical trial phase



compared to the previous year 2012, a decrease in the number of applications was reported unlike in other EU MS. Most of the applications are Phase III studies: international, multicentric, randomised, blinded, placebo- or active-substance controlled clinical trials conducted by foreign sponsors. Of the total number of 413 applications for authorization/notifications of clinical trials, 12 clinical trials were submitted by non-commercial entities (academic research); 8 applications involved orphan drugs (medicines for rare diseases) and in 34 cases these were clinical trials that included children or were directly designated for pediatric population. During the assessment process, 29 applications for authorization/notifications of clinical trials were withdrawn which is 7 applications less than in 2012. No application was rejected by the Institute. The number of submitted amendments to clinical trials was 17 % higher than in the previous year.

Table 7 – Indication groups of clinical trials assessed in 2013

Indication groups	Number
Oncology	83
Respiratory + Allergology	30
Healthy volunteers	31
Neurology	29
Cardiovascular system	4
Rheumatology	41
Other	48
Psychiatry	13
Diabetology	16
Infectious diseases	23
Urogenital diseases	8
GIT	8
Hematology	23
Metabolic defects + Endocrinology	7
Dermatology	9
Transplantation	8
Ophthalmology	2
Gynecology	5
ENT	5
Anesthesiology and Resuscitation	2
Pain	1
Examination methods	4
Internal medicine	0

In 2013, 11 ethics committees for multicentric clinical trials were active. One working meeting of the representatives of the Working Group for Multicentric Ethics Committees and the representatives of the Institute's Department of Clinical Trials took place. One meeting with representatives of regulated entities and interest groups (AIFP, ČAFF, professional companies, ethics committees, contract research organizations, Forum of Ethics Committees, representatives of the Union of Patients) was convened.

The Institute organized four workshops for regulated entities (two for sponsors, contract researching organizations, monitors, academic research and two for academics and manufacturers of advanced therapy medicinal products).

In 2013, 6 applications (grant projects in particular) for project assessment were assessed to determine whether it was a clinical trial regulated by the Institute or not.

Specific Therapeutic Programmes

55 applications for opinions on proposed specific therapeutic programmes were submitted, which is 6 applications more than in 2012. Opinions were issued for 56 applications; 3 were pending and brought forward to the next year.

Use of Non-authorized Medicinal Products

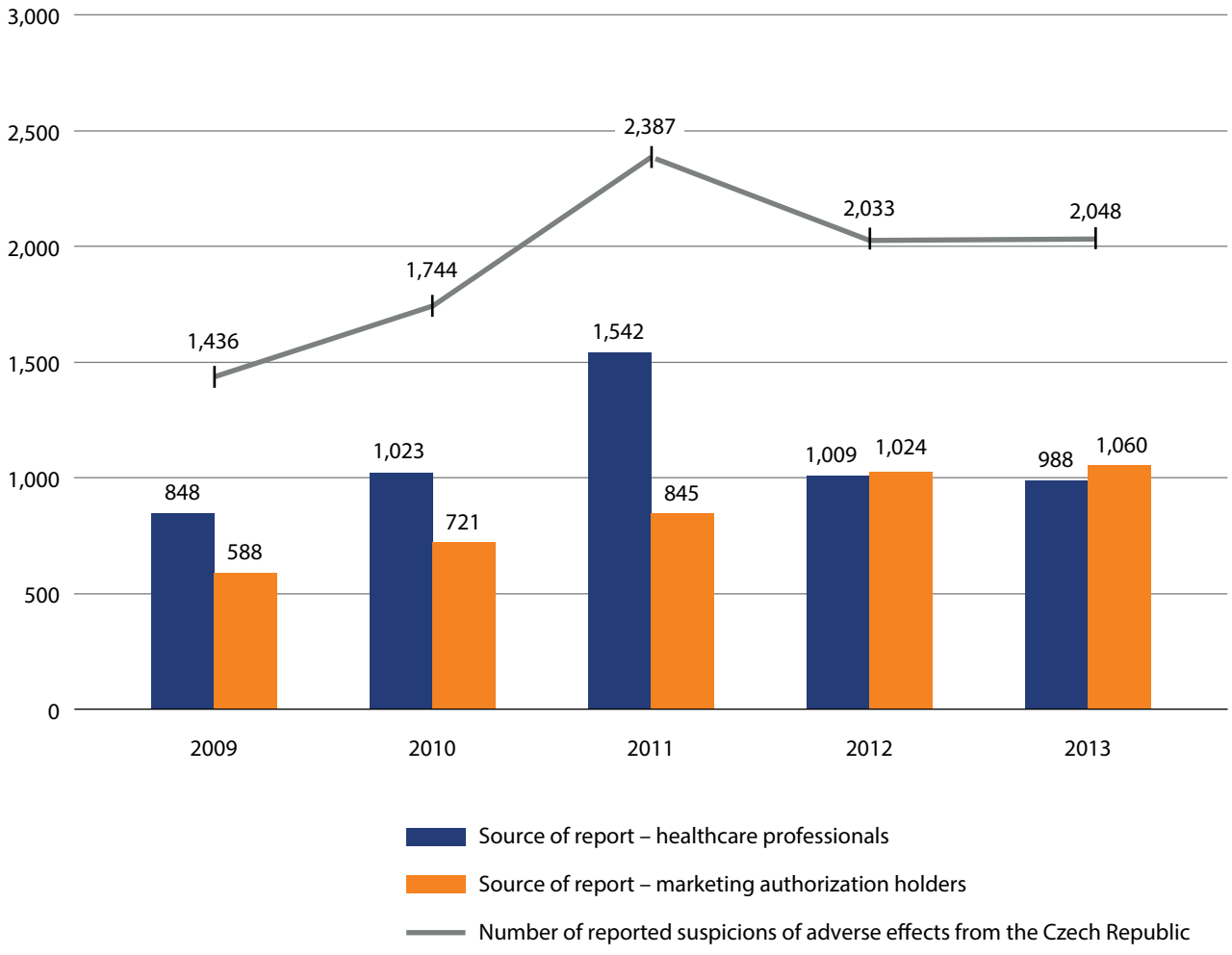
In 2013, 2,207 notifications of the use of non-authorized medicinal products were received, which is 16 % less notifications than in 2012.

In 2013, we provided 29 consultations and issued 10 written opinions on issues covered by the activities of our department in addition to consultations.

4.5 Pharmacovigilance

In 2013, the Institute received 2,048 primary reports of suspected adverse reactions from the Czech Republic, and 107

Fig. 2 – Number of suspected adverse reactions reported from the Czech Republic and the source of the report



follow-up reports relevant thereto were made (verification or obtaining of additional information from the reporter).

Periodic reports on the safety of individual products (PSUR) were – as in the previous year - evaluated only for products for which a safety risk has been identified or for which it was necessary to review the information about the medicinal product in relation to the EU regulatory procedures or renewal of authorizations. In 2013, 1,341 reports were submitted.

The conclusions of the CHMP and the Pharmacovigilance Risk Assessment Committee (PRAC) were being transposed to the Czech clinical practice in cooperation with the Marketing Authorization Department on an ongoing basis. The Institute published information intended for health care professionals or for the general public on the safety of medicinal products 50 times on its website in Farmakoterapeutické informace (Pharmacotherapeutic Information, FI) or in other media. In cooperation with the marketing authorization holders, the Institute published 54 letters for health care professionals regarding updated information on the safe use of medicinal products as well as 87 educational materials targeted at increasing the safety of the use of newly authorized medicinal products in particular.

The Institute published 4 editions of the Information Bulletin "Adverse Reactions to Medicines" which provided current information on the safe use of pharmaceuticals.

Seven inspections of the pharmacovigilance systems of marketing authorization holders were performed.

SURVEILLANCE BRANCH

The Laboratory Control Section conducts analyses of pharmaceuticals required by the law (e.g. random inspections of pharmaceuticals on the market, release of batches), at the request of other units of the Institute, or other units of the state administration and within international cooperation. The laboratories are integrated into the international network - General Network of Official Medicines Control Laboratories. The laboratories do not perform analyses at the request of any commercial entities (except for batch release under the Act on Pharmaceuticals). The Pharmacopoeial Department is involved in publishing of the Czech Pharmacopoeia and drafting of the European Pharmacopoeia.

The Department of Pharmacy and Distribution ensures monitoring of compliance with legislative requirements in the wholesale distribution of pharmaceuticals with a focus on the principles of good distribution practice and issues authorizations for wholesale distribution activities including administration of a register of brokers of medicinal products, and it also performs supervision over dispensing, sale and preparation of medicinal products. Controlled entities are wholesale distributors, pharmacies, vendors of selected medicinal products, specialized units of healthcare facilities. The inspection of handling medicinal products is also performed in all other healthcare facilities. The inspection is ensured by individual regional units of the Institute according to their territorial competence.

The Inspection Department ensures supervisory activities in pharmaceuticals, good clinical and laboratory practices, issuing of binding opinions on the import and export of medicinal products, including cooperation with customs authorities. It also oversees donation, procurement, testing, processing, storing and distribution of human tissues and cells aimed to ensure their quality and safety. This activity includes issuing licenses for operating tissue establishments, procurement centres or a diagnostic laboratory, performing inspections, monitoring serious adverse events and reactions or suspicion of the above, and in cases of doubt deciding whether these are tissues and cells which are regulated by applicable law.

The Department of Quality Defects addressed defects in the quality of pharmaceuticals and excipients available on the Czech market. The Department of Legal Support of Enforcement specializes in identifying and penalizing infringements and in enforcing the law in cases where an illegal status is detected, i.e. unauthorized handling of medicines. Within law enforcement, the Institute cooperates with other institutions in the Czech Republic and abroad (particularly with the Police of the Czech Republic, Customs Administration, the State Agriculture and Food Inspection Authority, supervisory authorities of EU Member States).

The exercise of supervision over compliance with the act on the regulation of advertising in the advertising of medicinal products for human use (HMPs) and sponsorship in this area (with the exception of radio and television broadcasting) is ensured by the Department of Advertising Regulation. It conducts investigations of complaints of incorrect advertising of HMPs, issues expert opinions on advertising material and advertising regulation.

The Institute also performs activities that result from the legislation relating to the safety of medical devices (MDs) marketed in the Czech Republic. It conducts investigations of adverse events of MDs and their evaluation, controls the conduct of clinical trials or clinical tests of MDs. It controls MDs at the sites of health care providers where it focuses primarily on the file-keeping and documentation of MDs.

4.6 Laboratory control

Laboratory control is performed by the Laboratory Control Section both within the requirements stipulated by the Act on Pharmaceuticals, i.e. it controls the quality of pharmaceuticals in circulation according to the previously prepared projects and releases batches of the defined medicinal products, and on requirements of internal applicants (other units of the Institute). This includes mainly addressing quality defects of

medicinal products, analysis of pharmaceutical samples, suspicion of counterfeit and illegal medicines, side effects etc. Laboratory departments at the Laboratory Control Section have been an active member of the international network OMCL (Official Medicines Control Laboratories) at the European Directorate for the Quality of Medicines (EDQM) since 1995. Employees of both laboratory departments participate in annual meetings of the OMCL and are members of working groups.

The Section has established a quality management system according to ČSN EN ISO/IEC 17025. In 2012, a regular verification of the established quality system was carried out by a group of auditors of EDQM under which the Certificate was issued.

Table 8 – Supervision over the quality of medicines in the market through laboratory analyses according to projects prepared in advance (projects closed in 2013)

Project name	Number of analyzed preparations	Number of analyzed samples	Number of compliant samples	Number of non-compliant samples	Number of comments on authorization documentation
1a/2012 Generics - products containing nimesulide	5	5	5	0	0
1b/2012 Generics - products containing furosemide	7	13	13	0	0
2/2012 Counterfeits*	160	160	–	–	–
3/2012 – Pharmacy samples *	50	227	226	1	0
4/2012 – Eye drops	29	53	47	6	4
5/2012 – products analyzed by LC/MS-TOF**	257	257	–	–	–
6/2012 - Verification of the quality of suspensions prepared before the release to the patient in a pharmacy	18	34	34	0	0
Verification of the shelf time IPLP	6	24	23	1	0
LAL test of selected blood derivatives	3	20	20	0	0
Validation of microbiological quality of selected LPs designated for pediatric patients	18	41	41	0	0
Total (without 2/2012 and 3/2012)	**86**	**190**	**183**	**7**	**4**

** Samples from the projects included in 2012*
*** The project was used to create a database, therefore the samples are not included in the total number*

Table 9 – Release of batches of identified medicinal products (MPs)

Type of product	Number of reported MPs	Number of reported batches	Released based on a certificate	Laboratory verification of samples	Total number of released batches	Not released
Blood derivatives	50	572	511	26	671*	0
Vaccines – import	39	337	266	0	372*	0

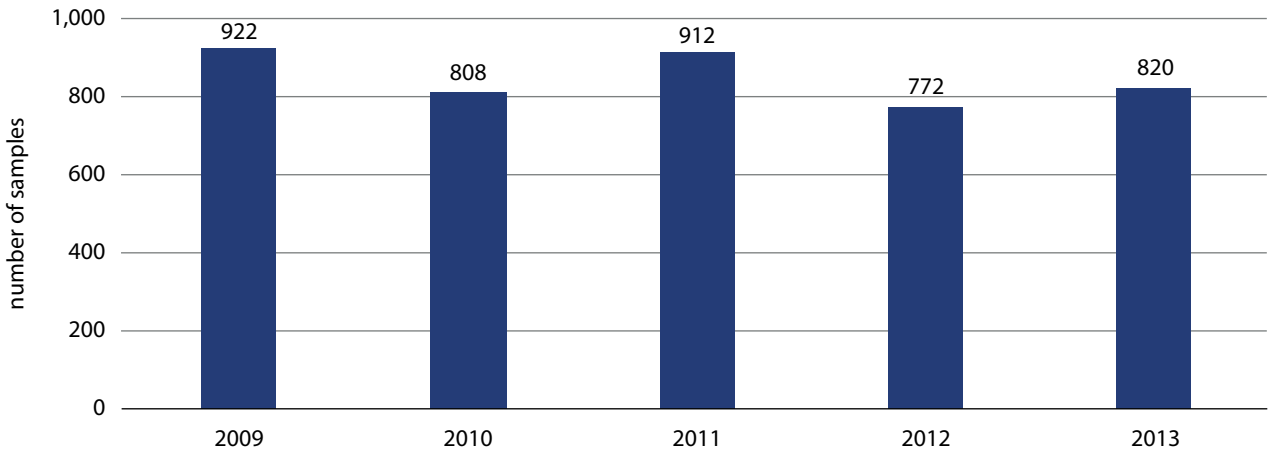
** Some batches were released repeatedly*

Table 10 – Laboratory control of pharmaceuticals and excipients requested by other sections of the Institute,other state administration bodies or EDQM

	Number of samples	Of which compliant	Of which non-compliant
Suspected quality defect of a pharmaceutical	61	55	6
Suspected counterfeit products, illegal samples*	177	–	–
Pharmacy samples	214	199	15
International studies within the scope of OMCL+	7	–	–
Purified water internal quality control	112	111	1
Verification of the quality of reference substances for Ph.Eur. or CP	5	5	0
Other analyses**	28	28	0
Total	**604**	**398**	**22**

** Cannot be assessed if sample is compliant or not*
*** E.g. LAL tests, requested microbiological inspections, other requested analyses etc.*

Fig. 3 – Number of sample analyses



International recognition of the quality management system is a condition of participation in international studies of centrally authorized medicinal products organised by EMA/EDQM, in the process of recognition of results of MRP/DCP product analysis and of international recognition of batch release of selected medicinal product (OCABR) within the EU.

The results of analyses of samples carried out in 2013 by both laboratory departments at the Laboratory Control are summarized in the tables below.

Projects are prepared based on a "risk-based" analysis. The criterion is particularly a high consumption of controlled products, less common dosage forms or methods of administration, target patient groups, or frequent complaints of patients and professionals among doctors and pharmacists. Drafts of these projects and the report on completed projects are approved by the SÚKL Quality Team. In addition to already completed projects, work continues on the completion of generics control projects (products containing glimepiride and donepezil) and the

Table 11 – Involvement in international studies

Study	Study title	Ratings
PTS133	Dissolution Test	good
PTS138	Optical Rotation	good
PTS139	Potentiometric Determination of pH	good
PTS140	Semimicrodetermination of Water	good
PTS141	Liquid Chromatography – Related Substances	good
CAP29/2013	Iressa	good
CAP54/2013	Ziagen	good
CRS 3	Methylprednisolon	good

PTS – EDQM Proficiency Testing Study. Quality control of the work of the laboratory; EDQM provides the samples, reference substances and method. Once the results are sent back to EDQM, they are statistically processed and the laboratory obtains the study rating. CAP – Analysis of Centrally authorized Product as part of the joint EMA and EDQM programme.

CRS – Verification of the quality of the reference substance for EDQM/Chemical Reference Substance.

verification of the quality of medicinal products with prolonged release. The following projects are planned for 2014: Verification of the sterility of eye drops, including a test of the effectiveness of antimicrobial additives, Microbiological inspection of medicinal products designated to treat the digestive tract, Microbiological inspection of medicinal products containing live microorganisms, Control of the quality of generics (products containing simvastatin, sumatriptan, topiramate, fenofibrate, clopidogrel), Control of the quality of hot drinks, products against influenza, Effect of storage on selected medicinal products (expectorants).

820 analyses of samples were performed in the Laboratory Control Section. There has been an increase in the analyses of samples that are suspected to be counterfeit or illicit products again (cooperation with the Department of Legal Support and Enforcement and through this department also with the Police of the Czech Republic and Customs Administration). The number of samples evaluated as non-compliant (excluding counterfeits and illicit products and international studies) increased compared to the previous year and reached 3.5 % (0.9 % in 2012; 3.7 % in 2011). These were mainly pharmacy samples and samples returned by doctors and patients. Defects of the pharmaceuticals were associated mainly with the content of active substances and the purity thereof.

Within the scope of the Institute's statutory task of batch release, all reported batches were released onto the market in time, i.e. within the timelines established by the Act.

International cooperation in the area of laboratory control

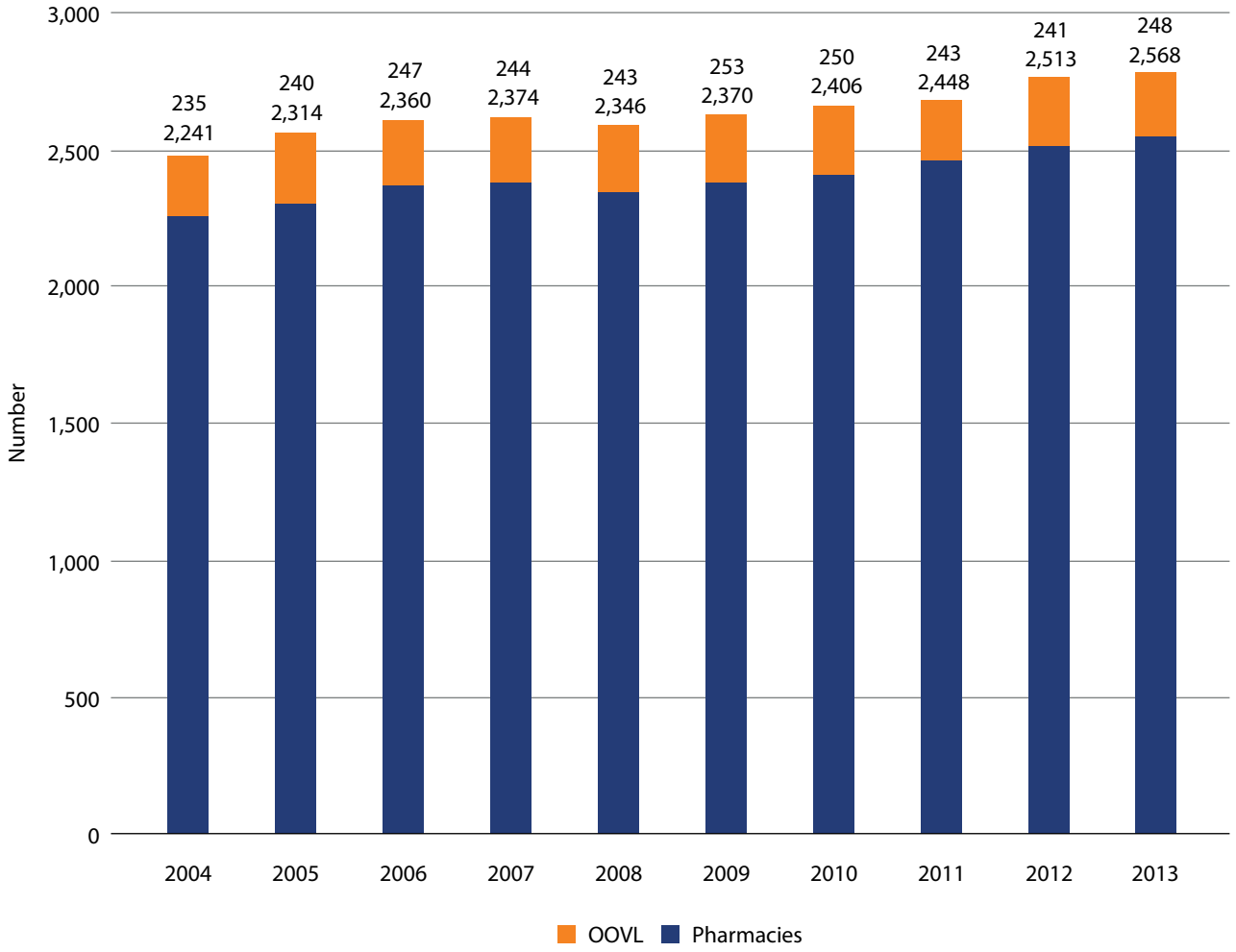
In addition to other international cooperation within the framework of the EDQM OCML network, the section is involved in joint studies in quality control of marketed pharmaceuticals, comparative studies, quality control of reference substances for the European Pharmacopoeia, as well as in the joint EMA/EDQM study in laboratory quality control of centrally authorized products (joint EMA and EDQM activity – CAP programme). In 2013, laboratory control of 22 samples was performed for foreign applicants from the OMCL network. In 2013, the Laboratory Control Section participated in collaborative international studies listed in Table 11.

4.7 Surveillance in the area of preparation, dispensing, sale and distribution of pharmaceuticals

The principal activities of the Pharmacy and Distribution Section include supervision of handling of medicinal products conducted by the Institute in pharmacies, at vendors of selected medicinal products, in health care facilities (including their specialized departments) and wholesale distributors of pharmaceuticals. The Pharmacy and Distribution Section is also entrusted with the performance of price inspections of medicinal products and foods for special medical purposes as well as with the inspection of handling of addictive substances and preparations in pharmacies. The Pharmacy and Distribution Section also keeps and regularly updates a database of regulated entities with the exception of heath care facilities.

At the end of 2013, SÚKL reported a total of 2,568 pharmacies, of which 4 fell within the scope of operation of the Ministry of Defence of the Czech Republic; moreover, the Institute reported 248 detached pharmaceutical and medical devices dispensing units (hereinafter referred to as OOVL), 369 medical device dispensaries, 734 vendors of selected medicinal products, 43 nuclear medicine departments of health care facilities and 425 wholesale distributors of medicinal products. The trend from previous years in the form of a slightly growing number of pharmacies continued and compared to 2012 the total number of pharmacies increased by 55 entities and the number OOVLs decreased by 7 entities (Fig. 4).

Fig. 4 – Number of pharmacies and OOVLs in the last 10 years (as of 2 January 2014)



In 2013, the inspectors of the Pharmacy and Distribution Section conducted 801 inspections in pharmacy health care establishments – pharmacies, of which 31 were hospital pharmacies of in-patient care providers. Of the total number of inspected pharmacies, 38 inspections were targeted inspections, carried out on the basis of reports.

Specific inspections aimed at handling of dependence-producing substances (DPSs) were carried out in 330 pharmacies – 305 inspections were planned inspections and 25 inspections were targeted inspections. Price control focusing upon compliance with the Act on Prices and rules of price regulation was conducted in 89 pharmacies, of which 66 inspections were targeted.

On the basis of the facts identified during the inspections, 38 orders – decisions to impose a fine for breach of obligations stipulated by the Act on Pharmaceuticals - were issued, the preparation of medicinal products was suspended in 6 pharmacies and the operation of the entire pharmacy was suspended in 2 cases.

The main reasons for the issuance of a decision imposing a fine included, in particular, dispensing medicinal products without a prescription or with an invalid prescription, including foreign prescriptions; storage and dispensing of medicinal products which should have been withdrawn from circulation based on a decisions of the marketing authorization holder; use of active substances and excipients for the preparation of medicinal products after the expiry date or without a proof of their quality; deficiencies in recording of incoming and dispensed products by piece; operating a pharmacy after the revocation of its registration; failure to provide information on dispensed medicinal products in the form of an announcement; absence of a qualified pharmacist; dispensing of prescription-only medicinal products by a pharmaceutical assistant; violation of the principles of good pharmacy practice and serious deficiencies in file-keeping on the operation and records of the pharmacy.

Table 12 – Inspection surveillance over pharmacies, nuclear medicine departments, health care facilities, and vendors of selected medicinal products in 2013

			Classification of shortcomings						Penalisation		
Inspected entity	**Inspection type**	**Počet**	**1**	**%**	**2**	**%**	**3**	**%**	**A**	**B**	**C**
Pharmacies	Regular inspections	801	488	60.9	200	25.0	113	14.1	6	2	38
	Price inspections	89	Not rated by classification of shortcomings						–	–	45
	Inspections of dependency-producing substances	330	244	73.9	48	14.6	38	11.5	–	–	29
ONM		17	9	52.9	1	5.9	7	41.2	–	–	–
HAV		2	1	50.0	–	–	1	50.0	–	–	–
Health care facilities		287	230	80.1	46	16.0	11	3.9	–	–	3
Vendors of selected medicinal products (3 x not rated)		43	29	72.5	7	17.5	4	10.0	–	–	–

Classification of shortcomings
1 – no or minor shortcoming identified
2 – major or repeated shortcomings
3 – critical shortcoming or serious breach of law

Penalisation
A – suspended preparation
B – suspended operation
C – fine imposed (administrative proceedings)

Table 13 – Occurrence of monitored types of shortcomings in %

Type of shortcoming	2009	2010	2011	2012	2013
Out-of-specification content of active substance	72.7	51.9	50.0	40.0	63.6
Out-of-specification total weight	18.2	29.6	30.0	40.0	9.1
Out-of-specification purified water Microbiological compliance	9.1	–	–	–	–
Out-of-specification galenic processing	–	7.4	–	–	18.2
Out-of-specification microbiological compliance	–	–	10.0	20.0	9.1
Active substance and excipient identity confusion	–	11.1	10.0	–	–

Within the inspections of handling of addictive substances in pharmacies, serious violations of the Act on Dependence Producing Substances were detected in 32 pharmacies and were addressed by a decision to impose a fine. In 19 cases, it was the failure to submit the annual report on the status and movement of dependence-producing substances and products and in other cases, it was a serious breach of the Act on Dependency-Producing Substances pertaining to record-keeping and documentation or entering incorrect data in annual reports.

Inspections focusing on the compliance with price regulation rules identified a breach of price regulations in a total of 45 cases. The most frequent reason was the failure to observe the officially fixed prices during sales and disregard for the conditions and procedures for their application stipulated in the price regulations of the Ministry of Health of the Czech Republic and a fine was imposed on the operators in accordance with the Act on Prices.

In 2013, a total of 287 inspections of the handling of medicinal products in health care facilities (HF) were conducted. The inspections were carried out in 12 in-patient hospital departments and in 275 separate out-patient offices of general practitioners and in other health care facilities. On the basis of reports received by the Institute in connection with the operation of health care facilities, where health care is provided, a total of 16 targeted inspections took place. A total of 3 fines were imposed for the identified violations of the Act on Pharmaceuticals

In other health care facilities authorized to prepare medicinal products (Nuclear Medicine Departments – ONM and workplaces preparing autogenous vaccines for human use – HAV), a total of

Table 14 – Other activities of the Distribution and Pharmacy Section

Initial pharmacy inspection	Establishment of a new pharmacy/OOVL	Defunct pharmacies/OOVLs
163	116/16	74/11
Initial OOVL inspection	**Initial inspection of medical device dispensaries**	**Consultations**
15	22	113

Table 15 – Distribution and intermediation of pharmaceuticals in 2013

	Received applications	Authorizations issued / registration
Application for distribution authorization	46	44
Application for variation to distribution authorization	117	103
Application for distribution authorization revocation	28	28
Application for entry in the register	6	6

Tabulka nezahrnuje počty nedořešených žádostí z minulého období

19 inspections were carried out; the findings of the inspections did not result in the need for the imposition of any sanction.

The summary results of inspections carried out in 2013 are provided in Table 12.

In 2013, inspectors from the Pharmacy and Distribution Section took a total of 214 samples of medicinal products during inspections in pharmacies, of which 113 were samples of medicinal products intended for extemporaneous preparation in pharmacies. Out of the 101 pharmacy samples (medicinal products prepared in pharmacies), a total of 11 were out-of-specification, the shortcomings being out-of-specification content of active substance in the medicinal product, galenic processing, total weight and unsatisfactory result of the sterility assay. Shortcomings in the labelling were detected in 5 other pharmacy samples. A lower number of samples taken corresponds to the long-term trend of decreasing preparation of medicinal products in pharmacies.

Comparison of occurrence of monitored shortcomings in out-of-specification pharmacy samples in the last years is provided in Table 13.

Other activities of the Pharmacy and Distribution Section include issuing binding opinions on the technical and material equipment of pharmacies and dispensaries of medical devices. In 2013, a total of 709 applications for an opinion were received from pharmacy operators, 722 positive binding opinions and 1 negative opinion were issued and 2 applications were withdrawn by the applicant. In the case of dispensaries of medical devices, a total of 26 operators applied for a binding opinion and the same number of opinions were issued.

In 163 cases, the issue of the binding opinion was associated with an inspection in the pharmacy (on-the-spot check of the technical and material equipment) and in 15 cases with an inspection of OOVL (Table 14). In this context, 22 initial inspections of medical devices dispensaries and 113 consultations on the technical equipment of existing pharmacies or the construction of new pharmacies and issues related to Decree No. 84/2008 Coll. and other implementing regulations for the Act on Pharmaceuticals or Act on Dependency-Producing Substances took place. Table 14 also provides data on newly established/defunct pharmacies/OOVLs.

Distribution of Medicinal Products

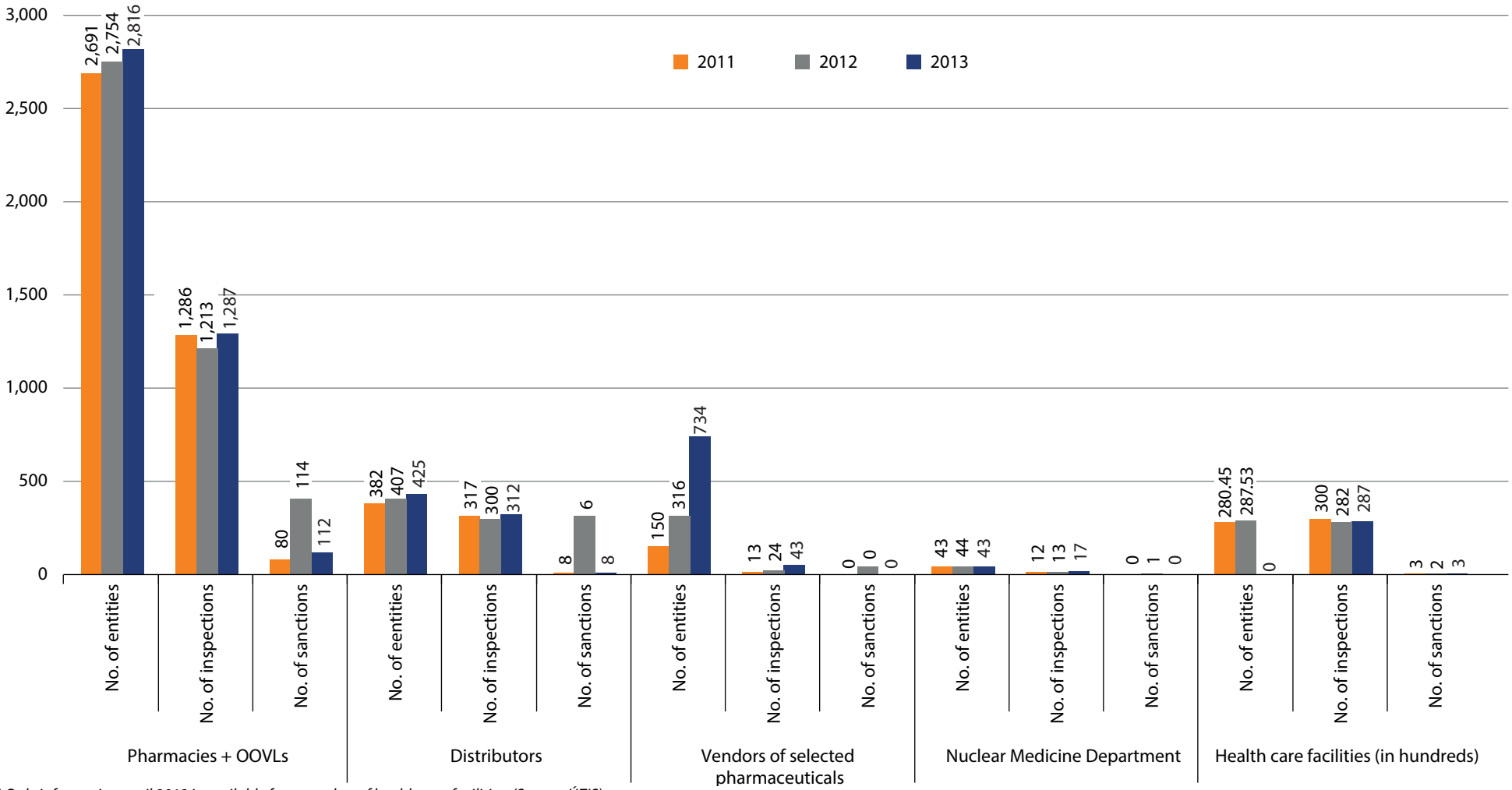
In 2013, the number of distributors increased by 18 entities to the total number of 425 medicinal product distribution authorization holders. Of the total number of approved distributors, 171 entities are both the pharmacy operator and a distribution authorization holder.

In 2013, 44 new distribution authorizations and 103 decisions on amending the distribution authorization were issued, and

Table 16 – Inspection surveillance over distributors

Number of inspections					Rating from the inspection			Action	
Total	Initial	Follow-up	Targeted	Variation	1	2	3	Breach of law	Fine
312	48	206	11	47	179	25	13	23	8

Fig. 5 – Information on surveillance activities



** Only information until 2012 is available for a number of health care facilities. (Source: ÚZIS)*

28 authorizations were revoked at the request of their holders. In connection with the amendment of the Act on Pharmaceuticals, a register of brokers of medicinal products was established, all applications for registration in the register received in 2013 were approved.

Table 15 provides an overview of received applications and issued decisions in respect of distribution authorization, variations thereto or revocation thereof, and the registration of brokers of medicinal products.

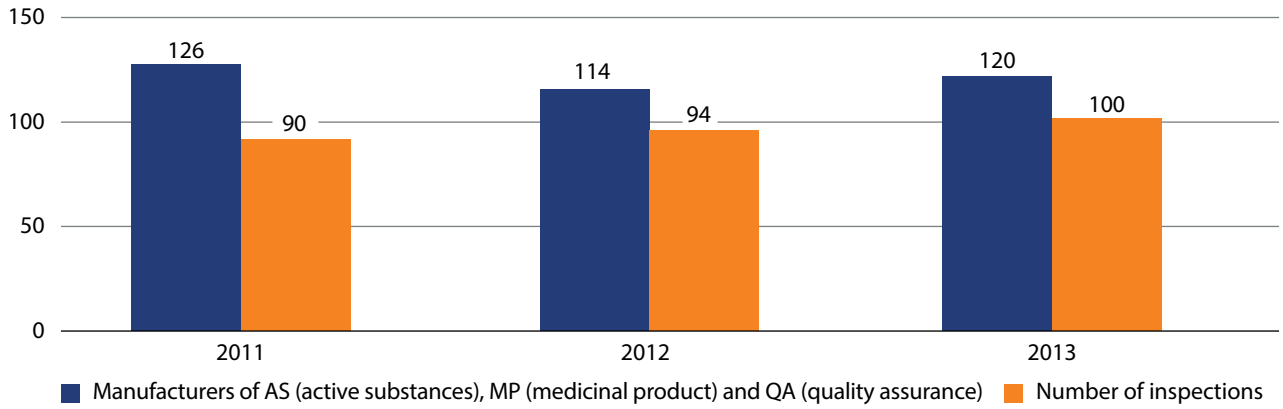
Following the Compilation of Community Procedures on Inspection and Exchange of Information, amendments to the Act on Pharmaceuticals and new EU Guidelines on Good Distribution Practice, since 1 April 2013, the Institute has been issuing distribution authorizations in the unified EU format and enters the data on issued authorizations and post-inspection GDP certificates in the central database EUDRA GMDP.

In 2013, a total of 312 inspections of distributors took place. Compared to 2012, an increase in inspections based on an application of the distributors for a variation to the existing authorization is particularly apparent. The number of such inspections increased by 21. In 2013, two inspections of distributors were conducted together with ÚSKVBL inspectors.

Of the total number of 217 rated inspections of distributors (subsequent and targeted inspections), 82.5% were rated with grade 1 (good), 11.5% with grade 2 (satisfactory) and 6 % with grade 3 (not satisfactory). A total of 8 administrative proceedings for fine imposition were initiated based on the identified facts.

The main reasons for the imposition of fines were mainly non-compliance with good distribution practice, sourcing medicinal products from pharmacies or unauthorized suppliers, distribution of non-authorized medicinal products or supplies to non-authorized customers.

Fig. 6 – Numbers of manufacturers of medicinal products, active substances and control laboratories and overview of completed inspections



For the failure to comply with the distributors' and manufacturers' duty to report to the Institute on supplies of human medicinal products under the SÚKL DIS-13 guideline, the Pharmacy and Distribution Section issued a total of 55 orders to impose a fine in 2013.

Within 10 price inspections carried out at the distributors, violation of price regulations and price regulation rules were found in 3 cases and they will be resolved in administrative proceedings. The results of inspections of distributors in 2013 are provided in Table 16.

Rating from the inspection

On the basis of the identified shortcomings and their severity the inspection is rated and according to the achieved point score, the overall level of compliance with the principles of good distribution practice is expressed by the following rating:

1 – good
2 – satisfactory
3 – not satisfactory

Comparison of the number of regulated entities, conducted inspections and imposed penalties over the last 3 years

4. 8 Surveillance in the area of manufacture of pharmaceuticals, human tissues and cells, good laboratory and clinical practice

Manufacture of pharmaceuticals

The updated lists of supervised entities in the sphere of manufacture and research of pharmaceuticals are provided on the website of the Institute.

In the sphere of manufacturers (incl. blood centres) the total of 122 applications for manufacturing authorization or variations thereto were received (Tab. 17). The number of applications

Table 17 – Applications in the sphere of manufacture of pharmaceuticals and in the sphere of human tissues and cells

Application type		2011		2012		2013	
		Received applications	Issued decisions	Received applications	Issued decisions	Received applications	Issued decisions
Application for manufacturing authorization	Manufacturer of medicinal products	4	2	7	7	6	4
	Control laboratory	3	3	4	4	5	4
	ZTS (Blood centres)	0	0	1	1	1	1
Application for variation to manufacturing authorization	Manufacturer of medicinal products	58	55	45	41	68	66
	Control laboratory	1	2	2	1	5	6
	ZTS (Blood centres)	28	27	19	17	33	31
Application for revocation of manufacturing authorization	Manufacturer of medicinal products	1	1	5	5	3	3
	Control laboratory	2	2	–	–	–	–
	ZTS (Blood centres)	3	3	–	–	1	1
Application for operating authorization	Tissue facilities	4	9	18	12	7	6
	Donation facilities	3	1	2	0	0	1
	Diagnostic laboratories	2	5	5	4	3	3
Application for variation to activities	Tissue facilities	28	24	16	15	34	35
	Donation facilities	0	0	2	2	1	1
	Diagnostic laboratories	12	10	7	7	6	9
Total		**133**	**149**	**145**	**116**	**173**	**171**

Explanatory notes: ZTS – Blood centres

and decisions issued for variation to manufacturing authorization increased significantly, compared to 2012. The number of applications for revocation of the manufacturing authorization slightly decreased. The number of cases transferred between years corresponds to the period of application processing.

Human tissues and cells

This is an area regulated by the Institute pursuant to Act No. 296/2008 Coll., on Human Tissues and Cells. In 2013, 51 applications for authorization of variations to authorization were received.

In 2013, the Institute carried out 314 inspections in total, of which 132 were associated with the regulated area of tissues and cells. Their nature and results of evaluation are provided in Table 18. A comparison of the number of inspections and breaches of the Act on Pharmaceuticals, or of the Act on

Table 18 – Inspections conducted in 2013 and their outcomes

	Number of inspections					Rating from the inspection			
	Total	**Initial**	**Follow-up**	**Targeted**	**Variation**	**Compliant**	**Non-compliant**	**Breach of law**	**Fine/Order**
Manufacturers of medicinal products	**68**	5	38	6	19	66	1	1	0
Manufacturers of active substances	**15**	0	9	2	4	15	0	0	0
Control laboratories	**17**	4	10	0	3	17	0	0	0
ZTS (Blood centres)	**45**	1	40	2	2	45	0	0	0
Blood banks (KS)	**17**	0	17	0	0	17	0	0	0
GCP inspections – Ethics Committees	**13**	0	13	0	0	13	0	0	0
GCP inspections – other	**7**	7	0	0	0	7	0	0	0
TE, PC, DL inspections	**132**	28	96	4	4	131	1	1	2

Explanatory notes: TE – tissue establishment; PC – procurement centre; DL – diagnostic laboratory

Table 19 – Comparison of inspections carried out in 2011 – 2013

	2011		2012		2013	
	No. of inspections	Breach of law	No. of inspections	Breach of law	No. of inspections	Breach of law
Manufacturers of medicinal products	64	0	57	1	68	1
Manufacturers of active substances	13	0	25	0	15	0
Control laboratories	13	0	12	0	17	0
ZTS (Blood centres)	51	0	44	0	45	0
Blood banks	4	0	22	0	17	0
GCP inspections + Ethics Committees	29	0	26	0	20	0
Tissue establishments, procurement centres, diagnostic laboratories	102	0	102	12	132	2
Total	**276**	**0**	**288**	**13**	**314**	**3**

Fig. 7 – Overview of inspections carried out by Clinical Practice and Surveillance over Biological Material Processing Dpt.

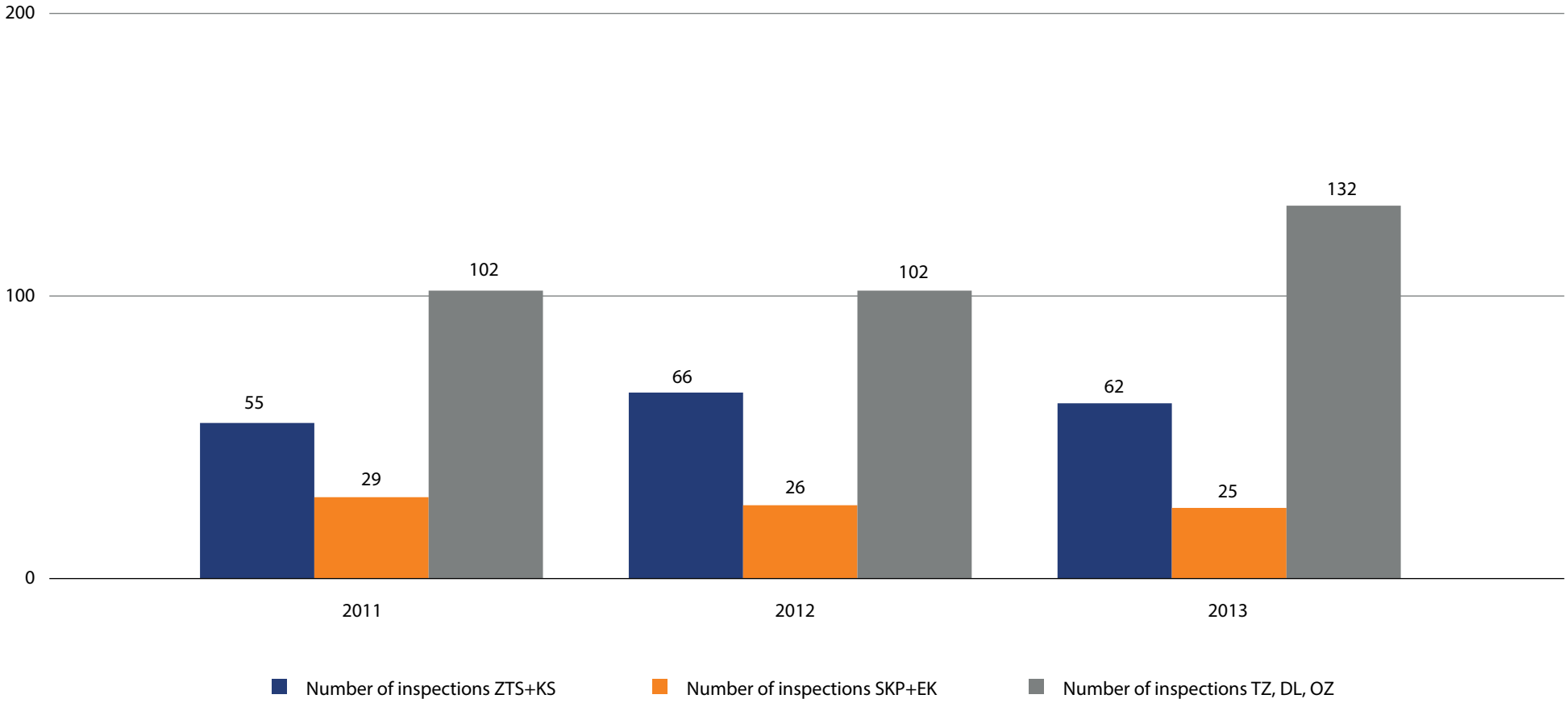
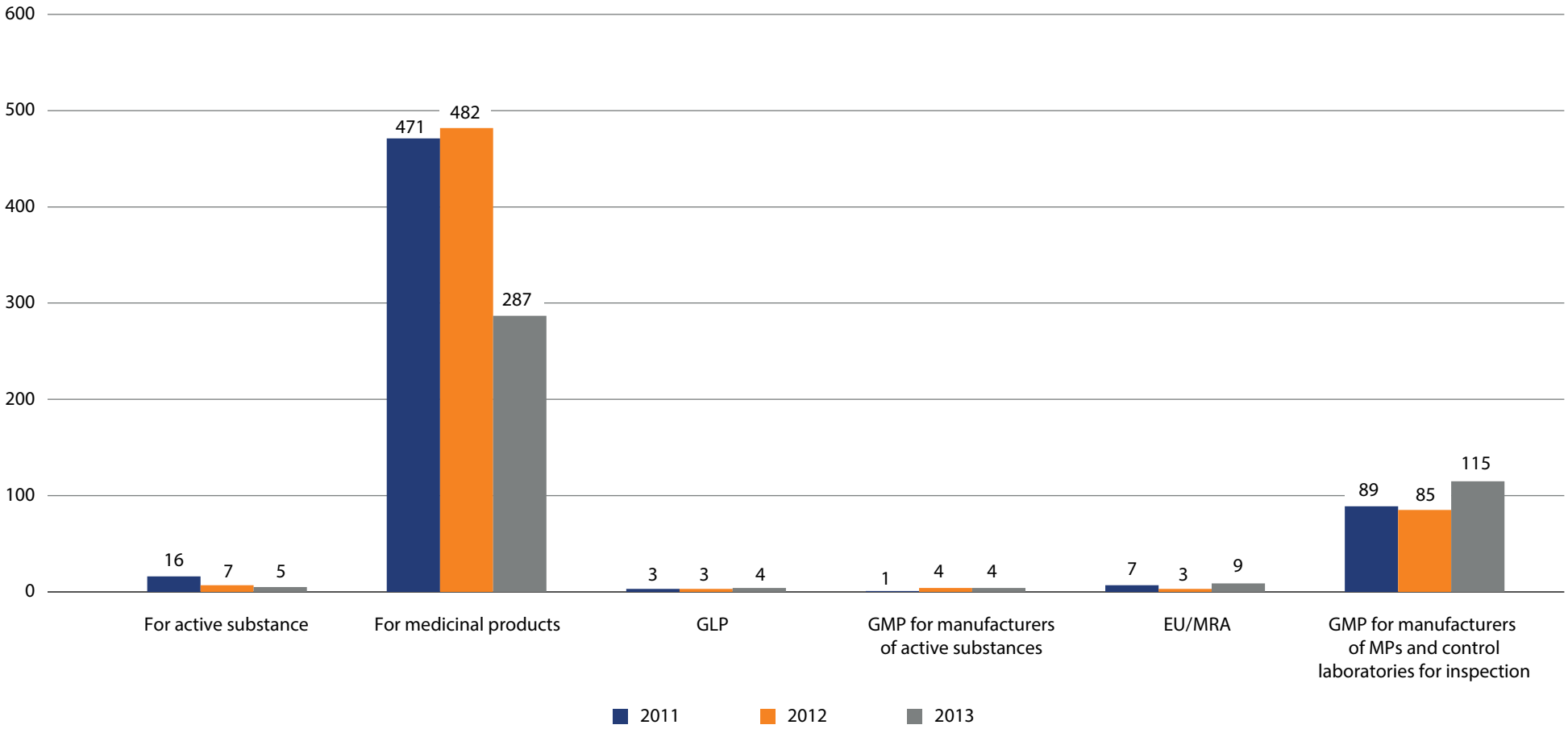


Fig. 8 – Issued certificates



Human Tissues and Cells, where applicable, in individual years is provided in Table 19.

The initial inspection was carried out in connection with an application for operating authorization under Section 63 (4) of Act No. 378/2007 Coll. Follow-up inspections were carried out at the sites of manufacturers of medicinal products or active substances, control laboratories or blood centres (hereinafter referred to as ZTS) at intervals established by Decree No. 229/2008 Coll. and for blood centres according to Decree No. 143/2008 Coll. An inspection related to a change is carried out only if the conditions, under which the activities were permitted, have changed. Targeted inspections are conducted in order to review a certain section of activities (e.g. an inspection associated with a quality defect of a medicinal product).

Out of the total of 100 inspections of manufacturers of medicinal products or active substances, and control laboratories, the Act on Pharmaceuticals was violated in one case. The level of Good Manufacturing Practice (GMP) in blood centres was mostly rated as good, no violations of the law were identified. The plan of follow-up inspections was fulfilled for all regulated entities and the inspection interval stipulated by the relevant decrees was complied with.

Inspections in tissue establishments, procurement centres or diagnostic laboratories are conducted pursuant to Decree No. 422/2008 Coll., on detailed requirements for the safeguarding of the quality and safety of human tissues and cells intended for human use.

Good laboratory practice (GLP)

In 2013, a total of 9 holders of Good Laboratory Practice Certificates issued by the Institute were registered, with prevailing scope of activities in toxicological studies; these are included in the National GLP Programme. In the same year, 4 follow-up inspections and one initial inspections of an applicant for the Good Laboratory Practice Certificate were conducted.

Good clinical practice (GCP)

During the year, the following inspections were conducted: 13 initial system inspections of local EK, 1 follow-up system inspection of a contract research organization (CRO) with a clinical unit, 1 follow-up system inspection of an investigator with a clinical unit, 1 follow-up system inspection of CRO implementing BA/BE studies based on an application for the GCP certificate, 2 targeted initial inspections of investigators in clinical trials involving advanced therapy investigational products, 1 targeted follow-up inspection of GCP. In case of GCP no decision on permission of activities of the inspected entities is issued.

Actions and penalties

In 2013, one breach of the Act on Pharmaceuticals was identified. The Act on Tissues and Cells was violated in two cases and 2 fines were imposed.

Certification

415 various certificates were issued in total (584 in 2012), of which, like in the previous years, the highest number was the number of certificates issued for medicinal products (287). Post-inspection good manufacturing practice certificates are entered in the EudraGMP database maintained by EMA. All certificates of medicinal products were issued within the 30-day period, and of good manufacturing practice within the 90-day period.

Assessment of GMP compliance within the proceedings on granting MA

A total of 1,128 cases (decreased by 48.4 % compared to 2012) were received, all of them were processed before the deadline.

Table 20 – Number of received reports

Quality defects	2009	2010	2011	2012	2013
Received reports in total	235	248	357	416	417
Reports from the Czech Republic	141	150	203	294	210
Reports from abroad	94	98	124	122	207
Resulted in recalls	19	47	129	84	77
Issues RWs	5	5	2	4	1
Issues RAs	2	1	5	7	3

RW – Rapid Warning, RA – Rapid Alert

4.9. Quality Defects of Pharmaceuticals

Between 2009 and 2012, there has been a major increase in the number of reports in the area of quality defects. The number of reports received in 2013 is comparable to 2012 (Table 20).

In 2013, the reports concerned not only authorized medicinal products but also raw materials for the preparation of medicinal products in pharmacies as well as non-authorized and investigational medicinal products.

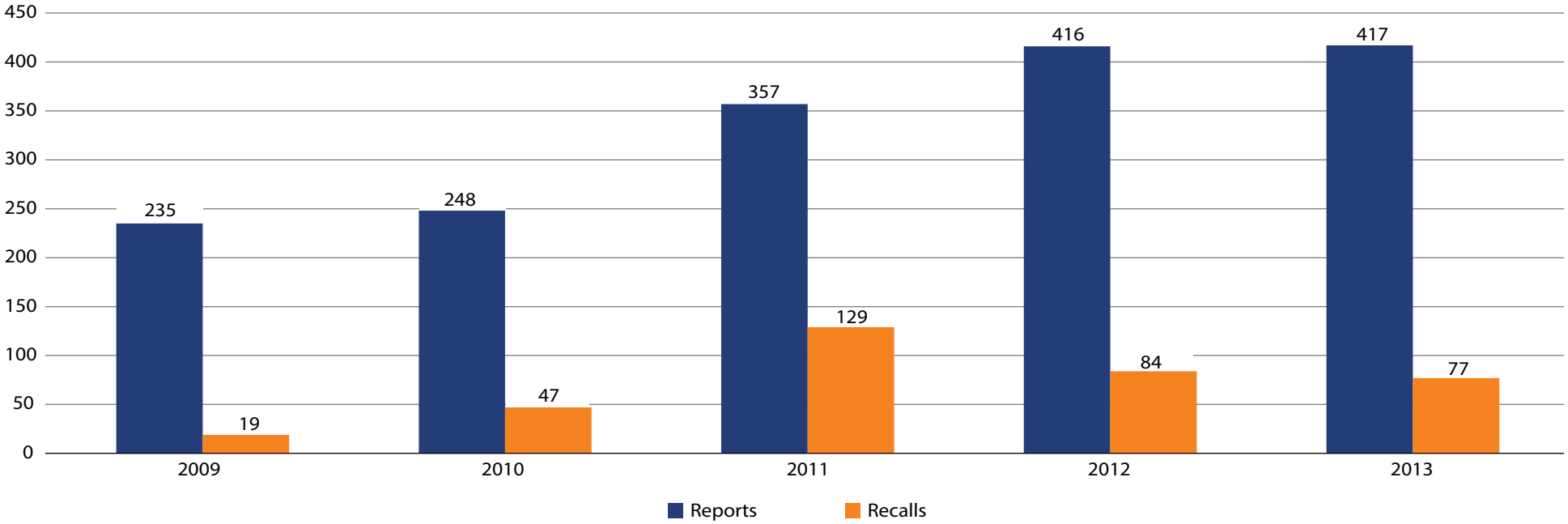
Through the Rapid Alert System of EU countries, MRA PIC/S, the Institute received and evaluated a total of 174 reports on quality defects of pharmaceuticals. Mutual exchange of information with ŠÚKL in Bratislava continued as in previous years and the Institute collaborated with ŠÚKL in Bratislava on several occasion in 2013.

Reports received from abroad also include reports on non-compliance of the manufacturing site of a medicinal product or an active substance with GMP (Good Manufacturing

Table 21 – Actions taken in 2013

Actions taken	Number
Recalls to distributor level	2
Recalls to health care facility level	76
Recalls to patient level	1
Suspended distribution, dispensing and therapeutic use	3

Fig. 9 – Number of reports and recalls of medicinal products



Practice) principles. The Institute received a total of 33 such reports in 2013.

Within the scope of the solution of quality defects of pharmaceuticals, effective actions have been taken to reduce the impact of the quality defect on patient health. Table 21 gives an overview of actions taken as part of addressing the quality defects in individual medicinal products (SÚKL codes) in 2013.

In one case, a patient-level recall was conducted. It applied to the medical product NovoMix 30 FlexPen 100 U/ML, inj. sus. 5x3 ml, batch No. CP51095, CP50904, CP50650 the recall was due to the fact that some packages of the above batches did not comply with the specifications for insulin content. In all cases, interventions were made by the operators themselves, with the Institute merely monitoring or adjusting their actions.

The Department also focuses on supervising of compliance with the obligation of marketing authorization holders stipulated in Section 33 (2) of Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, which requires marketing authorization holders to notify the Institute of the date of the actual placing of the medicinal product on the market in the Czech Republic by package size and packaging type after the issue of the marketing authorization, specifically within 2 months after the actual placing on the market; in the same manner, they are also required to notify the Institute of a suspension or termination of placing the medicinal product on the market in the Czech Republic at least 2 months in advance. If the medicinal product is re-introduced to the market, the marketing authorization holder must inform the Institute of this fact immediately.

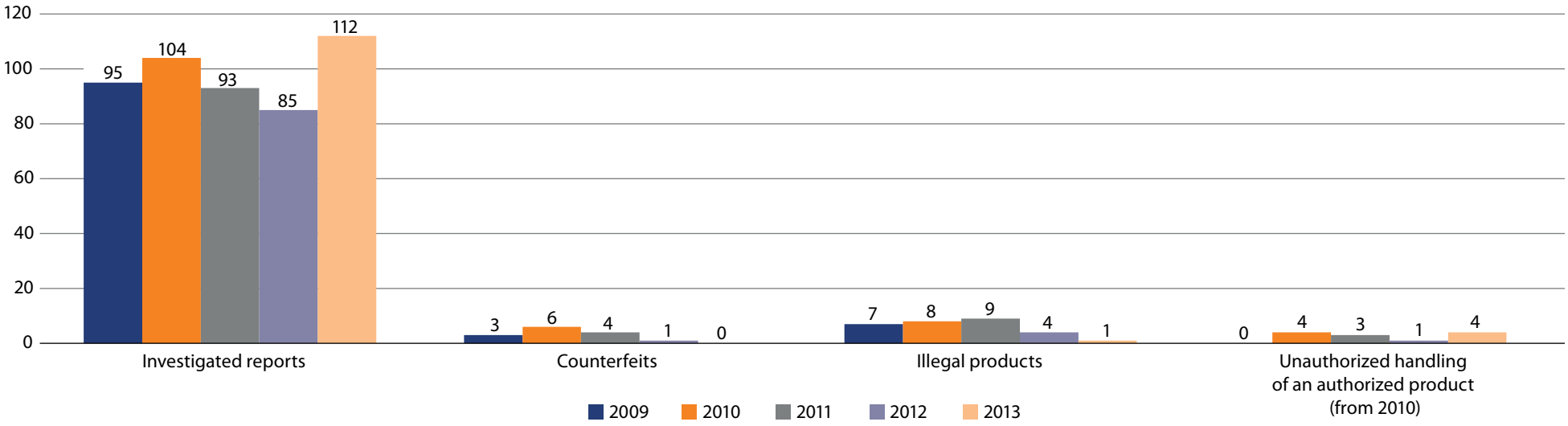
4.10 Enforcement

In 2013, active surveillance in the area of illegal handling of medicinal products focused, in particular, upon the identification, investigation, and penalisation of the cases of distribution and

Table 22 – Results of investigated cases

Cases concluded by:	2011	2012	2013
Administrative procedure with proposed fines	2	2	1
Reports of crime	6	2	3
Case forwarded to other authorities (CAFIA, etc.)	3	4	3

Fig. 10 – Control activities



sales by unauthorized persons and upon monitoring the internet, where illegal sale of medicinal products is being carried out.

In the sphere of enforcement, the Institute closely cooperates with the Czech Customs Administration, Czech Police, Czech Trade Inspection, Czech Agriculture and Food Inspection Authority (CAFIA), and the Trade Licensing Offices (ŽÚ). Cooperation also includes foreign partners, not only in the exchange of information, but also in the investigation of individual cases with potentially international impact.

In 2013, a total of 112 reports (either the Institute's own or received reports) were investigated. During control activities on the Internet, the employees of the Institute identified and investigated 1 case of unauthorized medicinal product and 4 cases of unauthorized handling of authorized medicinal products.

In 2013, the Institute prepared a total of 57 expert opinions for the customs authorities for the purposes of release/non-release of medicinal products imported from third countries. These opinions concerned medicinal products that have been authorized neither in the Czech Republic, nor in any other EU Member State, were not properly labelled and their import was not in compliance with the applicable legislation. For the Czech Police and the Customs Administration, the Institute prepared 17 expert opinions for the purposes of identification of medicinal products and for clarification of legislation governing the dispensing, distribution, import, and export of medicinal products.

4.11 Surveillance in the area of regulation of advertising for medicinal products

In 2013, the Institute investigated a total of 103 reports of suspected breaches of Act No. 40/1995 Coll., on Advertising Regulation, as amended (Act on Advertising Regulation). Compared to 2012, the Institute received 161 less new reports in 2013 (264 newly received reports in 2012). In 2013, 21 administrative procedures were completed that resulted in imposition of 33 fines in the aggregate amount of CZK 4,855,000.

Investigation of advertising applied to printed advertising material (66 %), websites (24 %), sponsorship (5 %) and promotional samples (2 %).

Advertising of prescription-only medicines accounted for 88 % of the investigated cases, advertising of over-the-counter medicines accounted for 12 % of cases.

Pharmaceutical companies or their legal representatives filed 14% of reports on suspected breach of law, 5% of reports were filed anonymously, 27% were lodged by private individuals, 3% by state administration bodies and 51% by the employees of the Institute.

Upon request, the Institute has issued/provided 39 expert opinions/consultations on the issue of the proposed advertising of medicinal products for human use.

Surveillance in the sphere of decisions regarding the nature of the product

In 2013, the Institute commenced investigations of 58 cases involving various products, most often dietary supplements and

Fig. 11 – Overview of investigated reports of suspected breaches of the Act on Advertising Regulation in %

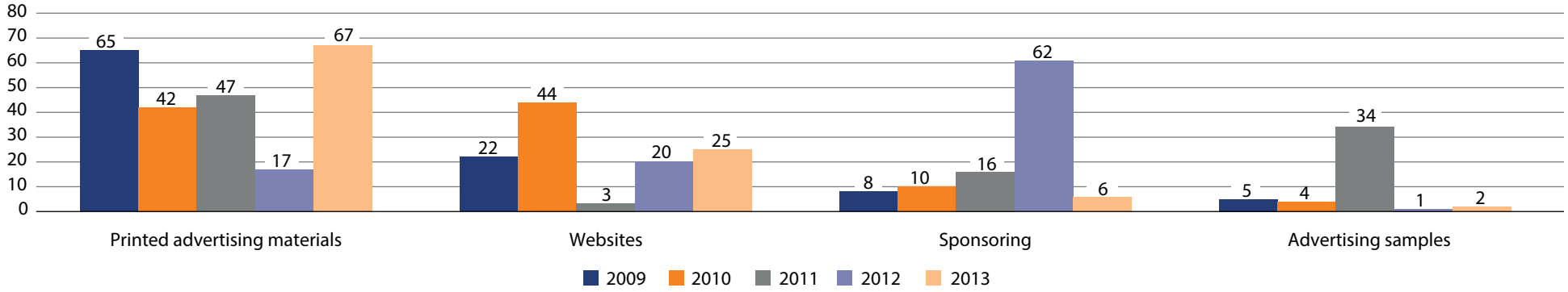
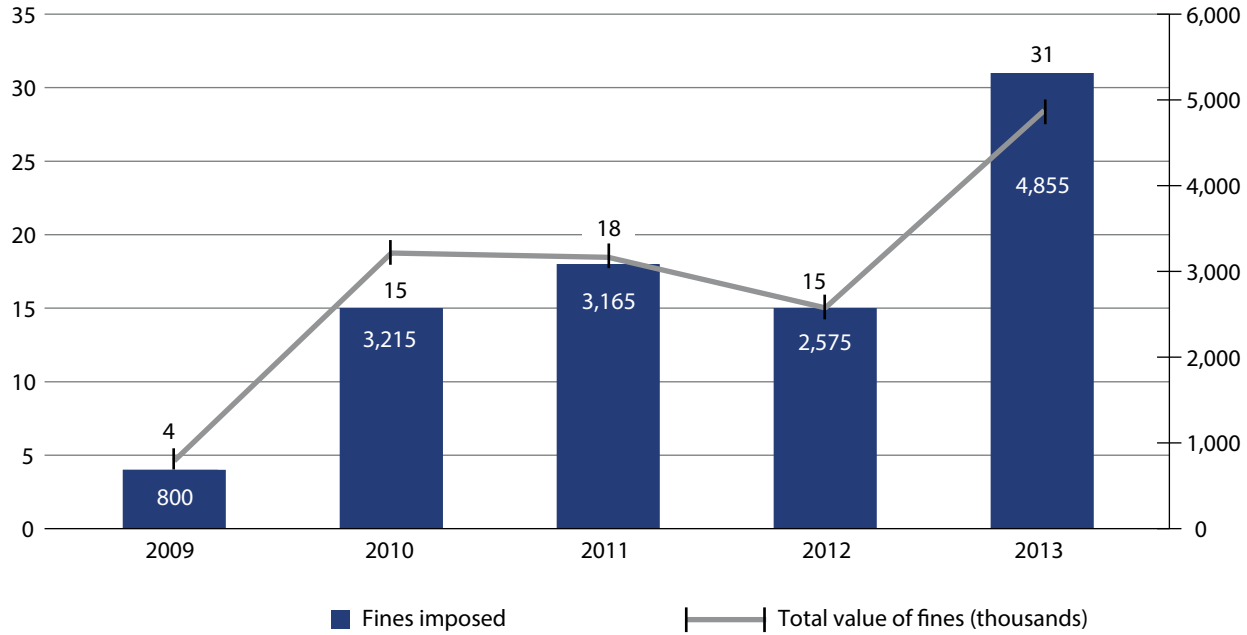


Table 23 – Overview of investigated reports of suspected breaches of the Act on Advertising Regulation

	Reports brought forward from 2012	Newly received reports in 2013	Total
Number of reports	15	103	118
Completed investigation	7	58	65
Forwarded for commencement of administrative procedure	7	13	20
Pending	0	11	11
Completed administrative procedure	1	17	18
Number of final decisions on fines	1	26	27

Fig. 12 – Overview of fines imposed for violating the Act on Advertising Regulation



cosmetic products, for suspicion that the product concerned might be a medicinal product. In 5 cases, an administrative procedure regarding that the product is a medicinal product in accordance with the Act on Pharmaceuticals was initiated, of which in 3 cases a decision on the nature of the product was issued, however, the parties appealed against the decision of the Institute. The decisions are not legally valid yet.

4.12 Inspections of medical devices of health care providers

In 2013, inspectors from the Pharmacy and Distribution Section carried out a total of 90 inspections of health care providers (both state and non-state health care establishments), during which 641 medical devices were inspected (hereinafter referred to as "MDs").

Table 24 shows the numbers of inspections and their overall rating using the 1 – 3 scale based on the occurrence and serious nature of identified defects.

In total, 128 devices, which were put into operation before the end of 1999, were inspected. 81 devices were found flawless,

Fig. 13 – Number of inspections of MDs

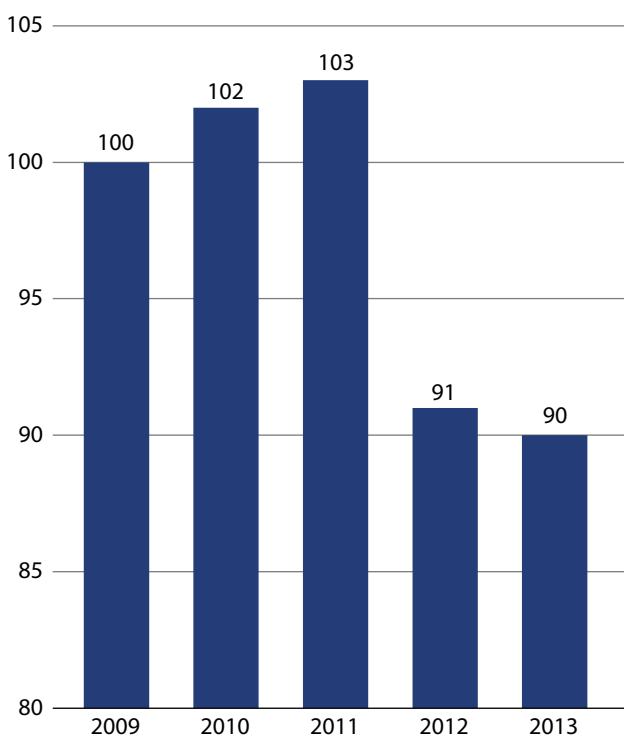
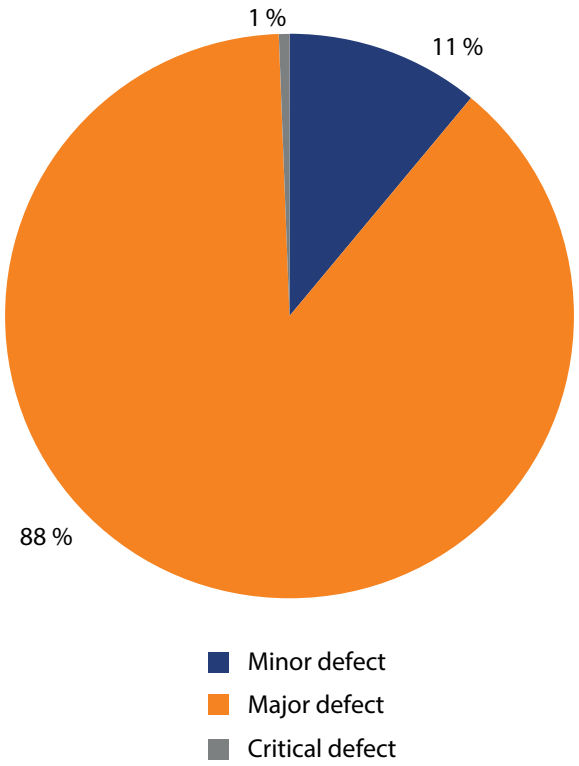


Fig. 14 – Ratio of defects in inspected MDs



140 defects were identified in 47 devices (18 minor defects, 120 major defects and 2 critical defects); while 21 devices were classified as Class IIb according to the degree of risk for users. For all of the 128 devices, documents on compliance with the conditions for the use of medical devices in health care were inspected.

The total number of inspected medical devices, which were put into operation after the year 2000, was 513 devices, of which 372 devices were found to be flawless. In 141 devices, a total of 361 defects were identified (37 minor defects, 323 major defects and 1 critical defect), defects were found in 61 devices classified as Class IIb according to the degree of risk for users. For all of the 513 devices, documents on compliance with the conditions for the use of medical devices in health care were inspected.

122 defined measuring devices were inspected in this period, of which 15 devices were unverified.

4.13 Standardisation and pharmacopoeial activities

The Pharmacopoeia and Pharmaceuticals Standardisation Department prepared a copy of the Czech Pharmacopoeia 2009 – Supplement 2014 (hereinafter referred to as the CP 2009 – Suppl. 2014). In the European part, this release contains translations of the new and revised texts of Ph. Eur. 8.0, Ph. Eur. – Suppl. 8.1 and Ph. Eur. – Suppl. 8.2. The decision to issue the 8th edition of the European Pharmacopoeia only in the

Table 24 – Inspections of medical devices carried out at providers of health care in 2013

Nature of the inspection		General rating						Penalisation (proposed fines)
Total	Of which initiated by report	1	%	2	%	3	%	
90	2	56	61.1	27	31.1	7	7.8	2

Classification
1 – No defects or minor defects, 2 – Major defects, 3 – Critical defects

Table 25 – Czech Pharmacopoeia 2009 – Supplement 2014

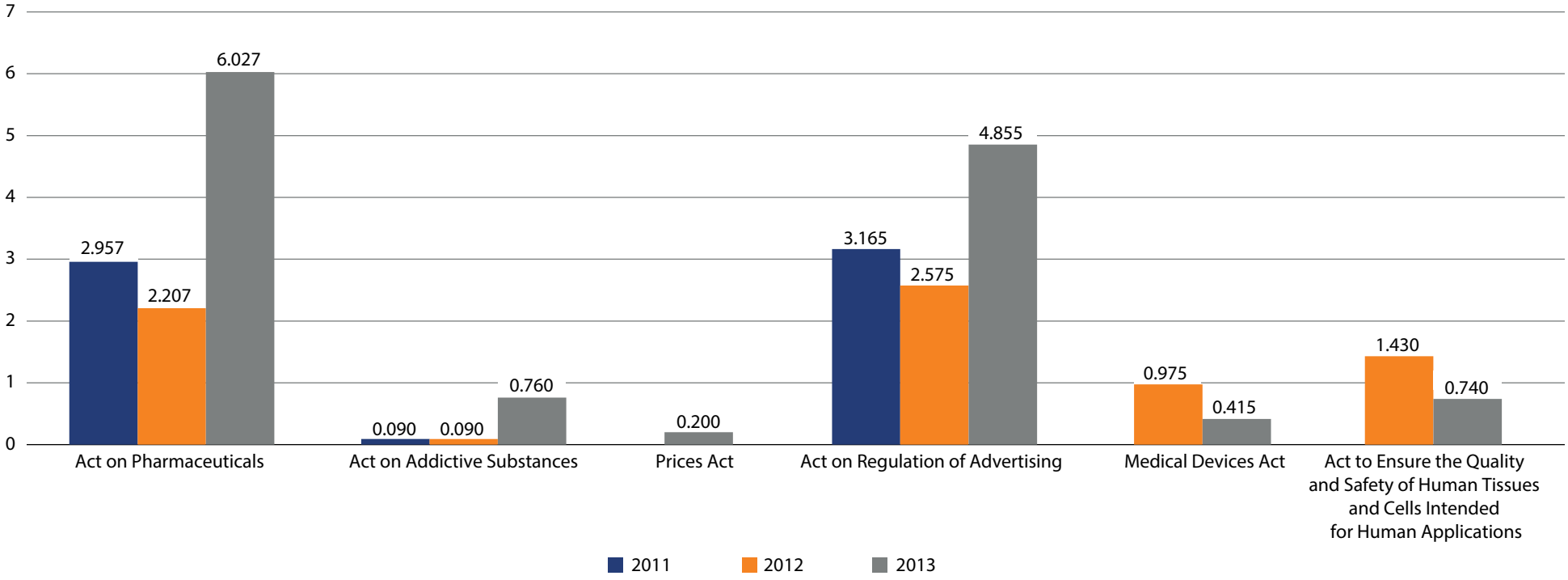
	General articles, tables	Articles	Total
European part	36	212	248
National part	11	10	21
Total	47	222	269

form of a supplement to the Czech Pharmacopoeia emerged from the assessment of the number of new (1% of all texts) and modified (3% of all texts) articles compared to unchanged articles.

The general part – the National part of the CP 2009 – Suppl. 2014 – includes the full tables I, II, III, IV, V, X and XII that were supplemented with information about newly added substances and also include medicinal products specified in CP 2009 and subsequent supplements.

Table XVI: Storage and expiry of products prepared in pharmacies, which was processed in cooperation with the analytical department of the Institute and selected hospital pharmacies, was revised and newly tested products were added to it. The Special section of the National part newly includes 11 articles

Fig. 15 – Sanctions imposed by the Institute that become legally valid in 2011 – 2013 (in mil. of CZK)



on medicinal products that reflect data acquired while monitoring their stability;these texts were submitted for public review (notified) and were reported under No. 2014/0042/CZ in compliance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, and the rules on information society services as amended by Directive 98/48/EC.

Besides the Pharmacopoeia Department, also other experts of the Institute contributed to the preparation of CP 2009 – Suppl. 2014. Czech Pharmacopoeia 2009 – Supplement 2014 will be binding as of 1 September 2014.

Cooperation with the European Pharmacopoeial Commission (hereinafter referred to as EPC) in the preparation of another edition of Ph. Eur. and in the preparation of translation and revision of the "Standard Terms" database continued. The Department of Pharmacopoeia informs about the binding nature of the Ph. Eur. editions in information media of the Institute. The Department regularly took part in the meetings of EPC and the secretariats of national pharmacopoeial commissions.

Standardisation

In 2013, 5 draft translations of Czech technical standards for medical devices were commented on within the scope of standardisation activities.

4.14 Penalties imposed by the Institute

Based on identified breaches of legislative requirements in the course of inspections or in the supervision of advertising and based on reports, the Institute initiates administrative proceedings within which penalties referred to in the applicable laws are imposed according to the severity of the identified problem. Since August 2011 the Institute started to take advantage also of the option to impose sanctions on the basis of the so-called administrative order, under the Administrative Procedure Code. The Institute observed this practice in 2013 as well.

PRICE AND REIMBURSEMENT REGULATION BRANCH

According to the Act on Public Health Insurance, the Price and Reimbursement Regulation Branch decides on maximum prices and reimbursement of medicinal products and foods for special medical purposes. In proprietary medicinal products, this is done in administrative proceedings that fully comply with the transparent procedures in accordance with European legislation. Administrative proceedings are conducted in cases specified by law ex officio (mainly in-depth and shortened revision) or at the request of the persons authorized by law (marketing authorization

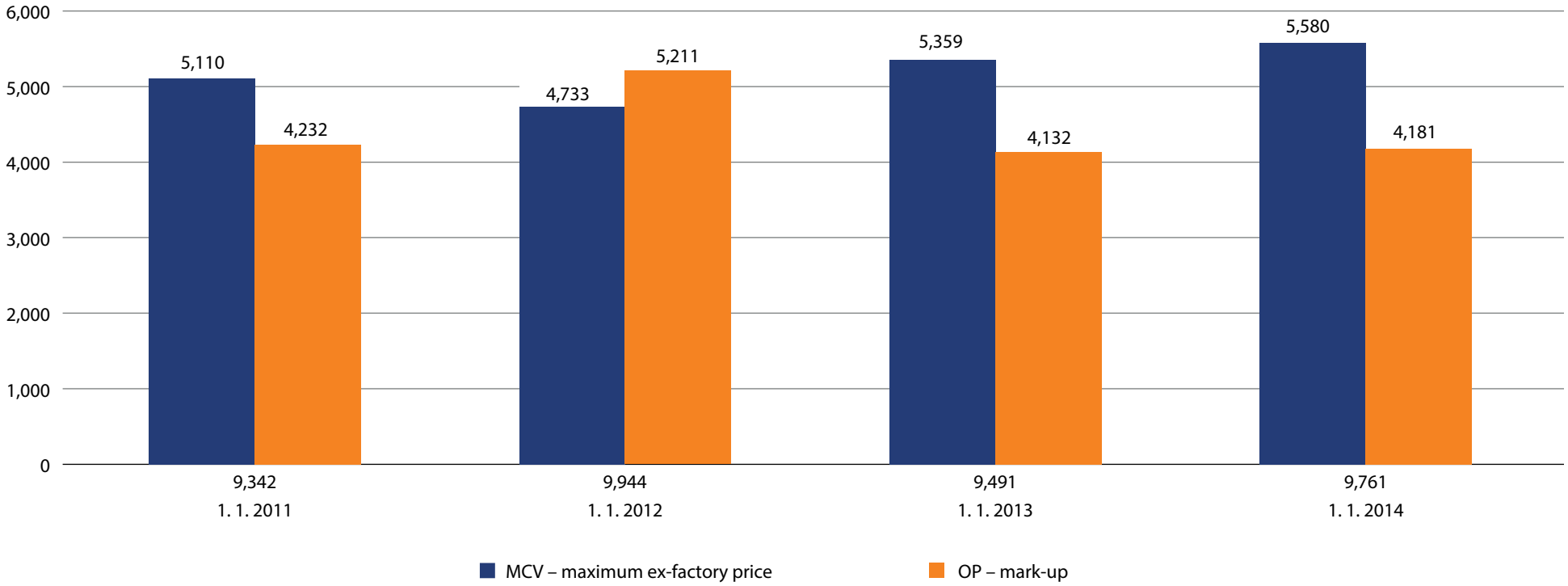
Table 26 – Overview of administrative procedures in 2013

Applications for maximum ex-factory price determination	No. of SÚKL codes
Initiated	772
Decided	771
Appeal proceedings pending	0
Came into force	761
Applications for maximum ex-factory price changes	
Initiated	151
Decided	130
Appeal proceedings pending	1
Came into force	113
Applications for maximum ex-factory price reduction - short version	
Initiated	5
Decided	5
Appeal proceedings pending	0
Came into force	5
Applications for maximum ex-factory price cancellation	
Initiated	21
Decided	2
Appeal proceedings pending	0
Came into force	2

holder in the case of an authorized medicinal product, importer or domestic manufacturer of medicinal products if the medicinal product imported or produced by it is used in the Czech Republic within a specific therapeutic programme or another person applying for a specific therapeutic programme; importer or domestic manufacturer of foods for special medical purposes; health insurance provider). The request to initiate administrative proceedings ex officio may be submitted by any person.

In July 2013, the Price and Reimbursement Branch underwent reorganization which was aimed to increase effectiveness of professional evaluation of medicinal products and to enhance the procedural knowledge of evaluators, or to provide legal assistance respectively. The types of administrative proceedings were divided between two departments: a department for coordination of administrative proceedings and a support department for other departments (administrative and specialized) that are responsible for the conduct of administrative proceedings. Therefore, the Price and Reimbursement Branch newly has 6 departments: Department of Preparation of Comprehensive Materials and Analyses, Department of Pharmaceutical Evaluation, Department of Selected Types of Administrative Proceedings, Department of Validation and Administrative Support, Department of Pharmacoeconomic Analysis and Department of Coordination of Administrative Proceedings.

Fig. 16 – Structure of reimbursed products by type of price regulation



4.15 Determination of Prices and Reimbursement

In the course of 2013, the Branch continued in the initiation of in-depth reimbursement inspections in accordance with the plan. At the same time, new types of administrative proceedings appeared in the administrative decision-making, which were introduced by an amendment to the Act on Public Health Insurance at the end of 2011.

Maximum ex-factory prices

A major legislative change in the area of price regulation was brought by the Price Regulation of the Ministry of Health of the Czech Republic 1/2013/FAR on the regulation of prices of medicinal products and foods for special medical purposes (hereinafter referred to as the "Price Regulation") and the Price Decision of the Ministry of Health of the Czech Republic 1/13-FAR laying down a list of ATC groups that are not subject to price regulation by setting a maximum price in the specified dosage form (hereinafter referred to as the "Price Decision"); both regulations adjusted the method of price regulation of 760 codes of medicinal products with effect from 1 January 2013. Holders of marketing authorizations for medicinal products, which became newly regulated by a maximum price, were required to request the maximum price by 31 January 2013. Overall, 232 administrative proceedings were initiated based on the requests for the

Table 27 – Overview of the number of codes of medicinal products/foods for special medical purposes in maximum ex-factory price zones as per the List of Prices and Reimbursements by month

Price zone	2013_01	2013_02	2013_03	2013_04	2013_05	2013_06	2013_07	2013_08	2013_09	2013_10	2013_11	2013_12
Up to 20 CZK inclusive	32	32	31	35	40	43	46	45	45	44	43	43
More than 20 CZK – 50 CZK inclusive	482	510	513	511	475	464	462	453	445	452	454	449
More than 50 CZK –100 CZK inclusive	641	640	642	635	630	662	668	673	673	683	697	699
More than 100 CZK – 200 CZK inclusive	751	752	758	748	770	794	797	792	806	806	827	829
More than 200 CZK – 300 CZK inclusive	470	454	455	448	424	430	425	427	450	431	435	438
More than 300 CZK – 500 CZK inclusive	550	568	567	565	558	540	550	556	569	560	574	579
More than 500 CZK – 1,000 CZK inclusive	679	663	667	673	689	666	666	668	670	663	665	672
More than 1,000 CZK – 2,000 CZK inclusive	600	602	602	608	621	627	613	621	621	601	613	617
More than 2,000 CZK – 3,000 CZK inclusive	246	241	241	242	246	243	247	244	248	250	251	251
More than 3,000 CZK – 5,000 CZK inclusive	340	332	331	337	341	353	352	354	355	356	350	341
More than 5,000 CZK – 10,000 CZK inclusive	249	259	260	260	273	277	281	283	283	293	296	303
More than 10,000 CZK – 20,000 CZK inclusive	172	170	169	168	176	181	180	180	184	184	186	190
More than 20,000 CZK – 30,000 CZK inclusive	59	60	59	59	62	61	60	60	61	61	62	63
More than 30,000 CZK – 50,000 CZK inclusive	39	40	40	40	38	38	40	40	40	40	40	40
More than 50,000 CZK – 100,000 CZK inclusive	35	35	36	36	38	38	40	39	40	40	40	40
More than 100,000 CZK	14	15	15	15	15	16	15	17	16	16	16	15
Number of codes	**5,359**	**5,373**	**5,386**	**5,380**	**5,396**	**5,433**	**5,442**	**5,452**	**5,506**	**5,480**	**5,549**	**5,569**

Fig. 17 – Prices of medicines regulated by the MCV and OP – comparison of average prices in Q4 2012 and Q4 2013 by price zones

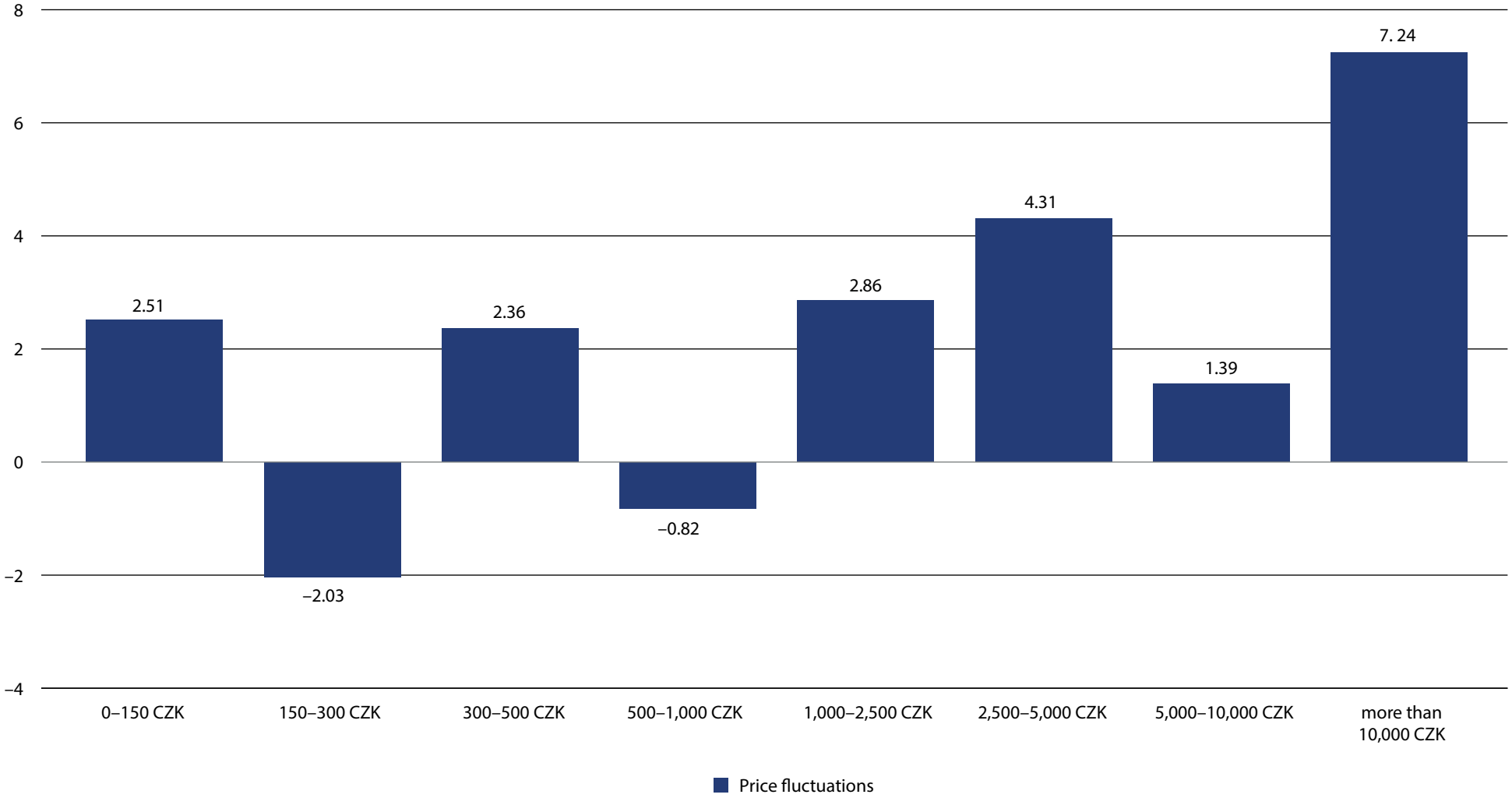


Fig. 18 – Price of medicines regulated only by OP – comparison of average prices in Q4 2012 and Q4 2013 by price zones

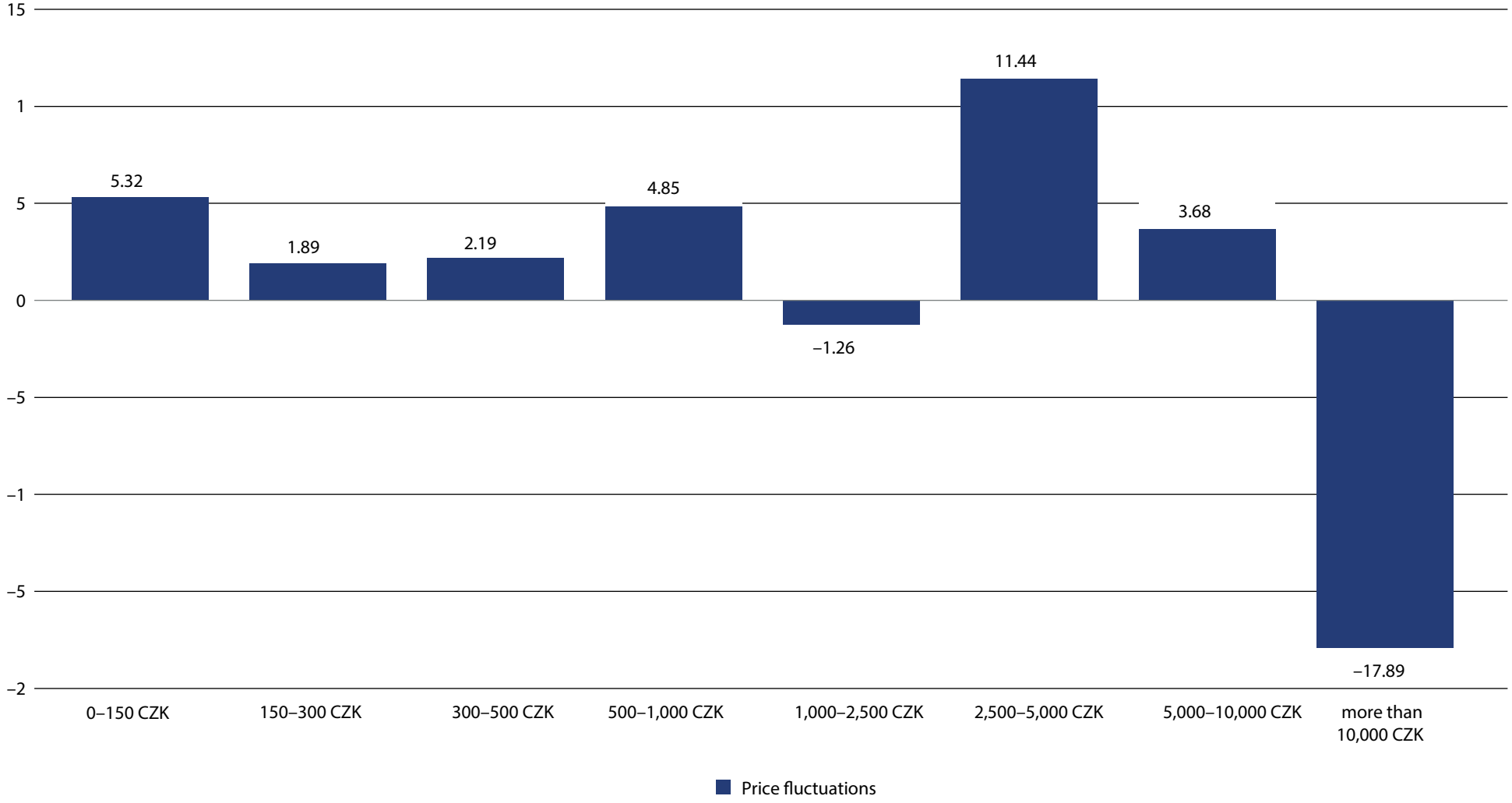


Table 28 – Ten most often distributed medicinal products by number of packages reported in compliance with DIS-13 for which the maximum ex-factory price was changed

Code	ATC	Name	Name supplement	No. of packages	Original price (CZK)	New price (CZK)	Change of price in %
0012023	A11CC05	VIGANTOL	POR GTT SOL 1 × 10 ml	739,173	33.65	62.84	86.8
0025366	A02BC01	HELICID 20 ZENTIVA	POR CPS ETD 90 × 20 mg	693,293	1,178.4	201.37	–82.9
0020132	N06AB10	CIPRALEX 10 mg	POR TBL FLM 28 × 10 mg I	680,205	452.17	364.04	–19.5
0026578	C09DA07	MICARDISPLUS 80/12,5 mg	POR TBL NOB 28	643,073	440.33	346.76	–21.3
0000536	C01CA03	NORADRENALIN LÉČIVA	INJ SOL 5 × 1 mg/1 mg	641,741	98.75	103.07	4.4
0001066	D06AX	FRAMYKOIN	DRM UNG 1 × 10 mg	625,260	31.91	33.32	4.4
0096696	C03BA11	INDAP	POR CPS DUR 30 × 2,5 mg	621,831	25.68	33.03	28.6
0044305	R03DA04	EUPHYLLIN CR N 200	POR CPS PRO 50 × 200 mg	620,199	86.15	72.55	–15.8
0002479	R06AX	DITHIADEN	POR TBL NOB 20 × 2 mg	524,388	51.6	52.41	1.6
0101211	C09AA04	PRESTARIUM NEO	POR TBL FLM 90 × 5 mg	462,382	983.17	433.5	–55.9

Table 29 – Ten most often distributed medicinal products by financial volume in CV reported in compliance with DIS-13 for which the maximum ex-factory price was changed

Code	ATC	Name	Name supplement	Financial volume in end user price	Original price (CZK)	New price (CZK)	Change of profit margin in %
0025566	L04AB04	HUMIRA 40 mg	INJ SOL 2 × 0,8 ml/40 mg	764,221,759	26,898.46	22,170.50	–17.6
0028028	L01XE01	GLIVEC 400 mg	POR TBL FLM 30 × 400 mg	500,873,220	50,554.55	51,568.32	2.0
0027953	A10AE04	LANTUS 100 jednotek/ml	SDR INJ SOL 5 × 3 ml SOLOSTAR	323,703,668	1,307.95	1,110.61	–15.1
0045958	R03AK06	SERETIDE DISKUS 50/500	INH PLV 1 × 60 × 50/500 MCG	289,942,422	1,251.45	991.02	–20.8
0045964	R03AK06	SERETIDE DISKUS 50/250	INH PLV 1 × 60 × 50/250 RG	273,021,116	927.74	736.02	–20.7
0027918	L04AB04	HUMIRA 40 mg	INJ SOL 2 × 0,8 ml/40 mg	253,953,910	25,585.50	22,170.50	–13.3
0025366	A02BC01	HELICID 20 ZENTIVA	POR CPS ETD 90 × 20 mg	238,253,340	1,178.40	201.37	–82.9
0032393	R03BB04	SPIRIVA	INH PLV CPS 30 × 18 RG	229,634,976	887.14	706.54	–20.4
0047995	C10AX09	EZETROL 10 mg TABLETY	POR TBL NOB 30 × 10 mg B	219,387,487	853.76	759.54	–11.0
0101211	C09AA04	PRESTARIUM NEO	POR TBL FLM 90 × 5 mg	196,141,083	983.17	433.50	–55.9

Table 30 – Overview of administrative procedures in 2013

Applications for determination or change of the reimbursement amount and conditions	No. of SÚKL codes
Initiated	107
Decided	69
Appeal proceedings pending	4
Came into force	63
Applications for determination or change of maximum prices and reimbursement amount and conditions	
Initiated	193
Decided	113
Appeal proceedings pending	0
Came into force	97
Applications for reimbursement cancellation	
Initiated	57
Decided	42
Appeal proceedings pending	0
Came into force	33
Applications for maximum price and reimbursement cancellation	
Initiated	173
Decided	159
Appeal proceedings pending	0
Came into force	155
Procedures initiated ex officio	
Initiated	4,967
Decided	3,348
Appeal proceedings pending	1,158
Came into force	680

» cont. table 30

Procedures on similar products	
Initiated	765
Decided	1,133
Appeal proceedings pending	4
Came into force	939

Table 31 – Overview of decisions on the revision of reimbursements and the impact on the public health insurance funds

Effective date	No. of SÚKL codes	No. of administrative procedures	Impact on health insurance funds
1/2013	400	18	–16,210,990
2/2013	107	2	78,630,525
3/2013	71	5	41,435,349
4/2013	263	9	117,185,973
5/2013	33	5	–19,324,986
6/2013	199	13	–37,263,711
7/2013	271	22	409,245,624
8/2013	65	20	71,990,118
9/2013	84	21	–12,684,197
10/2013	357	24	–140,725,514
11/2013	54	16	15,449,281
12/2013	63	18	46,865,490

Note: A positive number shows savings in health insurance, negative number an increase of impact on the budget.

Table 32 – Overview of the number of codes of medicinal products/foods for special medical purposes in reimbursement price zones according to the List of Prices and Reimbursements by month

Price zones	2013_01	2013_02	2013_03	2013_04	2013_05	2013_06	2013_07	2013_08	2013_09	2013_10	2013_11	2013_12
Up to 20 CZK inclusive	156	156	165	164	165	166	166	172	169	170	182	182
More than 20 CZK – 50 CZK inclusive	736	711	717	706	707	708	698	694	684	709	733	761
More than 50 CZK –100 CZK inclusive	1,121	1,114	1,126	1,104	1,094	1,112	1,107	1,123	1,148	1,190	1,259	1,311
More than 100 CZK – 200 CZK inclusive	1,587	1,591	1,600	1,582	1,579	1,579	1,605	1,602	1,636	1,572	1,676	1,638
More than 200 CZK – 300 CZK inclusive	878	868	867	859	859	882	895	908	926	932	927	935
More than 300 CZK – 500 CZK inclusive	1,016	1,030	1,031	1,031	1,028	1,063	1,041	995	1,027	998	1,034	1,017
More than 500 CZK – 1,000 CZK inclusive	1,365	1,374	1,382	1,387	1,387	1,360	1,396	1,438	1,413	1,404	1,407	1,384
More than 1,000 CZK – 2,000 CZK inclusive	973	968	965	981	984	982	986	959	967	979	956	924
More than 2,000 CZK – 3,000 CZK inclusive	416	411	411	418	430	433	409	407	423	434	393	390
More than 3,000 CZK – 5,000 CZK inclusive	373	367	374	380	379	376	373	369	376	373	349	346
More than 5,000 CZK – 10,000 CZK inclusive	437	446	439	440	448	450	450	456	447	438	390	394
More than 10,000 CZK – 20,000 CZK inclusive	241	244	245	249	259	263	262	264	263	266	273	278
More than 20,000 CZK – 30,000 CZK inclusive	92	90	91	91	95	96	95	95	94	94	92	94
More than 30,000 CZK – 50,000 CZK inclusive	47	49	49	49	48	48	50	49	51	51	51	52
More than 50,000 CZK – 100,000 CZK inclusive	39	41	41	41	42	42	43	43	41	41	41	41
More than 100,000 CZK	14	15	15	15	15	16	16	18	18	18	18	17
Number of codes	**9,491**	**9,475**	**9,518**	**9,497**	**9,519**	**9,576**	**9,592**	**9,592**	**9,683**	**9,669**	**9,781**	**9,764**

establishment of maximum prices. Administrative proceedings regarding one code of a medicinal product are appealed, other administrative proceedings were effectively concluded. The proportion of medicinal products regulated by a maximum ex-factory price increased with regard to the change of price regulation (Fig. 16).

Development of average prices for end users

As of 1 January 2013, an amendment to Act No. 235/2004 Coll., on Value Added Tax (hereinafter referred to as "VAT") came into force, which increased the VAT from 14% to 15%. Despite that, the price for the end users decreased in the case of both groups of medicinal products with different methods of regulation.

In the case of medicinal products that are regulated by a specified maximum price (maximum price of the originator specified in the administrative proceedings and a mark-up according to the Price Regulation), the average price for the end user decreased by 9.4 %.

In the case of medicinal products that are regulated by the announced price and a mark-up (according to the Price Regulation and Price Decision), the average price for the end user decreased by 6 %.

Overview of the most often distributed medicinal products for which the maximum ex-factory price was changed

On the basis of the periodical distributor reports on performed supplies of medicinal products, an overview of ten most often distributed medicinal products was compiled, along with ten

medicinal products with the highest financial volume according to ex-factory price, for which the maximum ex-factory price was changed.

Compared to last year, the scope of group of the most distributed medicinal products, the maximum price of which changed, was altered, or extended to medicinal products from the price zones 3 – 5. The maximum price of this group of medicinal products decreased significantly (Table 28).

Medicinal products with the largest volume of funds can be found in almost the entire spectrum of price zones. The maximum prices of nearly all medicinal products were reduced significantly (Table 29).

Amounts and conditions of reimbursements from health insurance

According to Section 39l of the Act on Public Health Insurance, the Institute is required, among other things, to assess the amount of the basic reimbursement, the consistency of the amounts of reimbursements for all principally therapeutically interchangeable medicinal products with the basic reimbursement, the uniformity and effectiveness of the conditions laid down above and compliance of the determined amounts and conditions of reimbursement with this Act, specifically meeting the expected results and reasons for pharmacotherapy, the effectiveness of the establishment of reference groups, the amount of basic remuneration, conditions of payment, assessment of the clinical and cost effectiveness and comparison with the original goals of pharmacotherapy. This process takes place within so-called in-depth revision of the reimbursement system. The Institute initiates ex officio even other types of administrative proceedings, such as short revision or individual administrative proceedings to change or revoke the amounts and conditions of reimbursement.

The establishment, alteration or cancellation of the amounts and conditions of reimbursement can be also requested by the parties in proceedings defined by the Act on Public Health Insurance. In the event of such proceedings, the applicant is fully in charge of its application and may deal with it in accordance with the law.

Since the end of 2011, parties in the proceedings have the option to submit an application in a new type of administrative proceedings to determine the maximum price and the amounts and conditions of reimbursement of a similar product which ensures that the maximum price and the amount and conditions of reimbursement are determined within 30 days of submission of the application if all statutory conditions are met.

Overview of the most often distributed medicinal products for which reimbursement from health insurance was changed

It is clear from the overview that there was a significant decrease in the reimbursement for individual packages of medicinal products in the group of medicinal products with the greatest volume of reimbursement from health insurance (Table 33).

On the other hand, the group of medicinal products that are most distributed is heterogeneous and the amounts of reimbursement are increasing as well as decreasing. With regard to the above group, this should not affect the total expenditure from the public health insurance budget (Table 34).

Validation of applications

It is clear from the overview of application validation that the number of applications has been constantly increasing. The number of applications has increased by nearly 15.8 % of applications (a total of 119 administrative proceedings) compared to the previous year. Similarly as the previous year, the number of applications submitted in January increased due to the change in price regulation according to the Price Regulation and the Price Decision. At the same time, the number of administrative proceedings suspended has been increasing due to deficiencies in the submission and shortcomings in the application, which are, however, later removed, and therefore the number of suspended administrative proceedings is decreasing for these reasons.

Individually prepared medicinal products (IPLP)

Legislative changes

As stated above, the VAT for medicinal products increased from 14 % to 15 %. However, in the case of reimbursement of IPLP, it was necessary to take into account raw materials, other materials and equipment necessary for the preparation, where VAT increased from 14 % to 21 %. As of the above date, three general proceedings (hereinafter referred to as "OPP") were finished in a short period, which in compliance with the VAT change adjusted reimbursements of individually prepared medicinal products in the group of prepared radiopharmaceuticals, prepared parenteral nutrition products for home therapy (hereinafter referred to as the DPV) and produced transfusion products. On this date, a new Price Regulation also came into force that leaves IPLP in material price regulation but which, among other thing, adjusted Art. IV, paragraph 5, by extending the exception for radiopharmaceuticals containing 99mTc, 51Cr and 111In. Based on the newly included Section 79a of Act No. 378/2007 Coll. on Pharmaceuticals and Amendments to Some Related acts (Act on Pharmaceuticals), as amended, which defines individually prepared medicinal products containing cannabis for medical use, OOP proceedings were carried out for the group of extemporaneous products in the first half of 2013. In the first half of 2013, the Institute carried out two revisions focused on verifying the validity of issued methodologies for the determination of reimbursement amounts for two IPLP subgroups, namely transfusion products and prepared radiopharmaceuticals. In the second half of the year, it carried out a evision focused on the DPV subgroup. Revised IPLP cost items in CZK were applied in the statistics according to the data provided

Table 33 – Ten most often distributed medicinal products by financial volume in end user prices reported in compliance with DIS-13, for which reimbursement from health insurance was changed

Code	ATC	Name	Name supplement	Financial volume in end user prices (CZK)	Original reimb. (CZK)	New reimb. (CZK)	Change in reimb. in %
0027283	L04AB02	REMICADE 100 mg	INF PLV CSL 1 × 100 mg	809,238,383.3	15,609.68	15,595.89	–0.09
0014075	C05CA53	DETRALEX	POR TBL FLM 60 × 500 mg	530,928,835.5	138.61	115.30	–16.82
0025366	A02BC01	HELICID 20 ZENTIVA	POR CPS ETD 90 × 20 mg	238,253,339.9	612.26	314.90	–48.57
0101211	C09AA04	PRESTARIUM NEO	POR TBL FLM 90 × 5 mg	196,141,082.6	303.46	202.25	–33.35
0093018	C10AA05	SORTIS 20 mg	POR TBL FLM 100 × 20 mg	186,535,915.5	874.69	435.30	–50.23
0014498	G04CA02	OMNIC TOCAS 0.4	POR TBL PRO 100 × 0,4 mg	186,321,350.5	848.11	547.17	–35.48
0026789	A10AB05	NOVORAPID PENFILL 100 U/ml	INJ SOL 5 × 3 ml	186,301,559.8	1,110.13	886.91	–20.11
0026486	A10AB01	ACTRAPID PENFILL 100 IU/ml	INJ SOL 5 × 3 ml	168,931,940.9	909.59	886.91	–2.49
0014821	M01AX25	CONDROSULF 800	POR TBL OBD 30 × 800 mg	145,002,938.8	193.93	166.97	–13.90
0089029	B02BD06	IMMUNATE STIM PLUS 1000	INJ PSO LQF 1 × 1 KU	133,118,496.4	10,893.40	9,022.09	–17.18

Table 34 – Ten most often distributed medicinal products by number of packages reported in compliance with DIS-13 for which the amount of reimbursement was changed

Code	ATC	Name	Name supplement	A (No. of packages)	Original reimb. (CZK)	New reimb. (CZK)	B (No. of packages)	Note:
0014075	C05CA53	DETRALEX	POR TBL FLM 60 × 500 mg	643,357	138.61	115.30	755,570	
0002592	M04AA01	MILURIT 100	POR TBL NOB 50 × 100 mg	740,652	44.80	47.63	663,328	
0098219	C03CA01	FURON 40 mg	POR TBL NOB 50 × 40 mg	313,827	58.23	66.60	301,265	*
0091788	N05BA12	NEUROL 0.25	POR TBL NOB 30 × 0.25 mg	204,268	6.98	5.37	222,304	*
0025366	A02BC01	HELICID 20 ZENTIVA	POR CPS ETD 90 × 20 mg	167,003	612.26	314.90	183,494	*
0000168	C03AA03	HYDROCHLOROTHIAZID LÉČIVA	POR TBL NOB 20 × 25 mg	319,557	22.96	26.97		×
0001066	D06AX	FRAMYKOIN	DRM UNG 1 × 10 GM	151,821	31.64	50.27	150,992	*
0096696	C03BA11	INDAP	POR CPS DUR 30 × 2,5 mg	289,012	34.43	40.46		×
0000269	H02AB07	PREDNISON 5 LÉČIVA	POR TBL NOB 20 × 5 mg	272,012	25.42	22.88	252,898	
0125599	A12BA01	KALNORMIN	POR TBL PRO 30 × 1 GM	240,860	20.24	24.22		×

** – period of one quarter of a year, x - period cannot be assessed, A – No. of packages distributed during 6 months before change, B – number of packages distributed during 6 months after change.*

by health insurance companies and they were compared with the data maintained by the Registry of Domestic Nutritional Support (REDNUP). In the course of the year updated methodologies pertaining to the procedure and conditions of reimbursement for individual IPLP subgroups were issued based on internal changes, legislative changes and in compliance with the results of the revisions.

General Measures

A total of 6 procedures regarding general measures were initiated and duly completed in the course of 2013. In the first quarter of 2013, three additional OOPs were issued based on the VAT change, where the amount of reimbursement associated with change of VAT of materials and equipment necessary for the preparation of IPLP, whose inclusion in the 21% VAT group represents a cost increase, was changed.

In the first half of 2013, OOP 04-13 was initiated for the group of extemporaneous products which defined individually prepared medicinal products containing cannabis for medical use. In Article 2 of the OOP, under the conditions of repayment, Section 5c), the item "cannabis for medicinal use" was added. This change did not affect the costs of this group of IPLP.

In the first half of the year, OOP 05-13 was issued, which was initiated by a report and notification of suspension of the manufacture and supply of radiopharmaceuticals with the active ingredients mefenin and mebrofenin and inclusion of a new radiopharmaceutical with the active ingredient efenin, code IPLP 0002022 for which it was possible to be included in the reimbursement system as replacement for the suspended manufacture based on an approved specific therapeutic programme. At the same time, the above OPP also reflected the results of the revision and proposed changes according to the conclusions of the revision for 2012. Furthermore, new price data for 2013 were taken into account based on the regular annual report. The implemented changes represent an increase of reimbursement by 2% on average, which does not exceed the permitted year-on-year limit determined by the relevant Price Regulation.

In the second half of 2013, OOP 06-13 was initiated and conducted based on a presented report of the scientific society for transfusion medicine. It resulted in the inclusion of a new code for the pediatric unit of deleucotized platelets prepared from pooled buffy-coat. This extension of paid transfusion products was assessed as improvement of record-keeping, better management of transfusion products and does not represent an increase in the total cost of the subgroup of transfusion products. In the second half of the year, a revision of the reimbursement in the subgroup of DPV used in private nursing homes was conducted and no significant deviations from the established system were found. In December 2013, the specific therapeutic programme for the product Peditrace was extended because it was not necessary to change the formula and thus the reimbursement for individual codes of the DPV group.

Fig. 19 – Development of IPLP costs in millions of CZK

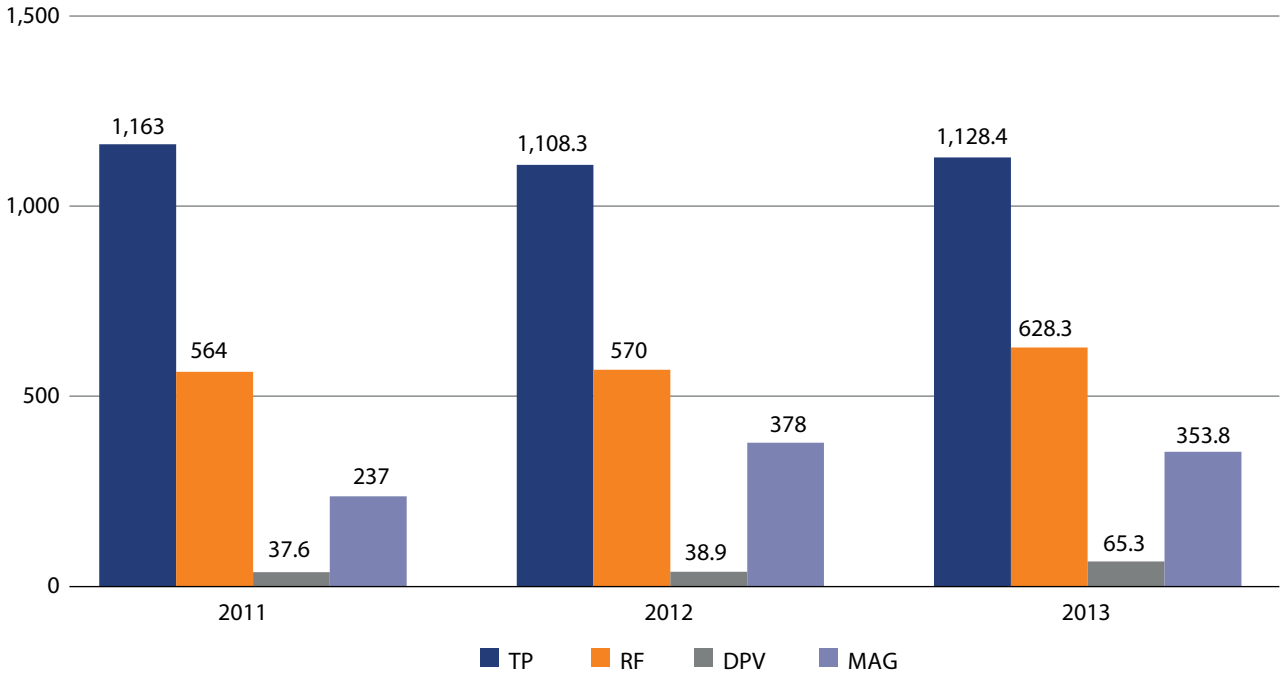


Fig. 20 – Development of IPLP consumption in thousands of DJ

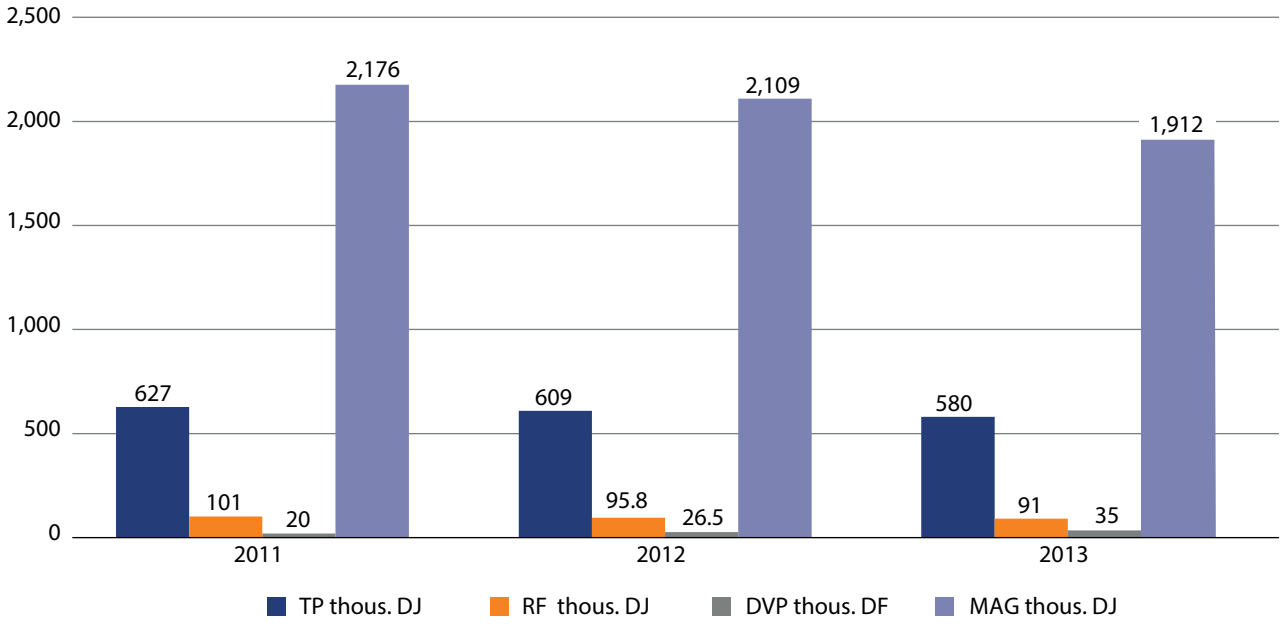


Table 35 – Validation of applications for determination/ change/cancellation of maximum prices and reimbursement amounts and conditions, for summary revision of system of maximum prices or reimbursement

2013	No. of applications submitted	Suspended due to defective submission and deficiencies in application	Discontinued in the validation phase
January	271	63	9
February	72	6	2
March	68	4	0
April	69	14	0
May	51	13	1
June	59	18	1
July	58	0	0
August	46	6	1
September	47	11	0
October	38	4	0
November	56	1	1
December	39	4	1
Total	**874**	**144**	**16**

Consumption and costs of IPLP

Compared to the previous year, costs of individual IPLP groups in 2013 were assessed in connection with the VAT change. It mainly affected those groups of products which use for preparation items included in the increased 21% VAT. During 2013, no changes in the amount of reimbursement were made in a subgroup of 12 transfusion products except for the VAT change and the total consumption of transfusion products corresponded to 2012. The increase in costs associated with the VAT change is 2 %, the total increase in costs in 2013 related to 2012 represents 4.6 % and is associated with increased costs of electricity and overheads. In a subgroup of 13 individually prepared radiopharmaceuticals, the VAT increase represented an average cost increase of 2 % compared to 2012. In the DPV group, only the VAT change was taken into account and therefore there is only 1% annual increase in costs per 1 DF. However, the total costs represent a 70% increase compared to 2012 due to an improvement of record-keeping and reporting of consumption by health insurance companies. In the group of IPLP extemporaneous, the laborum tax was changed in 2012 which is strongly reflected in the annual cost for this group of medicinal products. In 2011, the average cost of one preparation of the medicinal product was CZK 108.90, in 2012 it was CZK 179 and in 2013 it reached the average cost of CZK 185. The overall decrease in costs of the subgroup 11 extemporaneous is the result of another gradual decrease in the volume of individually prepared products in pharmacy establishments.

MEDICAL DEVICES BRANCH

The Institute also performs tasks in the regulation of medical devices (MDs). In 2013, it performed activities in vigilance, clinical trials and inspections of healthcare providers in relation to MDs.

The Institute responded to the development in the area of regulation of MDs by splitting the activities performed from February 2013 into a separate branch which reports in the section of regulatory activities directly to the deputy director for regulatory activities. Creating the Branch for Medical Devices allowed the launch of the 2014 Agenda for Medical Devices project during the year. By this project, the Institute was getting ready during 2013 for the tasks arising from the draft act on medical devices.

In December 2013, the preparations were completed for the transfer of the inspections of MDs at the sites of healthcare providers medical services from the Surveillance Branch to the Medical Devices Branch as of 1 January 2014. For the purposes of this annual report, the report on inspections at the providers' sites is included under the Surveillance Branch where it belonged during the entire year of 2013.

Separating the activities related to MDs into a separate branch was the first step towards building the infrastructure necessary to start getting ready for the changes brought into the activities of the Institute by the new act on medical devices. As of December 2013, the phase of the stabilization of the branch was completed for the purposes of implementation of competences, which are entrusted to the Institute by the current Act No. 123/2000 Coll., on Medical Devices, and amending certain related acts, as amended, and based on the Institute's written authorization issued by the Minister of Health on 30 September 2013.

Authorization issued by the Ministry of Health of the Czech Republic

On 30 September 2013, the Institute was authorized by the Minister of Health to perform activities in the area of MDs beyond the current activities. Based on this authorization, the Institute was performing the following tasks until the end of 2013:

1. It collaborated with the Department of Medical Devices of the Ministry of Health of the Czech Republic in commenting and drafting expert opinions on the draft legislation for MDs at the EU level. This cooperation also required attendance of a representative of the Institute at a meeting of the EU Council.

2. It initiated preparation for coordination of the process of creating a category tree of hospital MDs. Before the end of 2013, a meeting regarding the first level of the category tree took place.

3. The Institute assisted health insurance companies in the development of a new code list of voucher-based MDs, including the removal and prevention of disputes between the health insurance companies and suppliers in the allocation of MDs in the category tree.

4. It intensively collaborated with KSRZIS and suppliers of the register of medical devices RZPRO, including user testing.

5. It ensured that the obligations of the Czech Republic were met in the transmission of information from statutory bodies in the fulfillment of reporting obligations to the European database of MDs Eudamed.

4.16 Department of clinical trials and medical devices vigilance

Within the scope of inspections of the conduct of clinical trials on medical devices at healthcare providers, 15 inspections were carried out, during which 13 tested medical devices were inspected. The selection of workplaces to be inspected was based upon positive opinions issued by the Institute in respect of the intention to carry out a clinical trial.

100 serious adverse incidents (SAE) were reported to the Institute in respect of the ongoing clinical trials on medical devices in the Czech Republic.

The intention to carry out a clinical trial was reported to the Institute for 24 MDs in 2013, 25 positive opinions were issued.

Investigation of adverse incidents and monitoring of corrective actions for medical devices.

289 adverse incidents with expected causality with the use of a medical device in the provision of healthcare within the territory of the Czech Republic were reported to the Institute. Furthermore, 16 adverse incidents occurring outside the territory of the Czech Republic involving medical devices of Czech manufacturers were reported. In all cases investigation was launched. Within the investigation of adverse events, 4 inspections at healthcare service providers ' sites were carried out.

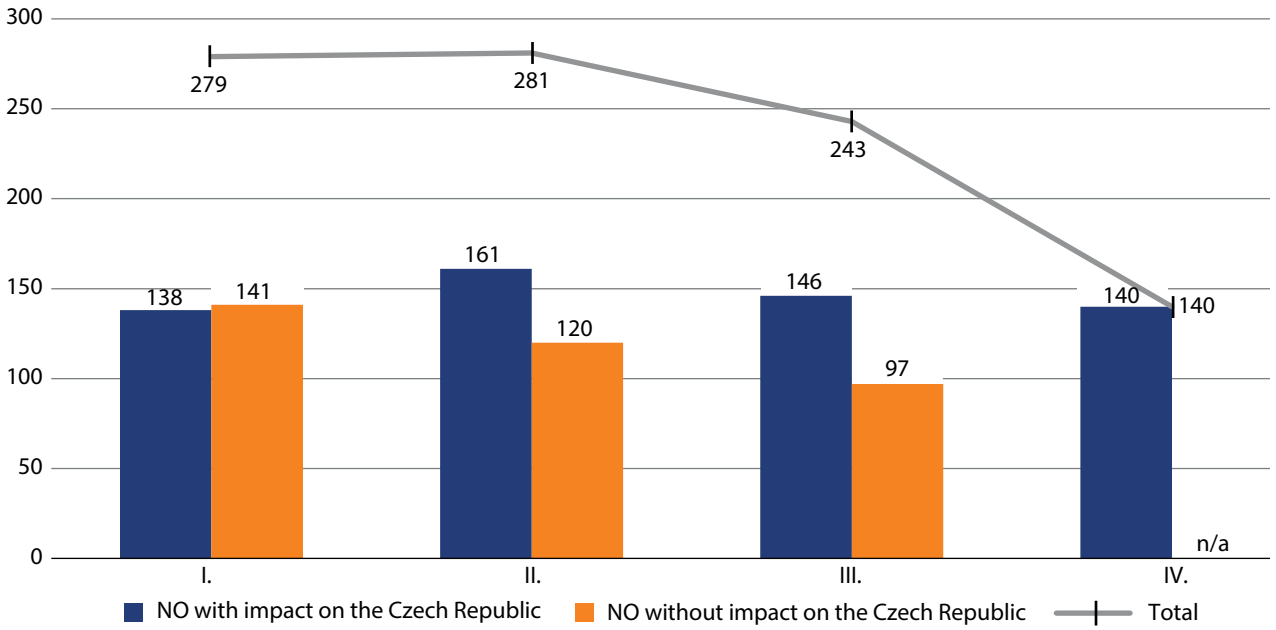
The total number of reports on corrective actions in respect of MDs received from competent authorities, manufacturers or their authorized representatives, distributors or importers, where applicable, was 943. Of the total number of received reports, 585 concerned MDs distributed within the Czech market (Fig. 21).

The number of received notifications of corrective actions regarding MDs in 2013 was comparable to 2012.

In 2013, the Institute published on its website 443 Field Safety Notices (FSN) pertaining to Czech users, which are distributed by the manufacturer, authorized representative or distributor in connection with the Field Safety Corrective Action (FSCA) in order to minimise possible recurrence of an adverse event.

Based on the results of the investigation of adverse events and findings in the fulfilment of reporting obligations, five fines

Fig. 21 – Report on corrective actions related to MDs adopted in 2013



for administrative offenses in the total amount of CZK 110,000 were imposed.

In the framework of international cooperation in the area of MD vigilance, inspectors of the Adverse Incident and Clinical Trial Department participated in 12 teleconferences in 2013 focused on the exchange of information about current vigilance cases between EU Member States.

Within national cooperation and their competences, supervisory bodies for MDs of the Institute and the Czech Trade Inspection (ČOI) mutually exchanged motions to initiate investigations.

In 2013, 5 draft translations of Czech technical standards for medical devices were commented on within the scope of standardisation activities.

4.17 2014 Agenda for Medical Devices Project

Since the beginning of 2013, the draft act on medical devices expected to take effect from 1 January 2014 was finalized. Due to this date and given the complexity of the preparations of the Institute for its new tasks, a draft of the project "2014 Agenda for Medical Devices" was approved in February 2013. The project set out to prepare the Institute during 2013 for the smooth and effective fulfillment of tasks that it will undertake according to the draft act on MDS. Its main elements include particularly support for the legislative process and preparation of the register of medical devices RZPRO as well as defining and describing in detail the processes and work procedures, personnel assignment for these processes and preparation of the technical and operating infrastructure. The deadline for implementation of readiness of the Institute was set for the date of expected effectiveness of the new act.

STATE AGENCY FOR MEDICAL CANNABIS

According to Act No. 167/1998 Coll., on Addictive Substances, as amended, the Institute performs the tasks of the State Agency for Cannabis for Medical Use. The Department of the State Agency for Cannabis for Medical Use was established on 1 January 2013. Its activities consist in granting licenses to grow cannabis for medical use, controlling compliance of the cultivation, processing and storage with legislative requirements, ensuring purchases of the grown and harvested cannabis for medical use and its safe storage, transport and distribution, or ensuring its export outside the territory of the Czech Republic. In addition, it also fulfils all reporting obligations towards the Ministry of Health of the Czech Republic and the Police of the Czech Republic.

4.18 Department of the State Agency for Medical Cannabis

In 2013, the main task of the Department was to develop a concept and conditions for the implementation of the amended legislation in practice, especially the amendment of Act No. 378/2007 Coll., on Pharmaceuticals, as amended, the amendment to Act No. 167/1998 Coll., on Addictive Substances, as amended, and Decree

No. 221/2013 Coll., laying down the conditions for prescribing, preparation, dispensing and use of individually prepared medicinal products containing cannabis for medical use.

Representatives of the Department of the State Agency for Cannabis for Medical Use regularly participate in the Working Group for the implementation of the law on medical cannabis into practice. The Institute regularly communicated with the inspector for narcotics and psychotropic substances of the Ministry of Health of the Czech Republic and also with the relevant specialized sections of the Ministry. In addition, cooperation with the regulation agency in the Netherlands was initiated. The agency has 10 years of experience with the use of medical cannabis and the issues related to cannabis in the Czech Republic have been intensively discussed with it.

The document titled "Good Cultivation Practice" was created and published. It specifies the procedure and conditions for growing and cultivating cannabis for medical use, not only as regards the protection of plants but also specific hygiene requirements and ensuring a standardized quality and the defined content of active ingredients.

At the end of the year, documents for the purpose of the tender were finalized according to which a licence will be granted to a selected grower. According to the amendments to the Act, it will be possible to make these documents public at the beginning of the second quarter of 2014.

On the website of the Institute, detailed information on prescribing, dispensing and use of medical cannabis, both for professionals and the general public, have been published. The preparations for communicating with patients and experts also includes a proposed design of dedicated website of the Agency, the operation of which will be launched simultaneously with the publication of the tender for the granting of a license for growing medical cannabis. This website will provide a comprehensive overview of information about cannabis for medical use in the Czech Republic.

5.1 Information technology

The IT Branch is responsible for flawless operation of the whole IT infrastructure, information technology supervision and IT infrastructure security against any outside attacks. The objective of the IT Branch is to provide high quality services to users in the Institute as well as cooperating entities.

The IT Branch actively participates in projects pertaining to the fulfilment of requirements by specialized sections, the development of information technology and data safety.

The consolidation of contractual relationships with suppliers continued in the IT Branch with the aim to achieve a higher quality and efficiency of the administration of IT services. There has been a significant progress in managing relationships with some major suppliers. The necessary steps were taken to achieve licensing compliance of SW tools and products that the Institute uses for work.

In connection with the requirement for mandatory electronic prescriptions, requirements for the availability and reliability of services were analysed and documents for the tender to build a new data centre and to expand and modernize the existing one were prepared. In accordance with legislative requirements, a new version of the electronic prescription and access to the register of medicinal products subject to restrictions were developed. The Information Technology Branch prepared the concept of the electronic prescription with the aim to increase the added value for patients as well as other entities that use electronic prescriptions. A website was developed for the Agency for Cannabis for Medical Use.

In the area of data management, the implementation of a powerful tool for BI was completed which significantly accelerated and improved processing of statistical reports for the management of the Institute, specialized units, governing bodies and the public. An analysis of reporting of the Institute will be processed as a basis for future development of the data warehouse.

In the field of medical devices, an interface for internal systems of the Institute to the register of medical devices was developed and an analysis of the expansion of the agenda in accordance with the planned legislation was processed.

The economic system was also linked to the National Treasury system and the application for filing and managing receivables was expanded. An effective solution for reimbursement tenders was prepared.

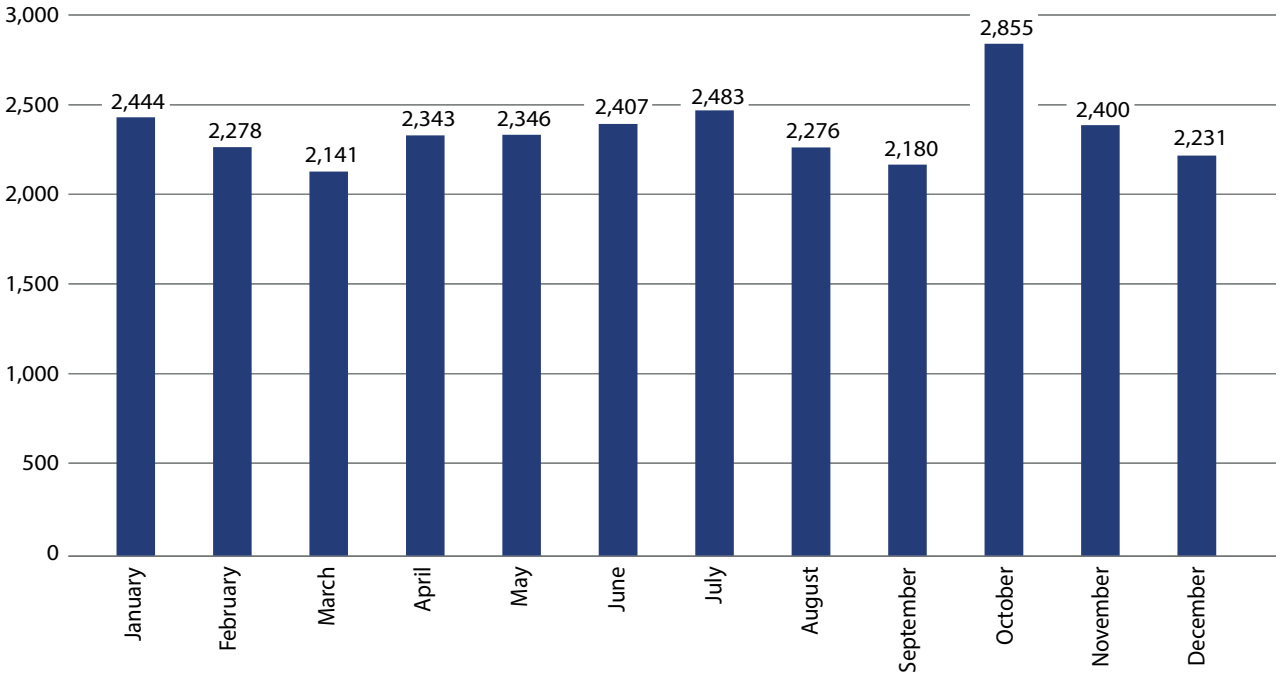
Advanced versions of the database of medicinal products and the database of adverse reactions were prepared in the area of pharmacovigilance.

In order to improve provided services and to reflect the IT trends, a number of technology measures were adopted:

- upgrade of the DMS database for records management
- IT security and equipping new facilities including IT equipment for new employees
- Partial upgrade of IT equipment for employees

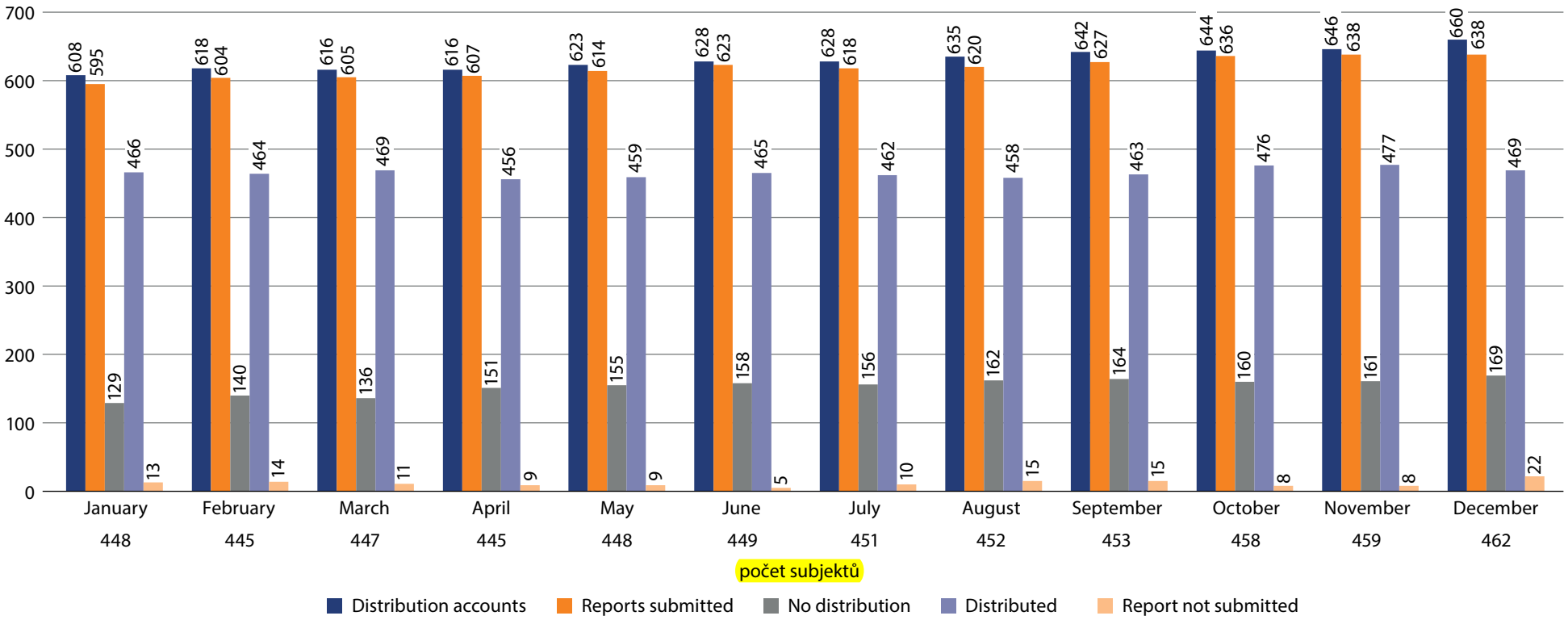
Throughout 2013, the IT Branch put emphasis on providing high quality service to cooperating entities. At the end of 2013, a total of 90 % of pharmacies participated in the system of data collection and 93% of distributors submitted reports on their activities within the deadline.

Fig. 1 – Document viewing via verso website service



5. Processing and provisions of information

Fig. 2 – Overview of reports from distributors in the DIS13 system in 2013



5.2 Database of medicinal products and monitoring of supplies to pharmacies

With regard to the obligation stipulated by the Act on Pharmaceuticals, the Institute maintains a registry of authorized medicinal products and provides for the publication of selected information in its information media. For the purposes of this registry, the Institute uses an internal database of medicinal products (DLP) which is updated on an on-going basis.

Registry of active substances

Currently, the Database of Medicinal Products (DLP) contains 22,262 substances, 320 new components were entered and data was updated for 8,669 components in 2013.

In 2013, update of flagging of doping components and of products containing such substances in DLP was carried out pursuant to The 2013 Prohibited List – The World Anti-Doping Code effective as of 1 January 2013, the latest edition of the European Pharmacopoeia 8.0 and its two supplements was inserted. Entering of the latest Japanese Pharmacopoeia J15 (important monographs of medicinal drugs of Traditional Chinese Medicine) was initiated.

Registry of Medicinal Products

In 2013, the Institute issued 494 decisions on marketing authorization (3,512 SÚKL codes). Authorization was revoked for 612 marketing authorization numbers, which corresponds to 5,489 codes. The authorization was cancelled

Table 1 – Selected subgroups of authorized medicinal products recorded in the SÚKL database as of 31 December 2013

	Total number of authorization numbers/marketed authorization numbers	Total no. of SÚKL codes/marketed SÚKL codes
Medicinal products in total (excl. homeopathic products)	**15,068/5,785**	**54,737/8,419**
Of which by MA numbers:		
MA numbers granted by the Institute	6,533/4,894	46,187/7,525
MA numbers of products authorized via Community centralized procedure	8,535/891	8,550/894
Of which by content:		
Single-component	11,977	46,518
Multi-component	3,091	8,219
Of which by type of dispensing:		
Prescription-only medicinal products	14,237/5,068	51,509/7,330
Sale OTC	877/730	3,193/1,077
Restricted Sale OTC	9/7	22/12
Restricted prescription-only medicinal products	3/0	13/0
Homeopathic products	**269/269**	**716/341**

either at the request of the marketing authorization holder (513 authorization numbers), due to the Sunset Clause (85 authorization numbers) or due to the fact that the holder did not apply for authorization renewal (14 authorization numbers). The validity of 6,663 codes in total expired (the period of final code sale expired or marketing authorization was revoked).

In the course of 2013, no distribution was reported for 46,318 codes (84.62 %) of medicinal products, excluding homeopathic products. Hence despite having a valid marketing authorization, these products were not placed on the market.

Authorized medicinal products contain a total of 2,448 various active substances.

Regular outputs from the database of medicinal products

For professionals as well as for the general public, the Institute regularly publishes data about authorized medicinal products, approved specific therapeutic programmes and foods for special medical purposes with all details within the scope of the database of authorized medicinal products.

Since 2008, the Institute has been publishing on its website the "List of prices and reimbursements of medicinal products and foods for special medical purposes", including its updates. In 2010, the system of so-called Control List publishing was established, which notifies professionals in advance of possible changes to maximum prices and reimbursements implied by completed decisions which came into force. In 2011, in accordance with Act No. 298/2011 Coll. the name Control List was changed to the Draft List.

Information from the database is also utilised in the overview of reports on placement on the market or suspension or termination of supplies of medicinal products on the market, in the overview of variations to marketing authorizations or in the overview of non-interventional post-marketing studies.

Evaluation of deliveries of distributed medicinal products

Evaluation of deliveries of distributed medicinal products based upon the mandatory reporting from entities authorized to distribute medicinal products in the Czech Republic was conducted on a monthly basis in 2013. The subject-matter of the reports concerned the deliveries of medicinal products to pharmacies, other healthcare establishments in the Czech Republic and abroad. In addition to the authorized medicinal products, also products used in special therapeutic

programmes and unauthorized products supplied on medical prescription to a pecific patient were included in the evaluation.

Data on the volumes of distributed medicinal products in number of packages, in financial volumes (in CZK), and in DDD (daily defined doses) were evaluated. With a view to the need to compare their value over the years, data on financial costs are provided in originator prices, i.e. ex-factory prices excl. VAT (VAT rates were changing over the years), and excl. profit margin (markup).. The regular quarterly evaluation of supplies of distributed products has been, since 2008, supplemented on the website of the Institute with a table showing deliveries for each active substance (further broken down by route of administration, where applicable).

In 2013, the Institute in evaluating supplies of distributed medicinal products each quarter newly focused upon a selected group of medicinal products and evaluated the long-term development within the concerned group in detail.

In 2013, 267.907 million packages of medicinal products were distributed, which corresponds to approx. 5,921.879

Fig. 3 – Authorized medicinal products in the period 2009 – 2013

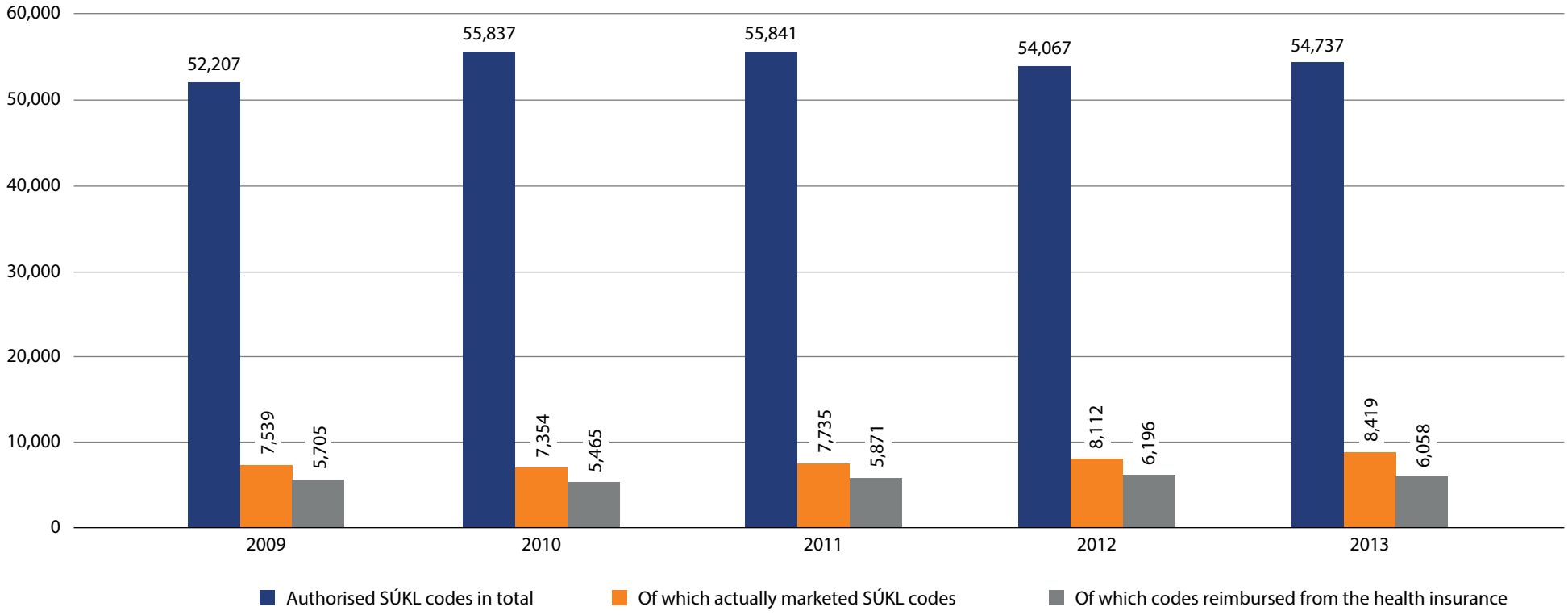


Fig. 4 – Deliveries of medicinal products in the period 2009 – 2013

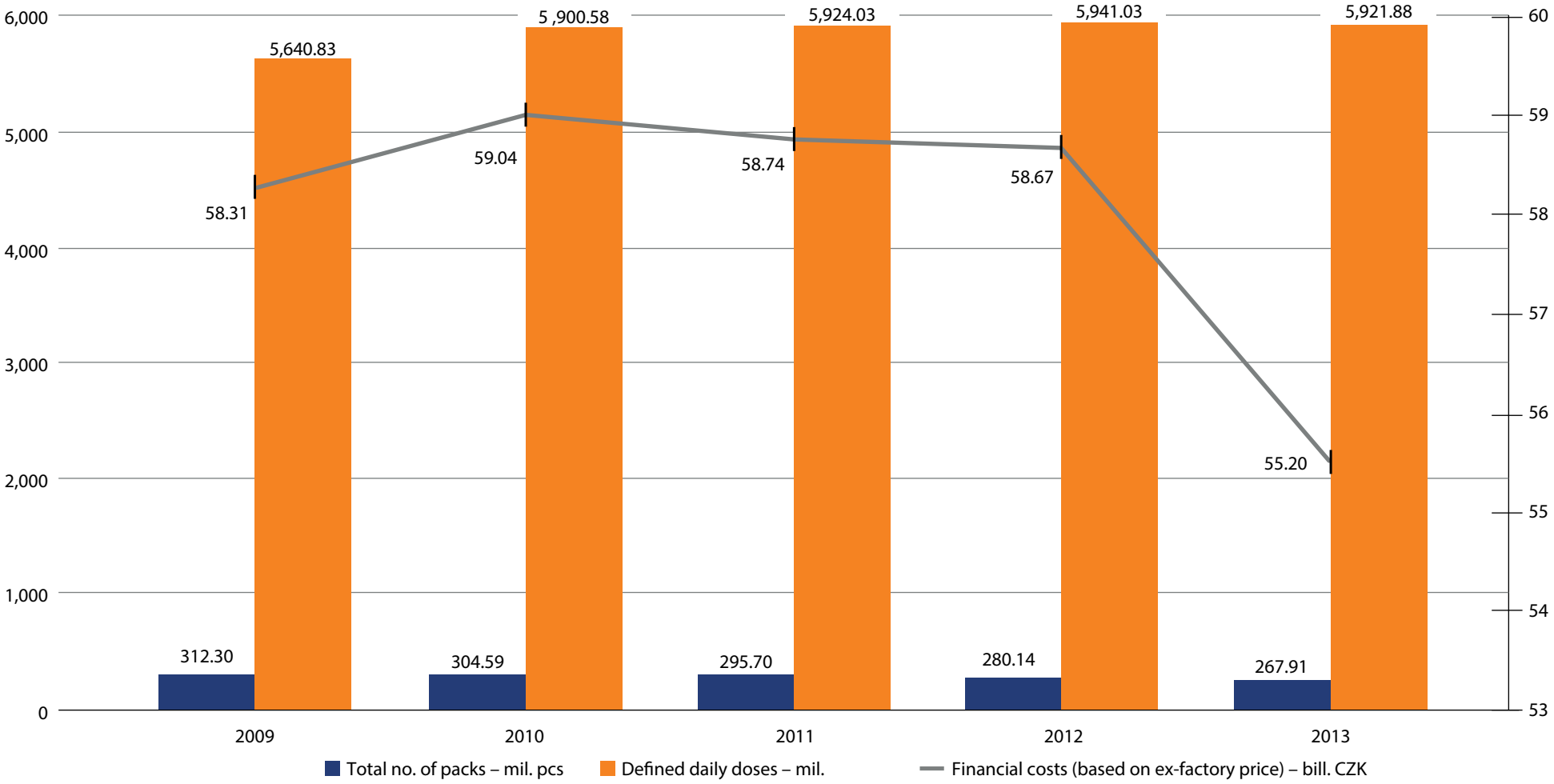


Table 2 – Deliveries of distributed medicinal products in 2013

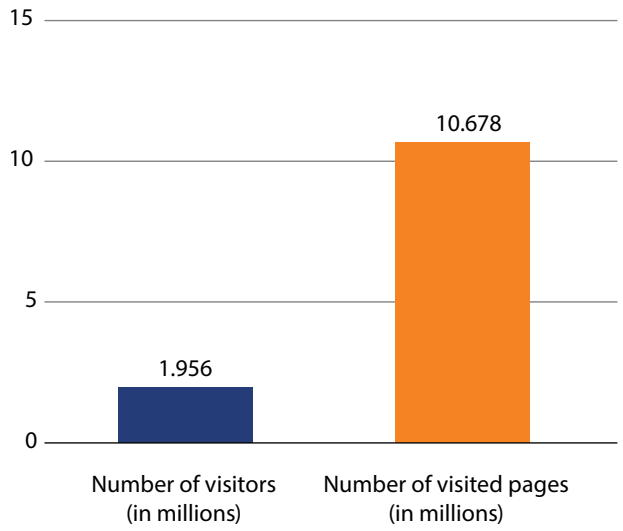
Medicinal products in total	Number
Deliveries to pharmacies and health care establishments (mil. packages)	267.907
Deliveries to pharmacies and health care establishments (mil. CZK based on ex-factory price)	55,199.357
Deliveries to pharmacies and health care establishments (mil. DDD)	5,921.879
DDD/1,000 inhabitants/day	1,543.232
Prescription-only medicinal products	
Deliveries to pharmacies and health care establishments (mil. packages)	182.554
Deliveries to pharmacies and health care establishments (mil. CZK based on ex-factory price)	49,208.582
Deliveries to pharmacies and health care establishments (mil. DDD)	5,360.237
DDD/1,000 inhabitants/day	1,396.870
OTC and selected pharmaceuticals	
Deliveries to pharmacies, health care establishments, and vendors of selected pharmaceuticals (mil. packages)	84.776
Deliveries to pharmacies, health care establishments, and vendors of selected pharmaceuticals (mil. CZK based on ex-factory price)	5,918.401
Deliveries to pharmacies, health care establishments, and vendors of selected pharmaceuticals (mil. DDD)	561.119
DDD/1,000 inhabitants/day	146.227
Restricted OTCs	
Deliveries to pharmacies and health care establishments (mil. packages)	0.578
Deliveries to pharmacies and health care establishments (mil. CZK based on ex-factory price)	72.375
Deliveries to pharmacies and health care establishments (mil. DDD)	0.523
DDD/1,000 inhabitants/day	0.136
Homeopathic products	
Deliveries to pharmacies (mil. packages)	1.678
Deliveries to pharmacies (mil. CZK based on ex-factory price)	147.574

million defined daily doses. The value of these deliveries was 55.199 billion CZK (based on ex-factory price).

5.3 Information activities

Keeping the general and professional public informed is the main task of the Press and Information Department (TIO). The most important source of guaranteed data for the general and professional public are websites www.sukl.cz, information site www.olecich.cz and the website of the campaign Nebezpečné léky (Dangerous Drugs) www.nebezpecneleky.cz. In addition, TIO runs Facebook profiles for the website for the public and to the Nebezpečné léky campaign.

Fig. 5 – Visitor rate at www.sukl.cz



In 2013, the website for professionals www.sukl.cz had nearly 2 million visitors who viewed more than 10 million pages. The address of the Public Information Portal www.olecich.cz was entered into the web browser by 227 thousand visitors who viewed over 282 thousand pages. The Information portal offers verified and accurate information on medicines to the public, ranging from a database of approved medicines, electronic forms for reporting adverse events and asking experts, and to the current information on the safety of medicines. The campaign website www.nebezpecneleky.cz has been seen by nearly 30,000 visitors who visited more than 83,000 pages.

In 2013, seven new issues of the publication for the general public called infoLISTY were published. This publication focuses on a selected topic from the area of health and medicines every month.

Via the "Ask Us" service, pharmacists and doctors – a general practitioner and paediatrician, gynaecologist, a physician specialising in travel medicine, paediatric pulmonologist and a physician specialising in sports medicine - answered questions from the public. The service was used by a total of 539 enquirers.

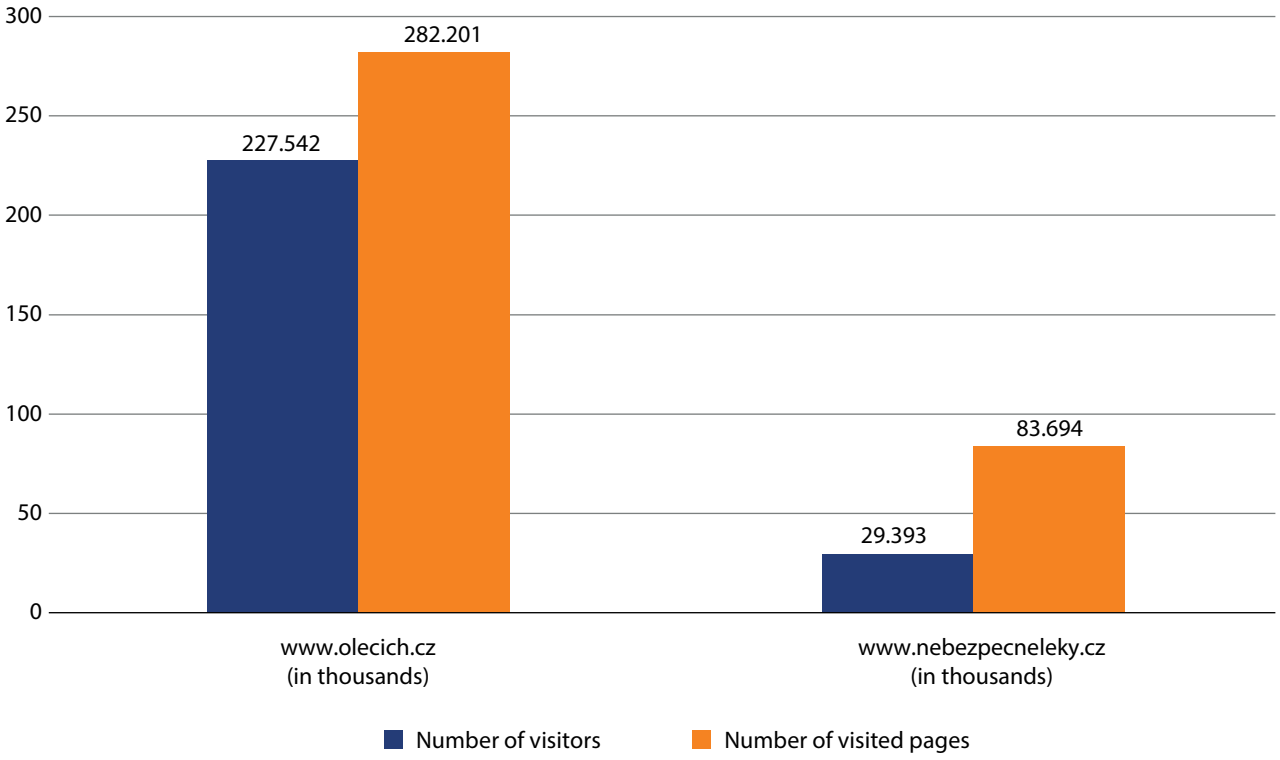
In collaboration with the author of the Stories of Medicines, TIO organized over 30 sessions on the topic of safe use of medicinal products for third-age universities, public libraries, senior clubs and senior homes throughout the Czech Republic.

TIO also maintains a specialized library of the Institute and is responsible for the preparation and publication of the SÚKL Bulletin, the drug bulletin Farmakoterapeutické informace (Pharmacotherapeutic Information, a member of the International Society of Drug Bulletins (ISDB)) and the electronic Adverse Drug Reactions Bulletin. All the above publications are available at www.sukl.cz.

In 2013, TIO processed 40 requests for information pursuant of Act No. 106/1999 Coll., on Free Access to Information, as amended, and via its information phone line and e-mail address it responded to 6,330 inquiries from the general and professional public.

The Department prepared responses to 152 inquiries from journalists and gave a statement for a TV or radio station in 60 instances. Two press conferences took place in cooperation with the Ministry of Health of the Czech Republic. The first one was on a survey of the Institute titled "The Actual Use of Medicines" and the other one was on a recall of a medicine containing insulin from the patient level. In addition, 11 press releases, notifications or responses were issued.

Fig. 6 – Visitor rate at www.olecich.cz and www.nebezpecneleky.cz

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6.1 Income and expenditure account for 2013

Income

In 2013, the Institute had extra-budgetary income in the total amount of CZK 519,905 thousand. The major part of this income was generated by reimbursement for expert activities which, pursuant to Act No 378/2007 Coll., on Pharmaceuticals, as amended, were conducted by the Institute upon request from manufacturers, distributors, vendors, and other legal entities and natural persons. The major part of the overall volume was represented by income from applications related to marketing authorizations of medicinal products. Income from conducted expert activities is used piecemeal by the Institute in compliance with Act No 218/2000 Coll., on Budgetary Rules, as last amended, for the funding of expenditures not covered by allocated financial resources from the state budget, namely for the funding of payroll, operating and investment needs. In 2013, a total amount of CZK 241,653 thous. were thus used through permissible excess expenditure. Of which CZK 229,414 thousand was used for non-investment expenses and CZK 12,239 thousand for financing of investment needs.

In addition to income from the reimbursement of costs for expert activities, other part of income came from the revenues of the state budget, such as selected administrative fees for submitted applications in the amount of CZK 29,563 thousand, revenues from fines in the amount of CZK 5,610 thousand, received insurance compensation, etc. An overview of the reported budget income is shown in Table 3 as of 31 December 2013.

Expenditure

Data concerning expenditure incurred in 2013 are provided in Tables 3 broken down by individual categories. Total operating expenditure amounted to CZK 12,236 thousand. Compared to 2012, the investment expenditure was lower by CZK 50,393 thousand. Investment resources were used to finance the replacement of the outdoor staircase and modernization of the building entrance No. 24 (CZK 1,540 thousand) and the interior of the building No. 24 (CZK 378 thousand), optical and wireless connection between buildings 8 and 24 (CZK 511 thousand), a camera surveillance system (CZK 218 thousand) and expansion of the attendance system (CZK 363 thousand). Laboratory devices (CZK 2,657 thousand) and service cars (CZK 2,807 thousand) were purchased. Other investment expenditures were made in the field of IT – purchase of licenses (CZK 490 thousand), delivery of a system for processing SŘDLP (CZK 300 thousand), E-learning (CZK 1,885 thousand), creating the portal of electronic prescribing (CZK 160 thousand), information technology (CZK 483 thousand), adjustment of the economic system RIS (CZK 250 thousand).

Operating expenditures were drawn in a total amount of CZK 426,815 thousand, of which CZK 1,737 thousand for the project co-financed from the EU budget within the Operational Programme Human Resources and Employment (Reg. No. CZ.1.04/4.1.00/59.00009 Increasing the Efficiency of the Administrative Agenda of the Institute). Of the total volume, extra-budgetary funds used to cover non-investment expenditure amounted to CZK 229,147 thousand, state budget funds to CZK 113,241 thousand and claims arising from unused expenses to CZK 84,427 thousand In comparison with the reality achieved in 2012, the non-investment expenditure increased by CZK 80,606 thousand in 2013. The increase in expenditure was affected by the extension of the activities of the Institute with new tasks and the related annual increase in average number of employees by 23. Expenditure on salaries, including mandatory coasts increased by CZK 53,548 thousand, of which salaries by CZK 38,851 thousand, other payments for performed work by CZK 1,073 thousand, severance pay by CZK 143 thousand, statutory charges by CZK 13,481 thousand. The increase in other operating expenses by a total of CZK 35,695 thousand concerned security services in information technology. At the same time, expenditure intended for funding of the OP HRE projects decreased by CZK 8,637 thousand compared to 2012.

Assets

The total assets of the Institute as of 31 December 2013 amounted to CZK 2,436,365 thousand. Of which fixed assets amount to CZK 329,728 thousand and current assets to

Table 1 – Funds and state budget

	2011	2012	2013
Average converted number of employees	313	318.57	341
Funds allocated from the state budget for the operation of SÚKL (in thousands CZK)	26,000	39,690	113,241
Allocation of income in the state budget (in thousands CZK)	42,705	46,986	38,951

6. Financial and material resources of the Institute

CZK 2,106,637 thousand. Of the total liabilities of CZK 2,436,365 thousand, equity amounts to CZK 2,408,760 thousand and short-term and long-term liabilities to CZK 27,605 thousand. Selected types of assets and liabilities of the Institute are listed in Table 2.

Other

A total of CZK 4,302 thousand from the budget of the Institute was use on international business trips. The purpose of most business trips was participation in regular meetings of various committees and working groups due to membership in relevant bodies. The Institute has its members or alternates in more than 60 working groups across the EU institutions and international organizations. Other business trips were approved with regard to the priorities of the Institute, the current nature and benefits of the discussed topics for the Institute.

Auditing

In 2013, an audit in the Institute was initiated on 25 February 2013 by the Ministry of the Interior of the Czech Republic in accordance with the rules of public administration on-site inspections according to Sections 12–21 of Act No. 320/2001 Coll. focused on the procedural, substantive and financial aspects of the project implemented under the Operational Programme Human Resources and Employment under the name Increasing the Efficiency of the Administrative Agenda of the State Institute for Drug Control and its organizational units. This inspection was not completed in 2013.

Due to the failure to employ persons with disabilities in accordance with Section 81 of Act No. 435/2004 Coll., on Employment, a fine of CZK 321,576 was collected by the Labour Office and paid to the state budget.

Table 2 – Overview of selected types of assets and liabilities of the organization in thousands of CZK

Name of Item		Past period 2012	Present period 2013
ASSETS		**2,179,946**	**2,436,365**
A. Total fixed assets		**361,611**	**329,728**
of which:	I. Intangible fixed assets – total	109,227	92,354
	II. Tangible fixed assets – total	252,384	237,374
	Lots	3,984	3,984
	Buildings	185,910	183,879
	Separate movables and sets of movables	62,424	48,802
	Small tangible fixed assets	0	0
	Unfinished tangible fixed assets	66	709
B. Total current assets		**1,818,335**	**2,106,637**
of which:	I. Inventory – total	54	52
	II. Short-term receivables – total	3,394	7,284
	III. Short-term financial assets	1,814,887	2,099,301
LIABILITIES		**2,179,946**	**2,436,365**
C. Equity		**2,154,163**	**2,408,760**
of which:	I. Assets of the accounting entity and adjustments	220,799	219,915
	II. Financial and monetary funds – total	1,794,659	2,073,281
	Fund for cultural and social needs	824	1,194
	Reserve fund	1,793,835	2,072,087
	III. Economic result	–17,084	–198,672
	IV. Income and expenditure account of the budget management	155,789	314,236
D. Total borrowed capital		**25,783**	**27,605**
of which:	I. Total long-term liabilities	40	21
	II. Total short-term liabilities	25,743	27,584

Table 3 – Budget income, budget expenditure and financing in thousands of CZK

BUDGET INCOME	Budget for 2013	Real values for 2013	
	Approved budget	*Corrected budget*	*Real values for 2013*
Administrative fees	9,000	9,000	29,563
Penalties received	1,000	1,000	5,610
Income from property lease	0	0	36
Non-equity contributions received	0	0	559
Income from provision of services	0	0	3
Received insurance compensation	0	0	75
Income from the sale of other tangible long-term assets	0	0	132
Transfers from reserve fund	0	0	241,653
Transfers from other own funds	0	0	1,443
Operating transfers from the National Fund	3,570	3,570	1,530
TOTAL	**13,570**	**13,570**	**280,604**
EXPENDITURE	**Budget for 2013**	**Real values for 2013**	
	Approved budget	*Final budget*	*Real values in 2013*
Employees' salaries	78,869	200,141	199,959
Other payments for performed work and severance pay	3,265	10,707	10,705
Mandatory premium paid by employer	27,860	69,346	69,284
Contribution to the Fund of Social and Cultural Needs	791	2,004	2,000
Operating acquisitions and related expenditure	4,919	147,347	144,867
Acquisition of tangible and intangible fixed assets	0	12,239	12,236
TOTAL	**115,704**	**441 784**	**439,051**
of which: operating expenditure	**115,704**	**429,545**	**426,815**
Capital expenditure	**0**	**12,239**	**12,236**

6. Financial and material resources of the Institute

Table 4 – Operating expenditure of individual units of the Institute as of 31 December 2013 in thousands of CZK

	Operating expenditure	Dedicated expenditure
Division of Director, Internal Audit, Quality Management Department	461	24,030
Deputy Director for Economic Issues	100	278
Deputy Director for IT	72	2,015
Deputy Director for Regulatory Affairs	96	2,334
Total	**729**	**28,657**
Service Activities Branch	172	18,831
Economic Issues Branch	72	2,598
Information Technology Branch; DAT, ERP	394	85,630
Surveillance Branch	2,905	3,064
Marketing Authorization Branch	495	0
Price and Reimbursement Regulation Branch	310	899
Medical Devices Branch	111	0
Total expenditure	**5,188**	**139,679**

Table 5 – Expenditure statistics in the period 2011–2013

	2011	2012	2013
Total operating expenditure (thous. CZK)	310,377	346,209	426,815
Non-investment expenditure (excluding salaries, insurance and fund for cultural and social needs) (in thousands CZK)	86,586	116,869	144,867
Investment expenditure (in thousands CZK)	56,025	62,629	12,236
Average converted number of employees	313	318.57	341
Expenses per employee (line 1/line 4) in CZK	992	1,087	1,252

7.1 Personnel Issues

During 2013, there were several personnel and organizational changes and a new organizational structure was implemented.

Given the increase in activities, which the Institute newly performs or will perform soon, there has been an increase in job positions. This planned number of FTEs was filled at 91.14 % which means that 383.449 job positions were occupied. The average number of used FTEs on a cumulative basis from the beginning of the year was 340.761 FTEs.

The number of physical employees on payroll as of 31 December 2013 was 401 persons, of which 322 were women (i.e. 80.3%) and 79 men (i.e. 19.7%).

Converted to FTEs worked under non-employment agreements (work agreement and agreement to perform work), a total of 28.41 employees were employed as of 31 December 2013, which is an increase by 26.7 % compared to 2012.

Age structure of employees

The average age of all employees compared to 2012 decreased by 1,28 %, i.e. to 40.92 years of age.

Working hours utilisation

Of the total number of 571,298 hours worked, 743 were overtime hours. Overtime work mostly concerned employees from the workers category (drivers).

In 2013, the employees of the Institute were absent for 1,211 working days due to sickness leave or nursing a family member (2,018 in 2012). Of the total number of employees, absence due to sickness or nursing a family member was observed in case of 136 employees (94 employees in 2012). Absence due to long-term illness concerned: 133 employees (89 employees in 2012), who were absent for up to 2 months, 2 employees (2 employees in 2012), who were absent for up to 3 months, and 1 employee (3 employees in 2012), who was absent for more than 3 months.

Table 1 – Age structure of employees in %

	% of employees under 35 years	% of employees aged 36 to 55 years	% of employees over 55 years
2011	37.00	48.35	14.65
2012	35.70	47.50	16.80
2013	41.20	43.60	15.20

Staff turnover

In 2013, 103 new employees started their jobs in SÚKL (2012 = 55). Employment was terminated with 44 employees (2012 = 40).

Table 2 – Qualification structure of employees by achieved level of education

Primary	Secondary technical	Secondary general	Secondary technical with GCE	Technical colleges	Bachelor's degree	University	University doctorates
			2011				
1	4	10	67	3	13	195	14
0.30 %	1.14 %	3.08 %	26.60 %	0.94 %	3.98 %	59.67 %	4.29 %
			2012				
1	3	10	86	4	15	208	12
0.30 %	0.88 %	2.95 %	25.37 %	1.18 %	4.42 %	61.36 %	3.54%
			2013				
1	5	12	86	3	16	264	14
0.25 %	1.25 %	2.99 %	21.45 %	0.75 %	3.99 %	65.83 %	3.49 %

7. Focus upon employees

The staff turnover is 12.91 % (a slight increase of 0.09 % compared to the previous year).

7.2 Employee education

In the area of employee education, similarly as in previous years, emphasis was placed especially on professional and international education. The total amount spent on education was CZK 3,194,879. An amount of CZK 1,276,704 was used for professional education. Due to higher demands on the qualification of the employees, the amount spent on education increased by 45 % compared to 2012.

Table 3 – Overview of employments terminated in 2013 by reason

Reason for termination of employment	In probationary period	Definite-time employment contract expiry	Termination by agreement	Notices given by employees	Termination due to organizations reasons	Total
Number	**2**	**10**	**11**	**10**	**11**	**44**

The Institute invested funds intended for sending employees abroad for the purpose of increasing or enhancing their qualification, which will give them a competitive advantage in the labour market and they will become valuable work force for the employer contributing to the competitiveness of the employer.

Table 4 – Overview of educational activities in 2013

Type of event	Number of events	Number of hours	Number of attendees	Costs in CZK
PC training	13	248	46	191,048
Language courses	30	1,374	103	395,559
Specialised courses and training	159	3,522	349	1,276,704
Managerial skills	6	162	38	342,309
Mandatory training	51	134	117	26,056
Foreign specialised training	26	776	41	963,204
Total	**285**	**6,216**	**694**	**3,194,880**


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The quality system of the Institute is certified in accordance with the requirements of ČSN EN ISO 9001:2008 and the Institute repeatedly underwent regular external surveillance audit.

In 2013, 20 internal audits were performed. The audits focuses on the key processes of the Institute and the impact of organizational changes on these processes.

The process efficiency is evaluated also through a customer satisfaction survey which is available at the website of the Institute.

The Institute also participates in the benchmarking programme of EU drug authorities and in 2013 it was preparing for the assessment that will take place next year within the benchmarking.


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9. Outlook for 2014

In 2014, the main priority of the Institute is ensuring quality, safe and efficacious medicines for Czech patients. In addition, the Institute is implementing the amended statutory provisions, particularly in relation to cannabis for therapeutic use.

In terms of price and reimbursement regulation, the Institute will focus on the precise fulfillment of legislative obligations in order to achieve further savings, both for patients as well as for the public health insurance.

The main tasks will continue to be its cooperation with the Ministry of Health, among other things, even in the evaluation of data and informing on potential shortages of important medicines on the Czech market.

The Institute will continue to maintain intensive communication with the professional and general public. It will focus on information and educational activities towards patients, especially in dealing with medicines and in the area of illegal and counterfeit medicines. Educational activities will also take place in the form of seminars for regulated entities and professionals with whom the Institute cooperates closely.

The main tool for communicating with and informing the public will continue to be the websites of the Institute **www.sukl.cz**, **www.olecich.cz** and **www.nebezpecneleky.cz** including Facebook profiles that make it possible to reach all target groups, i.e. both regulated and cooperative entities as well as the patient public and other consumers. Discussions organized in libraries and organizations that bring together seniors will serve as a supporting aspect in the education on medicines of Czech patients. During these discussions, the publication Stories of Medicines will be introduced in addition to the necessary information.

In 2014, all activities of the Institute will continue to be directed at fulfilling its legal obligations in the highest quality to ensure maximum safety of Czech patients.

10. Overview of essential contacts for individual spheres of operation of the Institute

Updated as of March 31, 2014. A detailed updated overview of contacts is available from the website of the Institute; the heads of individual units are specified in the organisational structure of the Institute.

	Prefix:	Ext.	E-mail
Director of the Institute			
PharmDr. Zdeněk Blahuta	272 185	834	zdenek.blahuta@sukl.cz
Mail and dispatch room	272 185	789	posta@sukl.cz
	272 185	806	
	fax: 271 732	377	
Quality Manager			
Ing. Radmila Foretová	272 185	861	radmila.foretova@sukl.cz
Internal Audit and Control			
Bc. Kamila Hrušková	272 185	225	kamila.hruskova@sukl.cz
Press and Information dept			
Head of department			
Bc. David Přinesdom	272 185	354	david.prinesdom@sukl.cz
Public Relations Officer			
Mgr. Lucie Šustková	272 185	756	lucie.sustkova@sukl.cz
Information Centre	272 185	333	infs@sukl.cz
ECONOMIC ISSUES DIVISION			
Deputy Director for Economic Issues			
Ing. Vilibald Knob – acting	272 185	873	vilibald.knob@sukl.cz
Economic Issues Branch			
Head of Branch			
Ing. Jana Přerovská	272 185	810	jana.prerovska@sukl.cz
Service Activities Branch			
Head of Branch			
Ing. Vilibald Knob	272 185	873	vilibald.knob@sukl.cz

	Prefix:	Ext.	E-mail
INFORMATION DIVISION			
Deputy Director for IT			
Zdeněk Vodička – acting	272 185	243	zdenek.vodicka@sukl.cz
IT Branch			
Head of Branch			
Zdeněk Vodička	272 185	243	zdenek.vodicka@sukl.cz
DIVISION OF THE DEPUTY DIRECTOR FOR REGULATORY AFFAIRS			
Deputy Director for Regulatory Affairs			
Mgr. Apolena Jonášová – acting	272 185	706	apolena.jonasova@sukl.cz
Surveillance branch			
Head of Branch			
Mgr. Apolena Jonášová	272 185	706	apolena.jonasova@sukl.cz
Marketing Authorisation Branch			
Head of Branch			
MUDr. Jana Mladá	272 185	729	jana.mlada@sukl.cz
Price and Reimbursement Regulation Branch			
Head of Branch			
Mgr. Helena Skácelová	272 185	403	helena.skacelova@sukl.cz
Medical Devices Branch			
Head of Branch			
Ing. Aleš Martinovský	272 185	890	ales.martinovsky@sukl.cz