KVETNÁ 11 | 825 08 BRATISLAVA 26

# ANNUAL REPORT 2009

**State Institute for Drug Control**
**Bratislava**

**Submitted by:**
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Head of Service Office and Director

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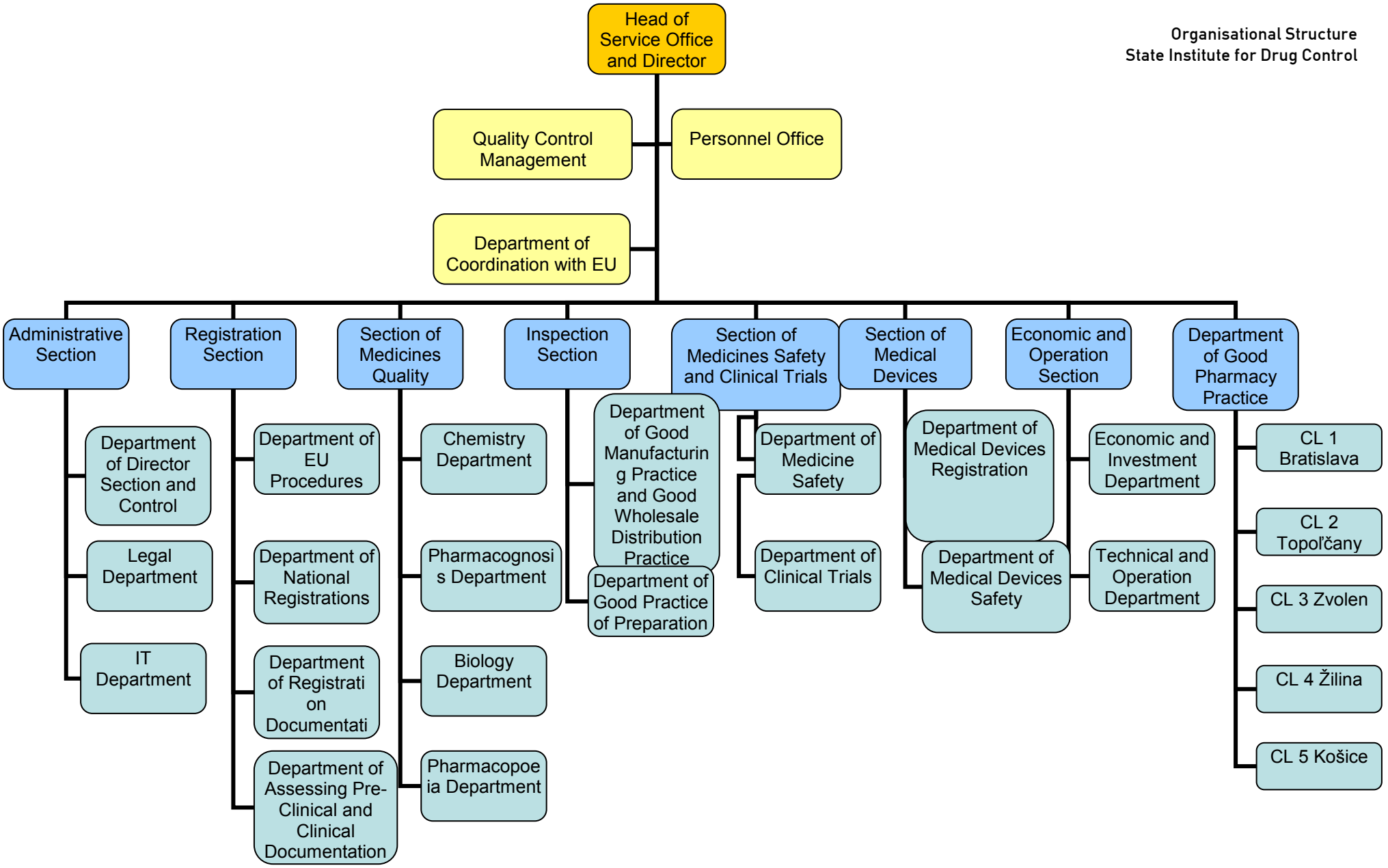
**1. SIDC Identification**

| | |
|---|---|
| **Name**: | State Institute for Drug Control |
| **Registered Office**: | Kvetná 11, 825 08 Bratislava 26 |
| **Government Department**: | Ministry of Health of the SR |
| **Head of Service Office and Director**: | PharmDr. Ján Mazag |

Organisational Structure
State Institute for Drug Control



**2. Mission and Mid-Term Outlook of SIDC**

The objects of business of the State Institute for Drug Control are defined in Act No. 140/1998 Coll. on Medicinal Products and Medical Devices as amended and in the statute of the State Institute.

The principal mission of the Institute for the next period is to enable entry of efficient, safe and quality of medicinal products and medical devices for the nationals and patients of the SR, to provide patients and expert public with concerned information on medicinal products and keep under surveillance the medicinal products and medical devices market within the meaning of the applicable legal regulations.

The Institute's tasks have been defined for the areas of registration of medicinal products and medical devices, post-registration control of medicinal products and medical devices, inspections of all pharmaceutical activities in terms of good manufacturing practice, good wholesale distribution practice, good laboratory practice, good clinical practice and good pharmacy practice and monitoring safety of medicinal products.

The Institute's activity in the area of human pharmacy has been influenced also by the tasks arising out of the legal regulations governing medicinal products and medical devices as adopted by the European Union (EU) directly applicable for the EU member states (the European Parliament and the Council of Europe regulations).

In 2010 as well, the basic indicators of evaluation of the Institute’s activity will comprise:

a.) elaboration of assessment reports and opinions in relation to the applications for registration and variations in the registrations of medicinal products and medicinal devices within the given periods,
b.) monitoring, analysis and settlement of post-registration control of medicinal products and reports of adverse effects of medicinal products and medicinal devices,
c.) assessment and permission of clinical studies,
d.) inspections at the human pharmacy sections based on risk identification and planning with emphasis on prevention of occurrence of shortcomings in manufacturing, wholesale distribution of medicinal products and medicinal devices, and in pharmaceutical care,
e.) control and analytical activity in monitoring observance of quality of medicinal products.

In the past years, we managed to put into practice measures concerning the Institute’s activity to reduce any useless and unduly inappropriate time limits of respective processes in the area of registration of medicinal products, post-registration control of medicinal products, including permission and assessment of clinical trials of medicinal products, in the area of medicinal devices and laboratory control of medicinal products.

As early as in 2009, we recorded not only an increased number of applications for expert opinions at all expert sections, but also increased demands on their quality.
In 2010, we intend to focus in terms of the basic indicators of the Institute's activity on consistent monitoring of performance of those indicators while increasing the quality of respective assessment reports within the defined deadlines.

In practice it means to perform the principal tasks and indicators at the respective sections (Registration Section of Medicinal Products, Section of Control of Quality of Medicinal Products, Section of Medicinal Products Safety and Clinical Trials, Section of Medical Devices, Inspection Section – entry, running and targeted inspections ).

In order to manage those tasks successfully in 2010 and in the next period, we plan to change the organisation of the Institute’s activity to the effect to enable us to manage the increasing number of tasks. In 2010, we want to reorganise the organisational structure at the Registration Section, the Section of Control of Quality of Medicinal Products, and the Inspection Section. The reorganisation should be implemented after general discussion between the Institute employees with the aim to focus on the logical areas in the "life cycle" of and medicinal product from the perspective of regulation (pre-registration and registration activities, as well as subsequent post-registration control of quality of medicinal products). The process should result in reinforcement of the personnel capacities to perform the increasing number of tasks.

Gradual changeover to and completely electronic submission of applications for registrations and variations in registrations of medicinal products will be and task of significant importance in 2010, which will after all enable use of new procedures in assessment of the Institute's activities, improve the quality and transparency of the respective processes.

We have defined the other tasks arising out of the Slovak and European legislation as priority areas of the Institute's activity, the performance of which is required along with the principal tasks:

a.) tasks with assessment of medicinal products in paediatrics,
b.) medicinal products for advanced therapy,
c.) re-assessment and assessment of new knowledge in the area of monitoring the adverse effects and risk communication to the expert public.
d.) continuation in the activities and tasks arising out of membership in the EU (the Slovak Republic as a reference member state with registration of medicinal products but also in the area of chemical, microbiological and biological control of the quality of medicinal products and medicinal devices and conduct of inspections affecting other member states of the EU),
e.) harmonisation of assurance of quality and safety of human tissues and cells for medical use with humans, new tasks for the Inspection Section,
f.) further electronisation of the Institute's activity, information provision quality improvement,
g.) analysis of new planned legislative amendments to the regulations governing medicinal products at the EU level (vigilance, fake medicinal products, information provision to patients, internet sale of medicinal products),
h.) amendments to the European and national legislation in the area of drug precursors.

Given the task summary for the immediate period, it is apparent that in order to perform them successfully, we would have to implement changes not only in the work organisation at the State Institute for Drug Control, but also with respect to the status of the Institute within the state administration authorities. In 2010, the Institute management will present a model of economic status of the Institute which could in terms of the Institute's budget facilitate management of the increasing number of tasks in the immediate period, thus enabling more effective motivation for our employees when performing the aforementioned increasing number of tasks.

## 3. Contract between the SIDC and the MoH of the SR

By Resolution No. 1370 of 18 December 2002, the SR Government imposed an obligation upon the ministers and chairmen of the central authorities to enter into contracts with the institutions fully funded from the State Budget and the institutions receiving contributions from the State Budget under their respective incorporation powers. In respect of the resolution, the Ministry of Health of the Slovak Republic entered with the State Institute for Drug Control into and contract for the year 2009. Performance of the contract will be assessed as instructed by the MoH of the SR in 2010.

## 4. Institute's Activities/Products

### *4.1 Department of Coordination with EU*

In the area of international activity, priorities for the year 2009 have been approved, which covered several areas of involvement of SK/SIDC as a reference member state and involvement in various forms of workload division within the cooperation in the network of the EU medicines agencies.
To support coordination of activities and exchange of current information among committees and working groups of the network of the EU medicines agencies, we organised monthly meetings attended by individual delegates. In 2009, we had 30 representatives of the Slovak Republic, out of which 7 external, in 36 various EU committees and working groups, in particular, with the European Medicines Agency (EMEA), the European Commission (the Directorate-General for Enterprise and Industry ) and the Council of Europe.

At the international cooperation level, we participated by active work in the below listed working groups:
a) Coordination group (CMDh), within which we were, inter alia, systematically submitting consensual expert opinions at the SIDC level to all arbitration procedures, in which the Slovak Republic was a concerned member state,
b) Working group for cooperation with patient organisations (PCWP), with reference thereto, we organised and meeting between the SIDC and the representatives of patient organisations in the SR,
c) Standing Committee for human medicinal products (Standing Committee) and
d) EMACOLEX (cooperation between lawyers of medicinal product agencies of the EU member states).

We cooperated by expert activity within the Advisory Committee of Experts for International Pharmacopoeia and Pharmaceuticals of the World Health Organisation. The EU Translation Centre based in Luxembourg requested our expert opinion, we gave and one-day seminar to educate the translators of texts dealing with the health system and medicinal products.

The Slovak and EU legislation has been implemented, proposals and analyses of impacts on new legal regulations have been processed.

We directed systematically the performance of the SIDC tasks arising out of the EP and Council Regulation No. 1902/2006 on Medicinal Products for Paediatric Use and coordinated expert assessment of paediatric use of one medicinal product (clarithromycin). We coordinated preparation for implementation of Regulation No. 1234/2008 of the EP and the Council concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, as well as analysis of the situation and conditions for implementation of submitting applications for registration and related documentation exclusively on electronic media.
We organised a working seminar with an employee of the MoH of the SR and the SR delegates in the concerned EU working groups, concerning the planned amendment to the EU legislation, the so-called "Pharmaceutical Package", concerning pharmacovigilance, the problem of fake medicinal products and the issue of access to reliable information for patients.
In 2009 as well, SIDC initiated regular meetings with the MoH of the SR, which were, in particular, focused on settlement of the issues related to legislation proposals and coordination of the SR obligations in the EU in the area of medicinal products and medicinal devices.

**Surveillance over advertising of medicinal products**

| Surveillance over advertising of medicinal products | | |
|---|---|---|
| Year | 2009 | 2008 |
| Number of Registered Reports | 1,286 | 1,424 |
| Number of initiated proceedings on violation | 3 | 11 |
| Number of issued decisions on ban on advertising | 3 | 7 |
| Number of discontinued proceedings | 2 | 7 |
| Imposed penalties | EUR 14,150 | SKK 930,000<br>ca EUR 30,870 |

In 2009, the cases related to surveillance over advertising of medicinal products were discussed at 6 meetings of the Advisory Committee for Advertising.
We implemented a new proactive approach to control of advertising materials, based on reports of pharmaceutical companies. We reviewed in this manner 47 materials.
We provided legal opinions upon request, related to registration of medicinal products, or advertising of medicinal products.
Over the year, we provided 16 internal legal opinions.

### *4.2 Quality Control Management*

International activities were developed by cooperation and exchange of information with the OECD member states as planned. We processed a summary and assessment of inspection activity "*Annual Summary of GLP in the Slovak Republic 2008"* and referred it to the OECD Environment Directorate, the European Commission and subsequently to all member states as instructed.
We processed an underlying report as requested for the permanent mission of the SR with OECD and assessment of OECD activities in the area of GLP. We continued in cooperation, communication and exchange of information with the OECD member states. We participated actively in the regular meetings of the working group for GLP OECD, as well as the working group GLP with the EC.

Within benchmarking, international cooperation with the European Medicines Agency (EMA) continued. Benchmarking intends to mutually compare the quality management system within the European medicine agencies with the aim to constantly improve and advance the effectiveness, transparency of the activities arising out of the agencies' missions. Each European agency is assessed in three-year intervals according to the model EN ISO 9004.

We participated actively in drafting the amendment to the Regulation No. 298/2007 of the SR Government on the principles of GLP and conduct of inspections.
In cooperation with the Slovak National Accreditation Service (SNAS), we participated in 3 GLP inspections.

To assure the Institute's quality system, our activity in 1Q focused on preparation of audit within the EMEA benchmarking. On the EMEA request, we prepared a questionnaire in a form of a self-assessment report according to EN ISO 9004, including the PERF III requirements. In March 2009, the SIDC was assessed within BEMA II by the EMEA, Germany and Sweden assessors. They assessed the degree of the quality system implementation. The assessment identified an adequate degree of implementation and quality maintenance. Most disagreements were identified with the key indicators that depend on availability of financial and human resources.

At the same time, company CENTIRE entire solution conducted, by decision of the MoH of the SR, procedural and organisation audit in 1H. the audit resulted in an analysis of the current status and proposal of a solution to increase and improve the quality of effectiveness of all processes under decreased costs.
In 4Q, the EDQM auditors audited the Section of Medicinal Products Quality Assessment according to STN EN ISO/IEC 17025.

Within administration of controlled documents, we developed and monitored a plan of updating controlled documents. Despite our efforts we managed to fulfil the plan only at ca 60 %. This failure was caused by overload of our employees and their critical deficit.
Based on the variations in documents, as well as fluctuation of employees, all the EISOD application data were reviewed and the database of employees, the database of documents and access of employees to documents updated. We systematically reviewed the currency of the controlled documents published on the Institute's internet and intranet sites. At the moment, only current documents are published on the sites.
We updated the quality policy, the quality manuals, and the guidance notes for external laboratories and processed a standard practice procedure for crisis management.

Summary of the Institute's issued (new, updated) controlled documents in 2009 and the total number thereof

| Controlled document (CD) | Issued in 2009 | Total number of CDs |
|---|---|---|
| Quality Manuals | 2 | 3 |
| Standard Practice Procedures (SPP) | 15 | 36 |
| Director's Order | 11 | |
| Guidance Notes | 12 | 19 |
| Internal Guidance Notes (IMG) | 4 | 10 |
| Standard Operating Procedures (SOP) | 109 | 597 |
| **Total number of controlled documents** | **153** | **662** |

Over the year, we held 3 meetings of quality managers (QMs) to discuss the procedure and implementation of the quality systems. In addition to performance of adopted of tasks, we discussed with the quality managers the requirements and tasks arising out of external audits.
We monitored the QMs' activities and performance of tasks and discussed problems. QMs were trained on quality systems at meetings. We assessed the level of performance of their obligations at semi-annual intervals.

Internal audits were conducted as planned. Out of the 11 planned internal audits, we did not manage to conduct 3 audits (IT Department, Personnel Office, Rovinka archives) for time reasons. We had to get prepared for 3 external audits.
Performance of corrective measures ensuing from the audits (external, internal) was reviewed by the management (Management Review).
We processed and assessed an employee satisfaction questionnaire. The survey identified a bit poor knowledge of the Institute's activities on the part of employees, the overall ambiance at the Institute was viewed negatively and almost half of our employees do not feel stability and certainty about their work. We will be coping with these issues in 2010.
Currently, we register 9 laboratories licensed to perform pharmaceutical testing. The list of laboratories is updated on the Institute's web site on any change therein. In case of any major variations, the list is published in the Lekárnik magazine.
Within surveillance over these laboratories, inspections were carried out as planned.

### *4.3 Administrative Section*

**Department of Director Section and Control**

Within the meaning of Act No. 10/1996 Coll. on Control in State Administration as amended and the Control Activity Plan for the year 2009 approved by order no. 2/2009 of Head of Service Office and Director, ***the Control Department*** carried out 7 internal control actions.
Despite the plan, 1 control, control of dangerous waste disposal was not carried out – for the reason of long-term work incapacity of the responsible employee and subsequent employment termination.
Given the control-identified shortcomings, the Head of Service Office and Director gave orders no. 5, 7, and 9, which comprise in total 24 measures to remove the identified shortcomings. Discharge of the measures will be controlled in January 2010.
The MoH of the SR carried out an extraordinary control focused on compliance with the generally binding legal regulations and the internal control acts in registration of medical devices, initiated by HMG & PARTNERS, s.r.o. in the case of failure to act on the part of administrative body in the case Ing. Andrej Džadoň – MEDSERVIS. Given the control results, order no. 11/2009 of 30 November 2009 was issued to remove the identified shortcomings. The measures were discharged.
A representative of the SIDC took part in an interdepartmental control under the charge of the Ministry of Economy of the SR. The control examined compliance with the provisions of Act No. 331/2005 Coll. and Ordinance No. 380/2005 Coll. of the MoH of the SR.

*Handling of petitions and complaints* – pleadings comprising essential elements of a petition – not delivered to the SIDC.

Within the meaning of Act No. 152/1998 Coll. on Complaints, the central registry of complaints registered 4 complaints. The investigation procedure deemed all the complaints groundless.
Compared to 2008, we registered 1 more complaint.
The special registry of complaints registered one compliant of a state employee of the SIDC. The investigation procedure was carried out within the meaning of Act No. 312/2000 Coll. on State Service as amended.
Investigation of the complaints concerning non-compliance with good pharmacy practice delivered to the SIDC is carried out within the meaning of Act No. 140/1998 Coll. on Medicinal Products and Medical Devices as amended – in a form of inspections. These are not registered in the central registry of complaints and petitions.
In addition, the Control Department took part in conducting control of discharge of measures in company MODRÁ PLANÉTA, s.r.o. (BLUE PLANET…)– contractual partner for dangerous waste collection, sorting and disposal.

***The PR & Communication Department*** was ensuring performance of tasks arising out of the status of the Department as a press body of the Head of Service Office and Director in compliance with Act No. 211/2000 Coll. on Free Access to Information as amended and Act No. 167/2008 Coll. on Periodical Press and News Agency Service – Press Act.
This Department was monitoring media for human pharmacy articles at daily intervals. In addition, it was monitoring the web sites of institutions important in terms of medicinal product policy and legislation.
It was coordinating the Institute's communication with media.
The PR & Communication Department settled 210 applications for information submitted by print and electronic media. The applications were settled in a form of official letters, electronically – by emails, by phone – for radios also in a form of phone call record and for television in a form of news submitted for reportage/interviews. In addition, personal consultations were provided.
A representative of the Department regularly participated in expert meetings and international projects concerning specific health issues or topics concerning medicinal products. In 2009, the SIDC organised an international conference under EU project cooperation (Pharmaceutical Health Information System - PHIS) for more than 120 guests – took an active role with respect to professional, as well as organisational aspects.
The Department was in charge of and took an active role in the publishing activity by providing expert contributions to certain professional periodicals (Lekárnik, etc. )
In cooperation with the IT Department, the Department regularly updated the Institute's internet and intranet sites, also upon requests of expert sections. It coordinated cooperation between the SIDC and external companies in internet site update. In cooperation with other Institute's sections, it took part in processing the the Institute's annual report. It coordinated translation activity and provided for the Annual Report release in the English language.

***The Department for Information Provision*** acted in compliance with Act no.211/2000 Coll. on Free Access to Information as amended, as well as in compliance with Guidance Note No. 102/2008 on registration and handling agenda concerning all applications for information provisions submitted to the SIDC by phone, or in an electronic or written form. In 2009, we received and handled 423 applications for information provision, i.e. 27 applications more than in 2008.
Holders of decisions on medicinal product registration, requested in their applications for information provision, in particular, information concerning registration of generic medicinal products and patent protection; the public mostly requested information concerning unavailability of medicinal products in pharmacies, proper use of medicinal products, occurrence adverse effects, mail-order dispensation of medicinal products, effect of herbal preparations and purchase of medicinal products from the so-called third countries.

***The Department for Cooperation with EU***
The principal activities of the Department for Cooperation with EU:
- coordination of transmission of current information and tasks of the SIDC, arising out of the SIDC integration in the EU structures in the field of human pharmacy (membership in advisory bodies of the European Commission and EMEA), SIDC representation in international organisations (PIC/Scheme-Pharmaceutical Inspection Scheme, EDQM - European Directorate for the Quality of Medicines, OECD for Good Laboratory Practice, WHO, etc.).

- update of nominations of the SIDC representatives and their substitutes in respective advisory bodies of EMEA and the European Commission
- coordination of activities of the SIDC representatives in advisory bodies of EMEA, EC, EDQM, PIC/S Scheme, WHO, OECD and the European associations in the area of human pharmacy
- technical implementation of foreign business trips (FBTs) of the nominated SIDC employees and external representatives (vide Table - Number of participants in respective FBTs per 2009 and Annex 2 - List of FBTs in 2009)

Table - Number of participants in respective FBTs per 2009

| | |
|---|---|
| By number of participants | 353 |
| Bratislava-Vienna-Bratislava Transfers | 159 |
| EC (European Commission) | 4 |
| EMEA (European Medicines Agency) | 110 |
| PIC/S Scheme, Pharmaceutical Inspection Convention | 5 |
| OECD, Chemical Committee and Working Group on Chemicals, PPP | 1 |
| EDQM (European Department for Quality of Medicines), Council of Europe | 13 |
| Participation on conferences, workshops, expert trainings, trainings, CTFG | 21 |
| Meetings falling under countries presiding the EU, HMA | 19 |
| PPRI | 4 |
| PHIS | 14 |
| Inspection | 3 |

***Metrology***

The quality of measuring instruments and measuring equipment mostly used at the Section of Medicinal Products Quality Assessment (SMPQA), but also at some other sections related to the SMPQA, was preferentially assured in compliance with the requirements of Act No. 142/2000 Coll. on Metrology and on Amendment and Supplement to Certain Acts as amended and with other related regulatory legislation of the Slovak Republic in the area of metrology. To prove the quality system operation in the area, the activities as required by STN EN ISO 9001 “Quality Management System” and STN EN ISO/IEC 17025 “General Requirements for Competence of Testing and Calibration Laboratories” are enforced and carried out. The requirements of STN EN ISO/IEC 17025 for the network of officially commissioned laboratories to control medicines are issued by the European control authority for quality of medicinal products and health care (EDQM). Performance of these requirements was audited by the EDQM.
All 9 internal controlled documents related to metrology were updated.
One GLP inspection was conducted under the agreement entered into between the SIDC and SNAS.
The Institute’s metrologist concurrently holds the office of quality manager at the IT Department and the Section of Medicinal Products Quality Assessment.
Within its competencies, it cooperated in preparation of BEMA II audit (Benchmarking of European Medicines Agencies), intended to compare the quality assurance system at the SIDC with other European medicines agencies. The audit was conducted in March 2009.
In cooperation with the Institute’s metrologist assistant, they took part in preparation of SMPQA for EDQM audit, held in October 2009, intended to assess the competencies of SMPQA laboratories to perform the audited methods. The results of the methods, the assessment of which was successful, will be internationally acknowledged in the future in the OMCL network, a fact that underlines the significance of this audit.
The cooperation focused on updated of controlled documents (updated in overall terms or newly prepared: 58), including issue of the principal quality document - SMPQA Quality Guidelines. Furthermore, the cooperation focused on conduct of audits (14) that facilitated implementation and improvement of the procedures required under STN EN ISO/IEC 17025.
In cooperation with the SMPQA management, remedial measures concerning the audit were developed, of which ca 40 % were implemented, others are in the process of development. The reviewed structure of

standard working procedures rendered many activities at the SMPQA more effective and introduced the same rules in performance of the procedures applied at every department.
The Institute's metrologist regularly participated in the meetings of the Commission for Certified Reference Materials, which is an advisory body of the Director of the Slovak Institute of Metrology.

**Legal Department**

***The Legal Department*** has no personnel*.*

The number of 65 cases for administrative procedure commencement was referred to ***the Department for Administrative Procedure*** under the period under review. Pursuant to Article 18 Act No. 71/1967 Coll. on Administrative Procedure in consolidated version, administrative procedures were commenced in 57 cases out of the total number. Decision on administrative procedure discontinuance was awarded in 3 cases of commenced administrative procedure. Within the meaning of Article 46 Act on Administrative Procedure, 52 decisions in total were awarded under the period under review, which imposed penalties to natural persons and legal entities for breach of Act No. 140/1998 Coll. on Medicinal Products and Medical Devices in consolidated version and Act No. 139/1998 Coll. on Narcotic Drugs, psychotropic substances and preparations in consolidated version and other applicable legal regulations. In 1 case, decision on imposition of penalty for breach of Act No. 264/1999 Coll. on Technical Requirements for Products and on Conformity Assessment and on Amendment and Supplement to Certain Acts was awarded and 1 decision ordering withdrawal of a medical device from operation within the meaning of Act No. 264/1999 Coll. For the reason of subject-matter jurisdiction, 1 file was referred to for settlement to the MoH of the SR.
The amount of imposed penalties totalled €82,650.88. As of 31 December 2009, the amount of paid penalties in a form of imposed penalties totalled €51,494.88. As of that date, the Legal Department had 11 cases of motions to commence an administrative procedure, which were referred for settlement to the SIDC Legal Department, Inspection Section in the late 2009.
Over the year, Guidance Note No. 124 - Administrative procedure with state administration execution in the cases of good pharmacy, good manufacturing, good wholesale distribution practice and practice of preparation of transfusion medicinal products.
The internal agenda of the Legal Department was related to provision of opinions and legal support to all those SIDC employees who had requested them. In addition, in the period under review, legal advice was provided not only to the SIDC departments but also to natural persons and legal entities under observance of the principle and precondition not to disclose information on any classified issues. The cooperation with the Inspection Section, including its external workplaces – control laboratories and with the Section of Medical Devices was intensified. Any correspondence concerning the Legal Department was handled on an ongoing basis.

***The Department for Drug Precursors*** focused on application of the community legislation of the European Union for drug precursors under the conditions of the SR. The Department closely cooperated in this activity with the competent authorities of the MoH of the SR, of the MoI of the SR and the Customs Directorate of the SR, which are competent to act in compliance with Act no. 331/2005 Coll. on State Administration Authorities in the cases of drug precursors and on Amendment and Supplement to Certain Acts.
In relation to the Slovak currency transition to euro, the SIDC internet site has been publishing since the beginning of 2009 a „Notice of administrative fee payment with submission of applications for variation in decisions on licence/registration to handle defined substances issued by the Ministry of health of the SR in compliance with Act no. 219/2003 Coll. on handling of chemical substances, which may be diverted to the illicit manufacture of narcotic drugs and psychotropic substances and on amendment to Act No. 455/1991 Coll. on Trade Licence Business (Trade Licensing Act) as amended. Act No. 465/2008 Coll. stipulated values of the fee stamps to be provided with applications for award of decisions and decisions on designation of variations in valid decisions on handling of defined substances.

By initiative of the MoH of the SR, work meetings on the issues of misuse of medicinal products containing pseudoephedrine for illicit manufacture of drugs were held. By virtue of the adopted measures, supplies of any medicinal products containing pseudoephedrine from manufacturers and distribution organisations, including respective supplies to public pharmacies and hospital pharmacies are monitored. The Department for Drug

Precursors receives underlying documents on carried out supplies of those medicinal products, these are subsequently referred to the joint workplace the MoI of the SR and the Customs Directorate for further processing and evaluation.
Monitoring of supplies of medicinal products containing pseudoephedrine was presented at a work meeting on the issues of misuse of medicinal products containing pseudoephedrine, held in September 2009, under presence of MUDr. Okruhlica, CSc. – the chief expert of the MoH of the SR for drug addiction medicine.
The Department for Drug Precursors cooperated in preparation and progress of a work meeting with the representatives of those organisations that signed voluntary cooperation in monitoring of undefined substances within the voluntary monitoring list of the European Union. Adopted measures concerning medicinal product policy with focus on medicinal products containing defined substances were presented at the meeting held in October 2009.
In relation to the planned amendment to Act No. 331/2005 Coll. on State Administration Authorities in the Cases of Drug Precursors and on Amendment and Supplement to Certain Acts, the sponsor – Ministry of Economy of the SR was submitted motions to amend this Act. With reference to ongoing trials, the activities of 2 business companies, which had been awarded decision on registration for handling of defined substances of group 2, was suspended.
An employee of the Department for Drug Precursors participated in control of registration maintenance, preservation and use of defined substances at company BEL/NOVAMANN International s.r.o., Bratislava, which is a holder of licence to handle defined substances of group 1 and registered to handle substances of groups 2 and 3.

Summary of awarded decisions and paid administrative fees:

| Decision Type | Number of Decisions | Administrative Fee (€) | Total € |
|---|---|---|---|
| Special licences and licences | 221 | 33.0 | 7,293 |
| Registrations | 6 | 33.0 | 198 |
| Variations | 194 | 16.5 | 3,201 |
| Withdrawals | 107 | - | - |
| Activity suspension | 2 | - | - |
| **TOTAL** | | | **10,692** |

**IT Department**
Within computer processing of registration documentation, the IT Department closely cooperated with the Registration Section. It was generating letters of indication, which form integral parts of every decision on registration of a human medicinal product and decision on variation in registration of a human medicinal product. It was assigning SIDC-codes for registered medicinal products. The department staff was on an ongoing basis populating the database of registered medicinal products by populating the decision card and the medicinal product card with required data.
The competent Institute's workplace was provided with consultancy services with respect to maintenance and population of corporate databases, creation of a list of medicinal product forms, application forms, creation of a list of efficient and auxiliary substances and maintenance of ATC groups in compliance with the WHO underlying documents.
The Department staff participated in work meetings of company MCR and the SIDC staff, concerning further development of information system for medicinal products and medical devices and on an ongoing basis carried out training, advisory and consulting activities for the SIDC staff.
An employee of the Department continued on an ongoing basis in scanning the working documentation (electronic archives of the Department).
A commissioned employee of the department (based on underlying documents of the PR & Communication Department and in cooperation with an external company) on an ongoing basis carried out works related to the SIDC internet site maintenance and renewal.
The cooperation between the SIDC and the AIGLP developers proceeded further in a form of reciprocal data exchange.
By virtue of the contract between the SIDC and the NOBEL application developers, software company PharmINFO spol. s.r.o, current outputs from the information system for medicinal products were regularly provided.

The Institute's IT operation was on an ongoing basis delivered. The Department was removing any minor IT failures by own efforts. In the event of occurrence of major failures, the Department ensured service with selected service companies. The Department staff cooperated with the management in purchase of IT and consumable supplies and provided expert assistance to IT users for work with installed applications.

### *4.4 Registration Section*

The Registration Section focused, in particular, on the following activities:

- electronic application implementation and the SIDC web site portal development
- introduction of a new advisory body – Sub-Commission for generic medicinal products
- preliminary actions in organisation of departments leading to implementation of a new Order on Changes
- execution of agenda in relation to "sunset clause"
- personnel back up of the section and systematic education of employees
- proliferation of assessment activity and quality of work of advisory bodies

The Section employees actively participated in cooperation within the network of the EU medicine agencies in several committees and working groups (Herbal Medicinal Product Committee, Notice to Applicants, QRD/PIM, Name review group, TIGes, EWP, SWP).

**Department of Registration Documentation Receipt**

The Department of Registration Documentation provided all entry, support administrative, registration and distribution processes for the Registration Section.

The Department's activities:

- receipt of applications concerning medicinal products (applications for new registrations, prolongations, transfers, variations, cancellations)
- filing of applications in PC system
- primary control of completeness of documentation with all types of applications
- documentation distribution to processors
- archiving and administration of registration documentation and decisions
- archiving and administration of registration documentation on electronic media
- coordination of documentation assignment to processors
- legitimating of decisions
- filing and administering medicinal product files
- filing of powers of attorney of companies' representatives

In 2009, the Department received 12,939 applications concerning registrations of medicinal products.

The Department participated actively in eApplication electronic system development, which, when put into operation on 7 September 2009, discharged the defined objectives:

1. electronic assignment of variable symbol to be used by applicant as identification for administrative fee payment
2. electronic monitoring of application fee payment
3. specified application data collection in an electronic form

**Department of National Registrations**

In the period under review, the Department of National Registrations focused on quality improvement of the processing of submitted applications and on elimination of any delay in processing of the received applications.

In terms of standard activities, the Department of National Registrations carried out the following activities:

- coordination of processing of assessment reports to applications for registration, registration variations and prolongation;
- processing of other types of applications, which do not require assessment reports from internal or external assessors;
- control of accuracy of SPC, PIL translations and designation of packages in compliance with QRD;
- providing applicants with directions with respect to implementation of new procedures in regulation of medicinal products;
- consultations with applicants with respect to submitted applications;
- enforcement of the provisions of Act 140/1998, Article 22, regulating the so-called "Sunset Clause";
- elaboration of requirements for update of medicinal product database and control of its implementation;
- getting ready for implementation of EC Regulation No. 1234/2008 on the method of processing variations.

Scope of the Department of National Registrations activity:

| Application Type | Received 2009 | Processed 2009 | Cancelled 2009 | Balance as of 1 January 2010 |
|---|---|---|---|---|
| New registrations | 97 | 74 | 23 | 292 |
| Prolongations | 41 | 186 | 31 | 226 |
| Transfers | 64 | 86 | 5 | 17 |
| Variations | 1,227 | 1,117 | 73 | 825 |
| Variations IA | 2,011 | 1,959 | 12 | 154 |
| Variations IB | 968 | 946 | 12 | 185 |
| Accompanying letter | 175 | 163 | 3 | 20 |
| Notification 61(3) | 150 | 114 | 5 | 48 |
| Cancellation | 158 | 161 | 2 | 5 |

| | | | | |
|---|---|---|---|---|
| Total | **4,891** | **4,806** | **166** | **1,772** |

**Department of EU Procedures**

The Department preferentially focused on processing of applications submitted by mutual recognition procedure and decentralized procedure, and carried out its standard activities as a concerned member state and further proliferation of its activities as a reference member state.

In terms of standard activities, the Department carried out the following activities:

- coordination of applications for registration, variations, prolongation and transfers in the role of RMS and CMS
- control of accuracy of SPC, PIL translations and designation of packages in compliance with QRD with medicinal products registered by centralized procedure (CP)
- cooperation with the European Medicines Agency in settlement of arbitration procedures and within reporting activities in expert committees (CHMP, HMPC)
- provision of guidance to applicants in implementation of amended procedures and requirements
- elaboration of requirements to edit and update the MCR database and control their implementation

In compliance with the original plan, 57 applications for registration by decentralized procedure or mutual recognition procedure with SK as reference member state were initiated within 10 procedures, where 3 references were positively completed in 2009. At the HMPC level, the role of a rapporteur for elaboration of monograph and assessment report to 2 drugs (Taraxaci folium and Taraxaci radix cum herba) was terminated.

Scope of the Department of EU Procedures:

SK as RMS

| Application Type | Received 2009 | Processed 2009 | Cancelled 2009 | Balance as of 1 January 2010 |
|---|---|---|---|---|
| DCP registration | 57 | 17 | - | 51 |
| MRP registration | 1 | 1 | - | - |
| Prolongation | 5 | - | - | 5 |
| Variations | 8 | 4 | - | 4 |
| Variations IA | 12 | 14 | - | - |
| Variations IB | 4 | 4 | - | - |
| Total | **87** | **40** | - | **60** |

SK as CMS

| Application Type | Received 2009 | Processed 2009 | Cancelled 2009 | Balance as of 1 January 2010 |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| DCP registration | 673 | 565 | 50 | 1,227 |
| MRP registration | 180 | 220 | 5 | 111 |
| Prolongation | 319 | 147 | 37 | 386 |
| Transfers | 139 | 124 | 1 | 24 |
| Variations | 1,446 | 1,036 | 130 | 1,589 |
| Variations IA | 3,182 | 2,562 | 135 | 1,623 |
| Variations IB | 1,846 | 1,377 | 103 | 1,248 |
| Notification 61(3) | 43 | 37 | 5 | 32 |
| Cancellation | 126 | 118 | 3 | 6 |
| Total | **7,954** | **6,186** | **469** | **6,246** |

**The Commission for Medicinal Products** met 10 times as planned, whereas it assessed applications for new registrations, CMDh referrals, registration prolongation, variations in registration and variations in the method of dispensation of medicinal products.
The Sub-Commission for Generic Medicinal Products met 4 times, whereas it assessed applications for new registrations and variations in registration.
The Sub-Commission for Phytopharmaceuticals and Homeopathics met 2 times, whereas it assessed applications for new registrations and variations in registration.

### *4.5 Section of Medicinal Products Quality Assessment*

The Section is structured into 4 departments:
- Chemistry Department,
- Pharmacognosis Department,
- Biology Department,
- Pharmacopoeia Department.

The Section was at various seminars getting ready for work with the new regulation on variations Reg. 1234/2008/EC issued by the European Commission effective since 1 January 2010. A new form for generation from MCR database for processing variations has been developed.
Amendment to Act No. 139/1998 Coll. was commented on.
In 2009, 269 applications for registration and 821 applications for IB type variation and 574 II type variations by national procedure were assessed (table no. 1). Since January, the section got involved in assessment of and commenting on applications for DCP registration procedure as the concerned state and assessed 47 applications. As a reference state, it elaborated 6 assessment reports in the English language for DCP reference and 1 assessment report for the 2$^{nd}$ MRP reference wave.
The Section elaborated opinions to 4 "referrals".
Since the beginning of 2009, the section was getting ready for external audits. From 23 March to 27 March 2009, EMEA conducted BMV. In October (from 7 to 9 October), the section as OMCL was subject to the first EDQM audit. For this reason, the Section's Quality Guidelines (2$^{nd}$ release) and subsequently, over the year, other controlled documents were updated. Current versions of three guidance notes intended for the public, 2 internal guidance notes, 13 SOPs valid for the entire Section and 47 SOPs for its respective departments were processed.
The employees nominated for the respective working groups of the European Commission, the Council of Europe, EMEA and EDQM set out for 22 foreign business trips. They assumed active roles in the working groups of QWP, EDQM and European Pharmacopoeia Commission.
The Pharmacopoeia Department, the SMPQA, the SIDC as a competent pharmacopoeial authority of the Slovak Republic performs the tasks arising out of Act No. 140/1998 Coll. as amended and the SR Government

Regulation No. 588/1995 Coll. one of them is the membership of the Slovak Republic in the European Pharmacopoeia Commission (the Council of Europe) and related assurance of implementation of the European pharmacopoeia in the national legislation, coordination of preparation of the Slovak pharmacopoeia and cooperation in creation of the European pharmacopoeia.

In 2009, the Section had the general sections and monographs of the 6th release of the European pharmacopoeia and supplements translated. In total, 482 translations of pharmacopoeia monographs and 66 control methods were translated and proofread. Within consultancy provided to internal and external clients, new translations of monographs and information on use of pharmacopoeia methods, names of medicine forms, medicines and auxiliary substances were provided. The Pharmacopoeia Department was supplementing new international approved names for pharmacopoeial substances (INN) and the Slovak names for pharmaceutical efficient and auxiliary substances, ATC groups, medicine forms and their abbreviations in the MCR database. The list of Slovak names of medicine forms was updated and synchronized with the European database EDQM and published on internet.

The nominated representatives actively participated in regular meetings of the European Pharmacopoeia Commission. Opinion to test 2.9.3 Dissolution Testing of Solid Oral Pharmaceutical Forms was processed and positive statement to publishing of this harmonised testing was sent after consultation with the Chemistry Department assessors.

Upon request of the Public Health Authority, 5 opinions to borderline preparations containing herbal drugs were processed.

In 2009, a Sub-Commission for Generic Substances. One of the assessors is a regular member of the Sub-Commission and processed underlying documents for registration of 2 problematic medicinal products.

An employee of the Section participated in the Commission for control of compliance with the principles and procedure with dangerous waste disposal.

The Pharmacognosis Department Head participated in the Sub-Commission for Phytopharmaceuticals and Homeopathics.

The Section Head participated in the meeting of the Commission for Medicinal Products.

The Section, as an OMCL within the meaning of Article 41 par. 3 Act No. 140/1998 Coll. as amended, has been within its competence controlling and releasing to the market vaccines, immunological medicinal products and medicinal products from human blood and human plasma since 1 May 2009. In 2009, it released 468 batches of medicinal products.

Within laboratory control of the quality of batches of medicinal products on the market as of 31 December 2009 (table no. 2), 187 samples of medicinal products were analysed.

Out of 187 samples (table no. 3), 5 samples were proved non-compliant within import, home production, or complaints.

The OMCL was checking the stability of the prepared purified water for the laboratory analysis (internal testing) from the perspective of conductivity. Seven water samples in this study proved non-compliant after two-day storage.

Seventy two certificates to the medicinal products on the market were controlled, whereof 11 proved non-compliant, mostly for the reason of disagreement with the approved specifications, or failure to supply the EU certificate. The concerned companies were asked to put the documentation into order by submitting variations.

We tested 102 samples for bacterial endotoxines and 5 samples by other methods oorder.

The OMCL was handling 2 complaints, whereas one was legitimate and 1 clinical complaint, which has not been settled yet.

The Chemistry Department employees entered into negotiations with company BIOTIKA a.s., Slovenská Ľupča in the case of inappropriate method to determine impurities in medicinal product Ampicilin inj. They called upon the company to develop the method further and submit variation in registration.

The Section participated in 5 PTS studies organized by EDQM in Strasbourg with food results (z-score up to 2.0 - compliant, up to 3.0 – subject to discussion, above 3.0 – non-compliant): PTS104 (0.52 and -0.11), PTS105 (2.5), PTS 106 (1.94), PTS107 (1.21) and PTS 108 (0.09).

Amlodipin besylat CRS 4 was analyzed in OMCL within cooperation with the European Pharmacopoeia. The analysis results were sent to Strasbourg, where they were used to determine the substance as reference material Ph. Eur. (Collaborative studies CS).

The laboratories reviewed the procedure of analysis results review beyond specification to be in compliance with the EDQM procedure.

Control of transmission of analytical methods was implemented in the laboratory control. This new element implementation improved the quality of analysis results, but concurrently increased their time demanding

aspect. The search process of the appropriate method for verifying the transmission of methods was one of the causes for the lower number of analyzed samples in 2009.
The following instruments were qualified at the SMPQA laboratories: polarimeter and spectrophotometers. The supplier of a new HPLC system DIONEX was qualified and put into operation.
In 2009, the Biology Department took actions to rebuild the clean premises used for sterility testing, which had not been in operation since the Canadian audit.

The Section's activity expressed in financial terms totals €503,502.02.

**Table No.1: Assessment Activity**

| | Number of assessment reports |
|---|---|
| | |
| registrations N/DCP- CMS | 269/47 |
| registration MRP/DCP- RMS | 1/6 |
| for variations IB/II | 821/574 |
| not recommended | |
| UP | 130 |
| other | - |
| TOTAL: | 1,848 |
| | |
| opinions for media and national institutions | 25 |
| questionnaires, opinions, Annual Reports for EDQM and EMEA | 18 |
| | |
| Total number of assessment reports per SMPQA: | 1,891 |
| Financial value: | €459,399.60 |

**Table No. 2: Analytical Activity**

| | Number of samples | Number of certificates |
|---|---|---|
| | | |
| to foreign registration | 9 | - |
| to national registration | 1 | - |
| release of vaccine and blood derivate batches | - | 468 |
| market control: import | 37 | 72 |
| on order | 107 | - |
| to clinical complaint | 1 | - |
| to complaint | 2 | - |
| internal testing | 24 | - |
| PTS/MSS/CS | 5/0/1 | - |
| CAP | - | - |
| other | - | - |

| | | |
|---|---|---|
| Total number per SMPQA: | 187 | 540 |
| whereof non-compliant | 12 | 17 |
| Financial value: | €44,102.42 | |

**Table No.3: Non-Compliant Samples**

| Non-compliant samples | | | |
|---|---|---|---|
| Medicinal Product Name | Batch | Holder | Defect |
| Aqua purificata (water stability study and applicability time for HPLC – 4x) | batch 280909 | room no. 130 | high conductivity |
| Aqua purificata (water stability study and applicability time for HPLC – 3x) | batch 280909 | room no. 15 | high conductivity |
| HYDROCHLOROTHIAZID Léčiva, tbl | batch 5010108 | Léčiva a.s, CZ | weight homogeneity of half tablets |
| GLIMEPIRID MYLAN 2 mg, tbl | batch 07852 | Generics Ltd, GB | incorrect registration number specified on secondary packaging |
| PANADOL RAPID tbl flm | batch 080839 | Glaxosmithkline Belgium | dissolution of respective tablets not homogenous, 3 tablets released less than prescribed in specifications |
| Dr. THEISS SCHWEDENBITTER sol | batch 01028 | Dr. Theiss Naturwarwn | low ethanol content |
| BRIMONAL 0.2 % int opo | batch 370308 | UnimedPharma sro, Bratislava | incorrect registration number specified on secondary packaging |

***4.6 Inspection Section***

In 2009, the SIDC Inspection Section was carrying out activities within the meaning of Act No. 140/1998 Coll. as amended, Act No. 139/1998 Coll. and Act No. 331/2005 Coll.

The principal activity of the of Section Inspections focused, in particular, on activities such as entry inspections focused on control of material, spatial and personnel equipment with manufacturers, distributors and in transfusion facilities, running inspections focused on compliance with the principles of good manufacturing practice, good wholesale distribution practice and good practice of preparation of transfusion of medicinal products, targeted inspections with manufacturers, distributors and in transfusion facilities, follow-up inspections with manufacturers, distributors and in transfusion facilities, coping with time delays with running inspections, post-registration control of the quality of medicinal products, assessment of applications for medicinal product registration and applications for variation in medicinal product registration, 24/7 service "Rapid Alert" provision and expert lecturers for health facilities.

In terms of international cooperation, the SIDC works actively in working groups - competent authorities on blood and blood components /EC, eudraGMP Database Sub-working Group Meeting/ EMEA, GMP/GDP Inspectors Working Group /EMEA, working Group of Enforcement Officers/ EMEA, experts on product quality defect and rapid alert /EMEA and PIC/S Committee.

The inspections are processed into output documents - assessment reports for material, spatial and personnel equipment within the meaning of Act No. 140/1998 Coll. as amended, assessment reports within the meaning of Act No. 139/1998 Coll., opinions within the meaning of Act No. 331/2005 Coll., certificate of compliance with good manufacturing practice (GMP), confirmation of compliance with the principles of good practice of preparation of transfusion of medicinal products (GPP), confirmation of compliance with the principles of good distribution practice (GDP) and inspection reports,

Total number of output inspection documents is illustrated in the below table:

| **Output Documents** | **Facilities** | | | |
|---|---|---|---|---|
| | **Manufacturers** | **Distributors** | **Transfusion Facilities** | **Total** |
| Assessment reports within the meaning of Act No. 140/1998 Coll. as amended | 5 | 22 | 3 | **30** |
| Assessment reports within the meaning of Act No. 139/1998 Coll. | 1 | 8 | / | **9** |
| Opinions within the meaning of Act No. 331/2005 Coll. | / | 6 | / | **6** |
| Certificate of GMP | 19 | / | / | **19** |
| Confirmation of GPP | / | / | 5 | **5** |
| Confirmation of GDP | / | 13 | / | **13** |
| Inspection reports | 28 | 54 | 15 | **97** |

The number of inspections carried out in 2009 is illustrated in the below table:

| **Inspection Type** | **Manufacturers** | | **Distributors** | **Transfusion Facilities** | **Total** |
|---|---|---|---|---|---|
| | **National** | **Foreign** | | | |
| entry | 7 | 0 | 27 | 5 | **39** |
| running | 19 | 1 | 17 | 5 | **42** |
| targeted | 1 | 0 | 6 | 3 | **10** |
| follow-up | 0 | 0 | 6 | 2 | **8** |
| **total** | **27** | **1** | **56** | **15** | **99** |

The Inspection Section lodged one motion concerning manufacturing and two motions concerning wholesale distribution of medicinal products and medical devices with the Ministry of Health to commence administrative procedure in the case of imposition of a penalty for breach of the provisions of Act No. 140/1998 Coll. as amended. In addition, 1 motion to discontinue an activity in compliance with Act no. 140/1998 Coll. as amended concerning wholesale distribution of medicinal products and medical devices was lodged.

The scope of the post-registration control of quality of medicinal products denotes control of quality of the medicinal products imported to the Slovak Republic, control of quality of medicinal products produced by national manufacturers, receipt and sending information on non-compliant quality of medicinal products, handling of complaints, provision of information on discontinuance or cancellation of medicinal product supplies to the market, ordering samples of medicinal products and reference materials, provision of information on withdrawn medicinal products and notices of non-quality sent to the press Zdravotnícke noviny and magazine Lekárnik, cooperation with customs authority, the SIDC central registration of samples assigns unique protocol numbers to applications for analysis of samples and to assessment of analytical certificates, stores samples and reference material under the prescribed conditions for storage, protects samples of medicinal products against theft and devaluation, prepares underlying documents to invoicing of samples for the Economic Department and maintains an electronic database of registered samples and analytical certificates.

The scope of the post-registration control of quality of medicinal products is illustrated in the below table:

| | **Received 2009** | **Processed 2009** | **Cancelled 2009** | **Balance as of 1 January 2010** |
|---|---|---|---|---|
| Control of quality of medicinal products | 67 | 67 | 0 | 0 |
| Notices of medicinal product withdrawal | 100 | 100 | 0 | 0 |
| Medicinal product withdrawal | 11 | 11 | 0 | 0 |
| Correction plan | 155 | 138 | 0 | 17 |
| Customs authority reports | 19 | 19 | 0 | 0 |
| Assessment report to application for registration | 125 | 106 | 0 | 19 |
| Assessment report to application for variation in registration | 76 | 66 | 0 | 10 |
| Error rate monitoring | 9 | 9 | 0 | 0 |
| Assessment of analytical certificates (imported medicinal products) | 64 | 73 | 0 | 1 |
| Samples assessed by laboratory testing (imported medicinal products) | 61 | 50 | 0 | 9 |
| Samples assessed by laboratory testing (medicinal products produced by national manufacturers) | 6 | 12 | 0 | 2 |
| PTS, CS samples | 8 | 7 | 0 | 1 |

Explanations: PTS ( Proficiency Testing Study - international tests verifying the testing method)
CS (assessment of the suggested reference substance Ph.Eur., controlled by EDQM).

### *4.7 Section of Safety of Medicinal Products and Clinical Trials*

**Department of Safety of Medicinal Products**

The Department focuses on routine pharmacovigilance, advanced pharmacovigilance, detection and processing of signals, initiation of variations in registration and settlement of crisis situations in pharmacovigilance. In addition, the Department processes reports of adverse effects of transfusion medicinal products.

Within routine pharmacovigilance, we focused on improvement of the system of electronic transmission of reports of adverse effects of medicinal products, on entry of reports in the Eudravigilance databank and development of national database eSkaDra application. The new application, the development of which is for reasons of insufficient capacity on the part of the developer slow, will provide an integrated solution to all requirements applicable for transmission of information, including the option of analysis and generation of summaries. We were gradually contacting the respective partners responsible for pharmacovigilance in pharmaceutical companies and testing data transmission. As of 31 December 2009, we have entered into 78 forms of agreements on mutual ICSR exchange between the SIDC and the holders of registration decisions. Reports are assessed and processed into an electronic form and in case of any serious reaction sent to the Eudravigilance databank. In case of any serious or unexpected reaction, the reports are sent also to the relevant holder of decision on medicinal product registration in an electronic or a written form in the prescribed print form type.

| Reports received from Slovakia | Number | % |
|---|---|---|
| in a paper form (health care personnel, non-professionals, holders) | 850 | 83.09 % |
| ....whereof sent to Eudravigilance | 97 | 11.41 % |
| in an electronic form (holders) | 173 | 16.91 % |
| Total | 1,023 | 100.00 % |
| whereof serious | 270 | 26.39 % |

| Reports received from abroad (EU and non-EU)* | Number | % |
|---|---|---|
| reports from abroad in a paper form (CIOMS) | 3,776 | 57.03 % |
| reports in an electronic form | 2,845 | 42.97 % |
| Total | 6,621 | 100.00 % |

** These reports need not to be sent to the SIDC as they are sent directly to Eudravigilance*

Four samples were sent for the laboratory control of samples of medicinal products in relation to occurrence of adverse effects (the so-called clinical complaints). We did not identify any error in the quality of those medicinal products that could cause any adverse effect.

In 2009, we received in total 1,623 reports on periodic analyses of safety of medicinal products (PSUR). We received 92 bridging reports, 37 addenda to reports (Addendum to PSUR) and 120 reactions to assessment reports. These reports represent information on safety, sent to the SIDC in addition to the documentation submitted with application for registration.

| Document Type | Number |
|---|---|
| PSUR | 1,623 |

| | |
|---|---|
| Addendum to PSUR | 37 |
| Bridging report | 92 |
| Reactions to assessment reports | 120 |
| Risk assessment plan (RMP) | 17 |
| Total number per 2009 | 1,889 |

We proceeded in the joint EU project "PSUR Work sharing", where our liability for 8 medicines was approved. In this project, we, as a reference state, processed and completed two assessments and sent comments on 4 medicines, assessed by other countries.

| Medicinal product (INN) | Allocated P-RMS/reference number | Assessment start date | Preliminary assessment report | Final assessment report draft | Final report + approved CSP text |
|---|---|---|---|---|---|
| sertraline | SK/H/PSUR/0001/002 | 30/06/2008 | 08/08/2008 | 12/09/2008 | 24/11/2008 |
| carteolol | SK/H/PSUR/0002/001 | 24/11/2008 | 02/01/2009 | 07/05/2009 | *April 2009 |
| atenolol + chlortalidone | SK/H/PSUR/0003/001 | 12/12/2008 | 29/01/2009 | 06/11/2009 | 31 December 2009 |
| granisetron | SK/H/PSUR/0004/001 | 06/04/2009 | 05/02/2010 | | |
| terbinafine | SK/H/PSUR/0005/001 | 05/01/2010 | | | |
| felodipine | SK/H/PSUR/0006/001 | | | | |
| lomustine | SK/H/PSUR/0007/001 | | | | |
| spirapril | SK/H/PSUR/0008/001 | 25/11/2009 | 04/01/2010 | | |

* In Pharmacovigilance Working Party (PhVWP), Slovakia has become the reference state for group pre-assessment of all beta-blockers used in ophthalmology.

The Commission for Safety of Medicinal Products and the Commission chairmanship met 6 times. Apart from participating in assessment of signals and assessment of reports of adverse effects, the Commission provided its statements to free sale of 6 medicinal products.

The Pandemic Commission met 5 times. Over the year, the below listed documents were processed and depending on the pandemic course regularly supplemented:

- SIDC Pandemic Plan
- Glossary of terms
- Notice of expiry prolongation of medicinal product Tamiflu
- Recommendation for the SIDC employees on foreign trips at the time of pandemic announcement
- Personal protective measures against flu
- Tamiflu and Relenza – expiry prolongation
- Call for anti-flu vaccination
- Call for reporting any suspicion of unwanted reaction in relation to pandemic vaccine use

In relation to flue pandemic A (H1N1) 2009, an internet site was created and various communications launched. The department staff actively participated in a seminar on safety of vaccines.

In addition, the Department assesses applications for variations in data of II. type in the summary of characteristic properties and in written information for users. We assessed 278 such applications, i.e. by 52 more than in 2008.

Another activity consisted in assessment of applications for prolongation, mainly, the first applications for prolongation in the national registration procedure. We processed 98 pharmacovigilance assessment reports, supplemented by control of texts of the summaries of characteristic properties and package leaflet of information, a notable drop by 130 in this application type compared to 2008.

The Pharmacovigilance Working Party meets 11 times a year and discusses the current problems of safety of medicinal products, suggests activities to decrease risk and provides statements to any proposed documents. Within this cooperation, we processed underlying documents for 40 not urgent applications for information, 6 alerts and 10 additional pieces of information.

We participate regularly in the meetings of the Working Group TIG (Telematic Implementation Group) organized by EMEA in London for the purpose of getting familiar with the procedures and works in the European NÚL Eudravigilance databank. The meetings are organized at quarterly intervals (4 times a year).

Monitoring of and commenting on the European and national legislation concerning the particular pharmacovigilance area.

**Department of Clinical Trials**

In the area of clinical trials of medicinal products and medical devices and good clinical practice, the SIDC provides for assessment of applications for clinical trials, issues objections and decisions on clinical trials permission, supervises its execution, approves workplaces, and inspects good clinical practice.

The activity of the Department of Clinical Trials (staffed by 1 university graduate and 1 secondary education graduate) consists in:

- control of discharge of requirements for submitting application for clinical trials, as set forth in Act No. 140/1998 Coll. and in vol X Eudralex

- assessment of clinical trials plans with regard to discharge of requirements, which ensure protection of rights and safety of any person participating in clinical trials – i.e. volunteers and patients on one hand, (informed consent, complete and compliant protocol, monitoring the study on the part of applicant, etc.), as well as the investigators and companies on the other hand (delivery of complete information on preparation, preparation suitability for clinical trials, observance of the dates for performance of studies and delivery of reports, etc.), approval of an appropriate workplace and responsible investigator,

- permission of only those studies that satisfy the legislative requirements, requirements for protection of the persons in clinical trials, as well as the requirements specified in the European Union documents (Directives, Guidance, Note to guidance, Helsinki Declaration). Assessment of non-intervention clinical trials of medicinal products, including post-marketing studies does not fall under the SIDC competence. The ethical aspects of clinical trials on healthy or unhealthy subjects are assessed by ethical commissions.

- international cooperation in the area of clinical trials of medicinal products, in particular, by use of the databank of clinical studies EudraCT and the databank of adverse effects Eudravigilance (module for clinical studies).

- continuous assessment of amendments and supplements to the plans of clinical trials, as well as annual reports on the clinical trial course

- monitoring of safety of trialled products by monitoring the occurrence of serious and unexpected events and reactions (SUSAR), occurring in the course of clinical studies, which the responsible investigators are obligated to report. When necessary, it decides on their solution,

- control final clinical study reports with focus on compliance with the approved protocol, accuracy and validity of results, and control of completeness of data and final report documentations,

- Good Clinical Practice (GCP) inspection with the investigator or assignor. In 2009, for the reason of departure of the GCP inspector and failure of three selection procedures, this activity lessened.

- information and education activity in the area of clinical trials and Good Clinical Practice,

- cooperation in creation of legislation and guidance notes in the area of clinical trials of medicinal products and medical devices and Good Clinical Practice,

- cooperation with the Section of Medical Devices in assessment of plans for clinical trials of medical devices,

- international cooperation within the Clinical Trial Facilitation Group and the Inspectors Group and other joint activities lessened for lack of staff.

The aforementioned tasks are performed in cooperation with external assessors and the Commission for Medicinal Products.

Summary of activities per 2009 and comparison with the previous period is illustrated in the below table:

| Activity | Number 2007 | Number 2008 | Number 2009 |
|---|---|---|---|
| Application for and approval of clinical trial | 154 | 159 | 145 |
| Approval of clinical trial | 131 | 138 | 129 |
| Objections/rejection of clinical trial | 10 | 5 | 4 |
| Application for approval of addendum to protocol | 231 | 266 | 237 |
| Application/notice of amendments to the Investigator's Brochure | 176 | 253 | 271 |
| Application for approval of a new centre | 38 | 38 | 52 |
| Award of consent of an ethical commission | 70 | 66 | 69 |
| Notice of clinical trial start date | 60 | 52 | 75 |
| Notice of clinical trial end date | 113 | 136 | 174 |
| Annual report on CT course | 83 | 143 | 403 |
| Report on adverse event from Slovak workplaces | 140 | 35 | 20 |
| Own activity | 1 | 0 | 0 |
| Other | 857 | 911 | 1,012 |
| Application for CT of a medical device | 2 | 2 | 2 |
| Total | 2,660 | 2204 | 2,593 |
| Monthly average | 221.6 | 183.7 | 199.5 |
| Other data | | | |
| Meeting of the Commission for Medicinal Products | 11 | 11 | 11 |
| Inspections | - | 1 | 2 |

### *4.8 Section of Medical Devices*

The SIDC Section of Medical Devices as the competent authority for medical devices (MD) in the Slovak Republic performs the tasks arising out of Act No.140/1998 Coll. as amended, Act No.264/1999 Coll. as amended and three government regulations (no. 569/2001 Coll. as amended, no. 570/2001 Coll. and no. 572/2001 Coll. as amended) and in a broader sense cooperates with the European Commission authorities as the representative of a member state in the area of medical devices. The Section of MD has 2 departments, the Department of Registration and Filing of Medical Devices and the Department of Safety of Medical Devices. The Section has in total 8 employees.

**Department of Registration and Filing of Medical Devices**

In the period under review, the Department was registering and filing all medical devices before placing them on the market or into operation in the Slovak Republic, registering MD manufacturers or their authorised representatives having registered offices in the Slovak Republic and registering manufacturers or their authorised representatives having registered offices in other member state. With regard to the free movement of goods within the European Union countries, most MD were registered based on CEs - manufacturers' certificates, issued by notified persons in some member state of the EU. Registrations and filings of MD class I. and IVD - other were received on the basis of EC declaration of conformity issued by manufacturer.
In 2009, we recorded again an increase in some indicators (number of received application forms, updated codes). In addition to registration/filing of new manufacturers and MD, we were, in particular, prolonging the validity of assigned codes based on new CE - certificates, expanding the series of registered/filed MD and changing the names of manufacturers or applicants, a very time-demanding activity. The Section makes full use of the new database of registered and filed MD, the search modification of which is published on the Institute's internet site. Since its placing into operation, data are continually populated in the new database (MD class, description, intended purpose, certificates and their validity dates) also with older applications for registration/filing, entered in the database earlier. The searching database of registered/filed MD is updated at weekly intervals. We publish at monthly intervals on the Institute's internet site the overall database in the ".xls" format. The Section of MD on an ongoing basis cooperates with the MoH of the SR in the process of MD categorisation.

**Department of Safety of Medical Devices**

The Department of Safety was processing reports on MD accidents, breakdowns and failures (MD ABF) from manufacturers, partner medicine agencies, distributors, hospitals and physicians and monitoring the course of their solution. The number of MD ABF reports increased by 208 reports compared to 2008 to the total number of 755, whereof 228 MD were according to the reports placed on the market in the SR. The Department managed to get stabilized in terms of its personnel.

Over the year 2009, we received 2 notices of commencement of MD clinical trials, the performance of which is coordinated with the Section of Safety of Medicinal Products and Clinical Trials.

The Section of MD proceeded in 2009 in active control of MD placed on the market in the SR, in control of MD designation, we managed to check thoroughly the contents of car first aid kits with all manufacturers placing car first aid kits on the market in SR in relation to the effectiveness of the new decree of the MoH of the SR no. 143/2009 Coll. on Contents of Car First Aid Kits. Owing to our efforts, the quality of the contents of car first aid kits and designation of its respective components is at a higher level than in the past. There are still some insufficiencies in MD control at health and other than health facilities and in adequate personnel and financial reinforcement of the Section that prevent us to perform real market surveillance.

The Head of the Section participated in the meetings of the working groups with the European Commission (MDEG) and in the meetings of the competent authorities for MD (CA meeting). Active cooperation of every member state is required in the EC working groups and therefore we must reinforce the Section's personnel to perform those activities.

The inspectors of the Section of MD carried out further in 2009 both entry and repeated inspections of wholesale distribution companies arising out of Act No.140/1998 Coll., whereas the number of entry inspections and thus the number of issued assessment reports was approximately the same as in 2008.

The Head of the Section regularly participated in the meeting of the Categorization Council for MD with the MoH of the SR.
The Quality Manager of the Section of MD regularly conducted internal audits of quality within the quality management system and supervised review of the standard working procedures, Guidance Note and GPP, which we were constantly updating.

Summary of the activities of the Section of MD per 2009

- number of received application forms for MD registration/filing 1,669
- new assigned codes 2,339
- updated codes 4,317
- total processed codes 6,656
- report of MD ABF 755
- report of MD ABF in the SR 228
- assessment reports for permission of wholesale distribution activity 12
- entry inspections of wholesale distribution companies 14
- repeated inspections of wholesale distribution companies 4
- notice of commencement of MD clinical trial 2

***4.9 Department of Good Pharmacy Practice***

This Department activity focused on inspection activity, collection of samples and control and analytical activity.

**Number of respective facilities as of 31 December 2009:**

| Control laboratory (CL) | CL 1 Bratislava | CL 2 Topoľčany | CL 3 Zvolen | CL 4 Žilina | CL 5 Košice | **Total** |
|---|---|---|---|---|---|---|
| Public pharmacies | 369 | 295 | 246 | 341 | 372 | **1,623** |
| Public pharmacies branches | 28 | 42 | 28 | 36 | 24 | **158** |
| **Total: pharmacies and branches** | **397** | **337** | **274** | **377** | **396** | **1,781** |
| Hospital pharmacies | 14 | 13 | 6 | 12 | 12 | **57** |
| MD Dispensaries | 47 | 29 | 34 | 40 | 71 | **221** |
| Poppy-seed growers | 15 | 35 | 3 | 2 | 7 | **62** |
| Opticians | 161 | 107 | 94 | 123 | 121 | **606** |
| Other facilities | 14 | 14 | 14 | 13 | 9 | **64** |
| **Total** | **648** | **535** | **425** | **567** | **616** | **2,791** |

The inspection activity was carried out at the facilities providing pharmacy care, at opticians, with poppy-seed growers and at other health and other than health facilities.

**Total number of inspections: 879**

**Total number of performed collections: 270**

The most frequent shortcomings identified with running inspections were: lack of expert staff, in particular, pharmacists, pharmacy does not provide comprehensive heath care – does not carry out individual preparation of medicinal products, does not prepare purified water, fails to control the purified water at the defined intervals, the problem of non-compliant quality of purified water is not coped with forthwith, but the water is still used with preparation of medicinal products, shortcomings with carrying out and registration of entry control of medicines and auxiliary substances, incomplete record documentation, fails to perform the metrological verification of weighing machines and weights at the defined intervals, shortcomings in registration of medicinal products containing narcotic substances of the II. group, missing licence to process defined substances, incomplete record documentation, non-complaince with conditions for storage of medicinal products, in particular, in summer months.

The targeted inspections were carried out upon complaints, initiatives of patients and citizens and the Slovak Chamber of Pharmacists.

We controlled disposal of medicinal products and medical devices collected by pharmacies from people by company Modrá planéta, spol. s r.o., Bratislava and, in cooperation with the Section of Medical Devices, the haematological analyzers and the distribution of any unregistered medicinal product.

Motions for administrative procedure were lodged with all justified cases of complaints.

**Administrative procedure**

With regard to the shortcomings identified by inspections, motions for administrative procedure commencement were lodged:

| Control laboratory (CL) | Number of motions | Total sum | Number of paid motions | Total sum |
|---|---|---|---|---|
| **CL 1 Bratislava** | 7 | €16,431.64 | 3 | €6,307.00 |
| **CL 2 Topoľčany** | 19 | €31,551.78 | 5 | €5,976. 00 |
| **CL 3 Zvolen** | 6 | €10,954.20 | 2 | €2,324.00 |
| **CL 4 Žilina** | 10 | €24,940.00 | 2 | €7,640.00 |
| **CL 5 Košice** | 17 | €58,724. 00 | 3 | €3,984.00 |
| **SUMMARY** | 59 | €142,601.62 | 15 | €26,231. 00 |

The most frequent cause for lodging motions for breach of Article 36 par. 2 letters a) and b) Act No. 140/1998 Coll. – pharmacy had no system of assurance of quality of medicinal products and medical devices created and used, licence holder did not operate pharmacy in accordance with the law, Special Licence awarded by the SIDC to process drug precursors was missing, dispensation of expired medicinal products, dispensation of medicinal products that require medical prescription without medical prescription, discount provision to licence holders, licence to process narcotic and psychotropic substances, awarded by the MoH of the SR on change in the expert representative, not amended accordingly.

**Control and analytical activity**:
The random sample collection control focused on chemical and microbiological control of randomly collected samples of medicinal products prepared in pharmacies and control of purified water in public and hospital pharmacies. We carried out 270 sample collections.
**The most frequent identified shortcomings:** non-compliant quality of purified water (in particular, high conductivity and non-compliant microbiological purity), non-compliant content of efficient substances, insufficient designation of medicinal products.

The sample control on request was carried out on requests of state and other than state health facilities. For the most part, chemical and microbiological control of purified water was carried out on pharmacies' requests. For the evaluation of control and analytical activity, see annexes no. 5 and no. 6.

The Department of Good Pharmacy Practice requires 4 additional university graduates - inspectors and 1 secondary school graduate - assistant for administrative works related to professional agenda (Assessment Reports, Opinions, and Certificates issued by the SIDC) of new facilities for the entire Slovak Republic.

**5. Institute's Budget**

The Ministry of Health of the SR, via the State Treasury information system, provided a breakdown of the Institute's current expenditures for the year 2009 in the volume of **€4,217,020,** whereof wages and salaries totalled: €1,719,445, insurance premiums and contributions to insurance companies: €600,943, goods and services €1,855,142 and regular transfers: €41,490. After adjustments implemented by the MoH of the SR, the budget of current expenditures as of 31 December 2009 totalled **€4,304,148**.
The Institute's capital expenditures for the year 2009 as of 1 January 2009 were not included in the breakdown. After adjustment implemented by budgetary measures of the MoF of the SR, the budget of capital expenditures as of 31 December 2009 totalled **€129,172.**

Budget performance as of 31 December 2009:

| Economic classification | Original budget as of 01/01/09 | Current budget as of 31/12/09 | Budget use as of 31/12/09 | % of perfo rmance |
|---|---|---|---|---|
| **200 Non-taxable income** | **431,521** | **295,900** | **317,029** | **106.,93** |

| | | | | |
|---|---|---|---|---|
| **600 Current expenditures** | **4,217,020** | **4,304,148** | **4,304,147** | **100.00** |
| whereof: | | | | |
| 610 Wages, salaries | 1,719,445 | 1, 760,445 | 1,760,445 | 100.00 |
| 620 Insurance premiums and contributions to insurance companies | 600,943 | 596,872 | 596,872 | 100.00 |
| 630 Goods and services | 1,855,142 | 1,921,962 | 1,921,961 | 100.00 |
| 640 Regular transfers | 41,490 | 24,869 | 24,869 | 100.00 |
| | | | | |
| **700 Capital expenditures** | **0** | **129,172** | **129,172** | **100.00** |
| whereof: | | | | |
| HPLC system | 0 | 96,142 | 96,142 | 100.00 |
| Rotomat | 0 | 33,030 | 33,030 | 100.00 |

Income

The allocated income budget totalled €431,521, adjusted to €295,900 by budgetary measure of the MoH of the SR. As of 31 December 2009, the Institute's incomes totalled **€317,029**, i.e. by €21,129 more than planned in the adjusted breakdown. The income came from provision of services, specifically, inspections of pharmacies, chemical and microbiological analyses of purified water, income from EMEA registration, income from issue of certificates and attests, canteen lease, additional payments from 2008, refunds and penalties. The income structure is illustrated below:

| | |
|---|---|
| **Total budgeted non-taxable income:** | **€317,029** |
| whereof: | |
| provided services | **€**200,502 |
| penalties | **€**60,080 |
| other (credit memos, refunds, canteen lease, other) | **€**56,447 |

In addition to the aforementioned budget income, the SIDC reported additional income of €4,942,299, from registrations which are not included in the budget. The applicants for registration pay administrative fees which tax authorities pay to the state budget. This income structure is illustrated below:

| | | |
|---|---|---|
| **Total income from registrations:** | **number** | **€ 4,942,299** |
| whereof: | | |
| award of decision on registration | 842 | **€**2,096,159 |
| prolongation of registration validity | 350 | **€**580,825 |
| variation in registration | 2,555 | **€**1,695,242 |
| MRP | 209 | **€**416,224 |
| other | 498 | **€**153,849 |
| **The Institute's total income** | | **€5,259,328** |

**Current expenditures** were used in compliance with the budget adjusted by the last budgetary measure of the MoH of the SR to €4,304148. The allocated binding limits were used at 100 %.
As of 31 December 2009, the Institute did not report any outstanding liabilities to its suppliers.

**Capital expenditures** of €129,172 allocated at the end of the year were used at 100 % to acquire HPLC system and rotomat for filing registration documentation.
The SIDC repeatedly applied with the budgetary chapter manager for release of capital expenditures to finance the ongoing investment CL Žilina Reconstruction. Since 2007, the reconstruction has not been in progress for the reason of non-allocation of funds. The SIDC records an outstanding invoice for €10,265 to the structure supplier, company URPE, s. r. o., Banská Bystrica, for works related to the structure conservation. The supplier

seeks the invoice payment by courts. The District Court Bratislava II. imposed a payment order to pay the outstanding invoice and related default interests, against which the SIDC filed a protest. The judicial proceedings will continue on 16 February 2010.

The safety and health protection at work control identified in 2009 serious shortcomings in the control laboratory in Topoľčany, in particular, breach of insulation of the building and the access communication. The budgetary chapter manager did not accept the SIDC's requirements for allocation of funds to remove those shortcomings.

**6. Personnel Issues**

The Ministry of Health SR for the year 2009 allocated for the State Institute for Drug Control a binding indicator of 203 jobs. This fact in confrontation with the increasing demands on performance of new tasks was a big problem from the very beginning of the year. In addition to this unfavourable fact, wages were reduced, and thus prevented us to motivate and appreciate the increased employee performances. Given the reduced number of employees and related reduction in wages, we could not perform all the tasks imposed on the State Institute for Drug Control.
Over the year 2009, the Personnel Office was repeatedly processing underlying documents and reasoning for increase in the number of employees and wages. It focused on compliance with all applicable legal regulations governing employment law and employee remuneration.

**Number and fluctuation of the SIDC employees**

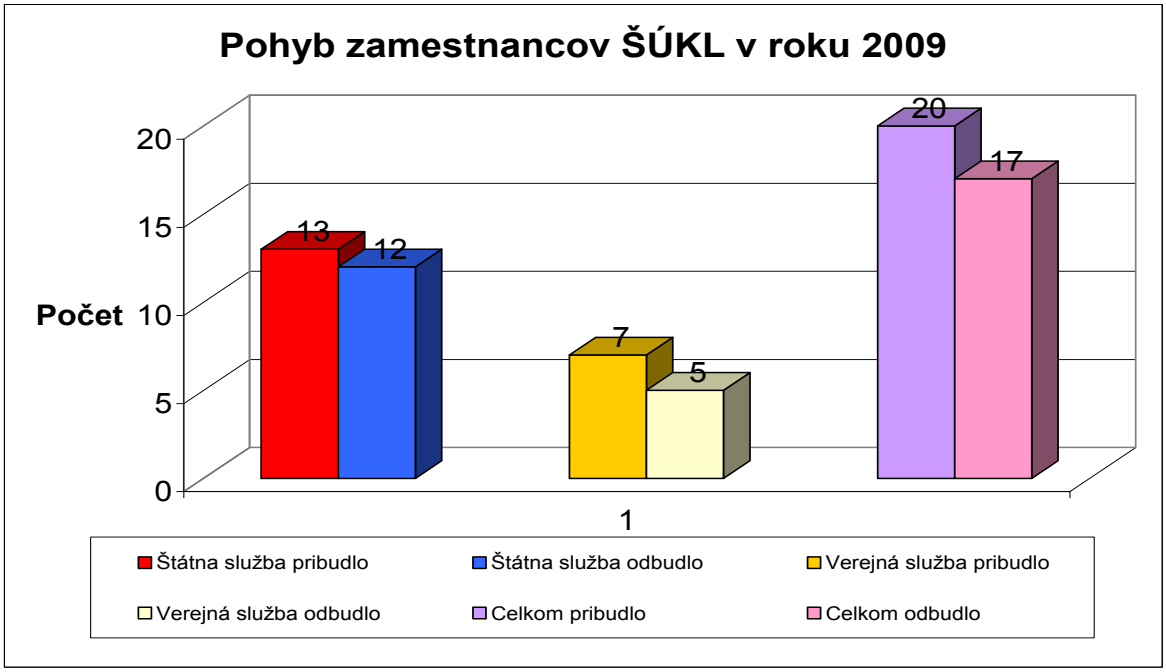
Imposed **number of employees** for the SIDC for the year **2009:** **203**

**whereof**

number of employees in civil service 93
number of employees in public interest 110

| **Employee fluctuation** | **employment start** | **employment termination** |
|---|---|---|
| civil service | 13 | 12 |
| public interest | 7 | 5 |
| **total** | **20** | **17** |

The employee fluctuation in 2009 totalled ca 18.2 %., i.e. less than in previous years. This fact reflects employee stabilization owing to the Institute’s management constant efforts to create a favourable work ambiance.




**Fluctuation of the SIDC employees**
**Number**
Civil service increase Civil service decrease Public service increase
Public service decrease Total increase Total decrease

**Limit of the number of SIDC employees for 2009 and its actual performance:**

| **year 2009** | **Civil Service** | **Public Interest** | **Total** |
|---|---|---|---|
| average registration number | 90,24 | 106,16 | 196,36 |
| average recalculated number | 90,04 | 106,23 | 196,27 |

| **status as of 31/12/2009** | **Civil Service** | **Public Interest** | **Total** |
|---|---|---|---|
| men | 14 | 16 | 30 |
| women | 76 | 91 | 167 |
| **total** | **90** | **107** | **197** |

**Development in used and adjusted wages**

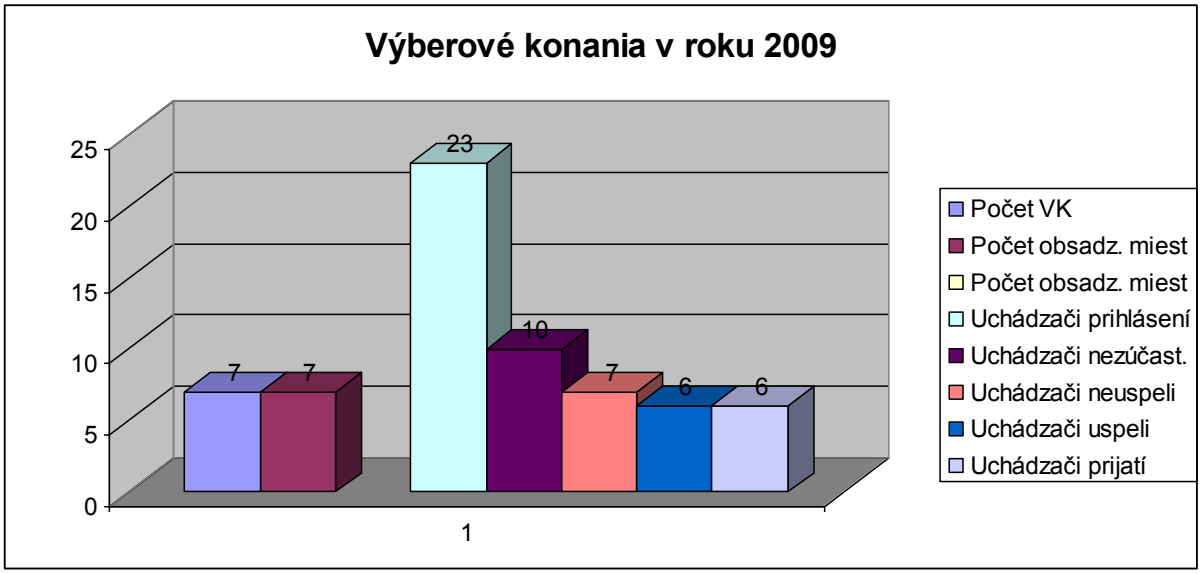
| | | |
|---|---|---|
| budget for the year 2009 | | €1,719,445 |
| adjustment since 01/11/2009 | €41,000 | |
| **total** | | **€1,760,445** |

**Used wages**

| | | | |
|---|---|---|---|
| civil service | €1,006,036.98 | average wage | €931.10 |
| public interest | €754,408.02 | average wage | €591.80 |
| total | €1,760,445.00 | average wage | €747.46 |

Selection procedures

More detailed summary of selection procedures is illustrated in the attached table no. 1




Selection procedures in 2009
Number of selection procedures (SP)
Number of vacancies
Number of vacancies
Registered applicants
Not attending applicants
Unsuccessful applicants
Successful applicants
Employed applicants

**Education**

Employee education was implemented according to an in advance developed and approved plan (internal seminars). Apart from the Institute's seminars, every Section/Department organized education focused n the issues of the specific activities according to developed plans. The plan and lists of attendants at the Institute's seminars are archived with the Quality Management Section.
External education was provided via national and international professional events (seminars, conferences, workshops, etc.).
The Institute’s employees processed and presented expert lectures at various national and international events and acted as lecturers at the Slovak Medical University. Six employees are studying at universities to advance their qualification. Given the limited current expenditures, the English language course was discontinued.

**7. Objectives and Summary of their Performance**

The SIDC actively cooperated within the network of the European medicine agencies, with priority focus on the mutual recognition procedure, decentralized procedure and activity in coordination group. It cooperated actively in the Coordination Group, CMDh and Committee for Herbal Medicinal Products, HMPC in the role of coordinators in preparation of documents, rapporteurs and delegates in other working groups (CHMP Working Group for Cooperation between Patients' and Consumers' Organisations, PCWP).

We proceeded in working on rational implementation of requirements of Act No. 342/2006 Coll. (amended Act on Medicinal Products) in the area of registration of medicinal products, in particular, in terms of patent issues.
We improved effectiveness of administration of registration documentation receipt and subsequent flow to internal and external assessors. Electronic assignment of registration numbers and payment automation. The time delay in application processing was notably reduced.
We assured quality procedures with assessment of applications in the SR in compliance with the EU procedures by means of training courses, control and individual management of new employees.
We supported the activity of the Commission for Human Medicinal Products to enable it to proved quality opinions for national decisions on medicinal product registration under the time-demanding conditions of the EU procedures and implemented the peer review system, systematically for CMDh referrals.
In terms of work quality improvement, we identified a need to reorganize the Registration Section, the Section of Medicinal Products Quality Assessment and the Inspection Section. We developed and discussed viable models with our employees.
The summary of performance of resolutions adopted by the advisory body of the Head of Service Office and Director – operative and panel meetings in the TASKMAN application (Annex No. 7).

**8. Main User Groups of the SIDC Outputs**

External SIDC customers:

a) patients,
b) legal entities (pharmaceutical manufacturers, manufacturers of medical devices, distributors of medicinal products and medical devices),
c) natural persons (pharmacies, dispensaries of medical devices),
d) applicants for clinical trials,
e) others (e.g. applicants for information, applicants for authorisation).

SIDC services provided to customers:

- award of decisions on registration of medicinal products,
- award of decisions on registration to process defined substances of group 2,
- issue of assessment reports for material, spatial and personnel equipment of the applicant for licence to process medicinal products,
- filing manufacturers of medical devices and the list of MD placed on the market in the SR,
- award of licences for clinical trials,
- approval of workplaces clinical trials, award of licences for clinical trials,

- entry inspections on request (pharmacies, dispensaries of medical devices, opticians, manufacturers of medicinal products, wholesale distribution, transfusion facilities, laboratories for pharmaceutical testing).

The SIDC outputs are intended for and used by the MoH of the SR and many other users, in particular, pharmaceutical manufacturers, wholesale distribution companies of medicinal products and medical devices, owners of public and hospital pharmacies, opticians, dispensaries of medical devices, as well as the general public.

Expert consultancy services and consultations in the area of registration of medicinal products and medical devices, the issues concerning the Slovak pharmacopoeial and pharmaceutical code and other professional services are provided by the respective professional sections and departments of the Institute.

The publishing activity in the year under review consisted in quarterly publishing of "Report on Quality of Medicinal Products", published for the needs of the general professional healthcare public. The report provides information on non-compliant preparations and related measures, or on preparations subsequently released for use in treatment.

The electronic form of the output is the database of registered medicinal products, used, inter alia, by the MoH of the SR and health insurance companies. Partial outputs from the database are provided to applicants for registration of medicinal products and the MoF of the SR for needs of medicinal product pricing.

**9. Annual Report Publication**

The annual report is published in writing in the Slovak and the English languages, delivered to the incorporator, i.e. the MoH of the SR, Slovak Medical University, and other national and foreign institutions which might be interested. In addition, the annual report is published on the SIDC internet site: www.sukl.sk.

**ANNEXES**

**Annex No. 1 Lecturing and Publishing Activities**

BAĎUROVÁ R.: Presentation: "Inspection focused on good practice of preparation of transfusion medicinal products", SMU Bratislava, 23/02/2009
BAĎUROVÁ R.: Presentation: "Inspection focused on good practice of preparation of transfusion medicinal products", SMU Bratislava, 03/04/2009

BAKOVÁ M.: Presentation: "Inspection focused on good practice of preparation of transfusion medicinal products", SMU Bratislava, 23/02/2009

BENKOVÁ M.: "The role of the European pharmacopoeia in assurance and control of quality of medicinal products", Bratislava, 28/10/2009

BEŇOVÁ P.: "Inhalanda", Bratislava, SIDC - SMPQA, 29/04/2009

KIŠOŇOVÁ K.: "Summary of the activity of the Department of Good Pharmacy Practice per 1Q 2009", Pharmacology discussion workshop, SMU Bratislava, 21 – 22/05/2009
KIŠOŇOVÁ K.: "Current situation in pharmacy and pharmacy business from the perspective of the SIDC control activity", Pharmacology discussion workshop, SMU Bratislava, 21 – 22/09/2009

KIŠOŇOVÁ K.: "Current problems and tasks of hospital pharmacies from the perspective of the SIDC Department of Good Pharmacy Practice", XVIII. working days of hospital pharmacists, Bratislava, 11 – 13/11/2009

MESKOVÁ M.: "Course of inspections at pharmacies and some identified shortcomings", Regional Chamber of Pharmacists Žilina, 15/06/2009

MLYNÁROVÁ M.: "Reagent designation and storage", Bratislava, SIDC - SMPQA, 25/02/2009
MLYNÁROVÁ M.: "Manufacturing process validation", Bratislava, SIDC - SMPQA, 22/07/2009
MLYNÁROVÁ M.: "Transmission method control", Bratislava, the SIDC – SMPQA, 28/08/2009
MLYNÁROVÁ M.: "Primary documentation filing and archiving in the medicinal product samples file", Bratislava, SIDC - SMPQA, 09/09/2009
MLYNÁROVÁ M.: "Analysis assessment and suspicion of OOS", Bratislava, the SIDC – SMPQA, 16/09/2009
MLYNÁROVÁ M.: "Verification of pharmacopoeial methods", Bratislava, SZÚ, 07/12/2009
MLYNÁROVÁ M.: "Verification of pharmacopoeial methods", Bratislava, SIDC – SMPQA, 16/12/2009

POTÚČKOVÁ L.: "QWP February meeting information", Bratislava, SIDC - SMPQA, 11/03/2009

SEDLÁČKOVÁ S.: "Medicine", Bratislava, SIDC - SMPQA, 25/03/2009

STREČANSKÁ E.: "Medicinal product manufacturing", Bratislava, SIDC - SMPQA, 29/04/2009

ŠIDLÍKOVÁ I: "STN EN ISO 9001:2008", SMU, Bratislava, Thematic course – "Preparation for internal quality audit"

TARÁBKOVÁ E.: "Analytical appliances and components to be controlled", 07/12/2009, Slovak Medical University, Bratislava
TARÁBKOVÁ E.: "Laboratory control system audit", 18 - 19/11/2009, Slovak Medical University, Bratislava

TARÁBKOVÁ E., BALOGOVÁ K.: "Quality Guidelines of the Section of Medicinal Products Quality Assessment", 21.01/2009, SIDC, Bratislava (Internal seminar for the SMPQA needs)

TARÁBKOVÁ E., BALOGOVÁ K.: “Processing draft/review of controlled documents”, 21/01/2009, SIDC, Bratislava (Internal seminar for the SMPQA needs)
TARÁBKOVÁ E., BALOGOVÁ K.: “Processing draft/review of controlled documents”, 23/01/2009, SIDC, Bratislava (Internal seminar for the Administrative Section needs)

VOJTEKOVÁ O.: INŠP employee training on work in EISOD system, SIDC

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SLÁVIK M.
On 18 May 2009, the SIDC Head of the Section of MD, MUDr. Marek Slávik, gave lecture and presented the “Role of the SIDC in placing MD on the market and into operation in the SR and current amendments to legal regulations” for specialists in continual education, integrated in the sub-specialty division: review pharmacology at the Department of Pharmacology, Faculty of Medical Specialty Studies, Slovak Medical University in Bratislava.

11/11/2009
SMU, Faculty of Nursing and Health Professional Studies
Department of Pharmacology
“Role of the SIDC in placing MD on the market and into operation in the SR”
11/11/2009
XVIII. working days of hospital pharmacists
Panel discussion on current issues of hospital pharmacology in SR

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Course no. 1 3065 TK current news in pharmacovigilance. Requirements for database of adverse effects and electronic information exchange.
SMU, Faculty of Medical Specialty Studies, Department of Pharmaceutical Control and Medicinal Products Quality Assurance
Venue: Research Base SMU Modra – Harmónia, on 26/02/2009

1. GIBALA P.: Introduction to the issues
2. GIBALA P., MAGÁLOVÁ T.: Pharmacovigilance systems of a pharmaceutical company and their description
3. KAMENSKÁ R., HARČÁROVÁ A.: Requirements for a database of adverse effects and electronic information exchange
4. MAGÁLOVÁ T., GIBALA P.: Periodical analysis of medicinal product safety, analysis report and PSUR worksharing project
5. FUNDÁRKOVÁ S., GIBALA P.: Variations in registration concerning medicinal product safety
6. GIBALA P., KAMENSKÁ R., MAGÁLOVÁ T., FUNDÁRKOVÁ S.: Panel discussion

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Communication course with risk of medicinal products VII. Current vaccine and vaccination problems, Interactions with NSA.
Venue: Centre of Clinical Pharmacology for assessment of medicinal products, Institute of Pharmacology, Faculty of Medicine, Comenius University, BA, 09/12/2009
GIBALA P., MAGÁLOVÁ T., KAMENSKÁ R.: Assessment of vaccine assets and risks
HARČÁROVÁ A., KAMENSKÁ R., MAGÁLOVÁ T.: Monitoring vaccine safety in the SR
FUNDÁRKOVÁ S., GIBALA P.: Preparation for pandemic from the perspective of the SIDC
KAMENSKÁ R., HARČÁROVÁ A., MAGÁLOVÁ T., GIBALA P.: Pandemic vaccines, monitoring safety after placing on the market

Special course SMU, Modra: Clinical trial with focus on bioequivalence studies
Lecturer: GIBALA P.

Environment for clinical trials and bioequivalence studies
News in requirements for clinical trials in Slovakia
Amended directive on bioequivalence studies
Requirements for bioequivalence studies according to WHO.

**Annex No. 2**

**F O R E I G N  B U S I N E S S  T R I P S**

06 - 08/01/2009, London/England
COMP
Doc. RNDr. Magdaléna KUŽELOVÁ CSc.

12 - 13/01/2009, London/England
EWP
PharmDr. A. Adameová

12 - 15/01/2009, London/England
MLWP + HMPC
Prof. Ing. Milan Nagy, PhD.

14 - 16/01/2009, London/England
CAT
Prof. MUDr. Peter Turčáni CSc**.**

18 - 21/01/2009, London/England
CHMP Pharmacovigilance
MUDr. P. Gibala

18 - 22/01/2009, London/England
CMD(h)
PharmDr. D. Stará

18 - 22/01/2009, Prague/Czech Republic
HMA
PharmDr. J. Mazag

27 - 28/01/2009, Brussels/Belgium
Meeting of the competent authorities for blood and blood preparations
Ing. R. Baďurová

29 - 30/01/2009, Velké Bílovice/Czech Republic
Meeting of 4 inspectorates
Ing. M. Nádaská

29 - 30/01/2009, Velké Bílovice/Czech Republic
Meeting of 4 inspectorates
Mgr. T. Ottinger

29 - 30/01/2009, Velké Bílovice/Czech Republic
Meeting of 4 inspectorates
RNDr. J. Rašková

29 - 30/01/2009, Velké Bílovice/Czech Republic
Meeting of 4 inspectorates
PharmDr. I. Berčík

03 - 04/02/2009, Strasbourg/France
Meeting of expert group no. 15 for vaccines and immunosera
RNDr. M. Bukovský

11 - 13/02/2009, London/England
CAT

Prof. MUDr. Peter Turčáni CSc.

11 - 13/02/2009, London/England
CAT
Doc. MUDr.Mikuláš Hrubiško,CSc.

15 - 17/02/2009, Berlin/Germany
PPRI network meeting
PharmDr. J. Mazag

15 - 18/02/2009, London/England
CHMP Pharmacovigilance
RNDr. T. Magálová

15 - 18/02/2009, London/England
CMD(h)
PharmDr. D. Stará

16 - 19/02/2009, London/England
CHMP Plenary
PharmDr. J. Mazag

23 - 25/02/2009, Prague/Czech Republic
CA
MUDr. M. Slávik

23 - 26/02/2009, London/England
QWP
RNDr. L. Potúčková

02/03/2009, Brussels/Belgium
Standing Committee
PharmDr. D. Stará

02 - 03/03/2009, London/England
Eudranet TIG
Ing. K. Blšák

02 - 04/03/2009, London/England
CTFG Plenary
MUDr. P. Gibala

02 - 05/03/2009, London/England
COMP
Doc. RNDr. Magdaléna KUŽELOVÁ CSc.

03 - 04/03/2009, London/England
Eudravigilance TIG
MUDr. R. Kamenská

04 - 05/03/2009, London/England
Management Board
PharmDr. J. Mazag

04 - 05/03/2009, London/England

PCWP
PharmDr. D. Stará

04 - 06/03/2009, London/England
TIGes
PharmDr. Z. Nouzovský

08 - 10/03/2009, Prague/Czech Republic
CMD ( h) Informal
PharmDr. D. Stará

08 - 10/03/2009, Prague/Czech Republic
COMP Informal
Doc. RNDr. Magdaléna KUŽELOVÁ CSc.

09 - 10/03/2009, London/England
Quality of Documents
Ing. M. Polláková

10 - 12/03/2009, London/England
HMPC
Prof. Ing. Milan Nagy, PhD.

15 - 18/03/2009, London/England
CHMP Pharmacovigilance
MUDr. P. Gibala

16 - 18/03/2009, Strasbourg/France
European Pharmacopoeia Commission
PharmDr. R.Martincová

16 - 18/03/2009, Strasbourg/France
European Pharmacopoeia Commission
PharmDr. M.Benková

16 - 19/03/2009, London/England
CHMP
PharmDr. J. Mazag

17 - 18/03/2009, London/England
CMD ( h)
PharmDr. D. Stará

18 - 20/03/2009, Brno/Czech Republic
GMP Project Cleaning and Validation
Ing. M. Nádaská

18 - 20/03/2009, Brno/Czech Republic
GMP Project Cleaning and Validation
Mgr. T. Ottinger

30 - 31/03/2009, London/England
EWP
PharmDr. A. Adameová

30 - 31/03/2009, London/England
EWP

PharmDr. A. Čorejová

31/03 - 03/04/2009, London/England
COMP
Doc. RNDr. Magdaléna KUŽELOVÁ CSc.

01 - 03/04/2009, Geneva/Switzerland
WHO Good Manufacturing Practices and Inspections
Mgr. T. Ottinger

15 - 18/04/2009, London/England
CAT
Doc. MUDr.Mikuláš Hrubiško,CSc.

16/04/2009, Prague/Czech Republic
Network Meeting of the Competent Authorities for Pricing and Reimbursement of Pharmaceuticals
PharmDr. J. Mazag

19 - 22/04/2009, Prague/Czech Republic
HMA WG of Enforcement Officers Meeting
Ing. R. Baďurová

19 - 22/04/2009, London/England
CHMP Pharmacovigilance
RNDr. T. Magálová

20 - 21/04/2009, London/England
CMD (h) Plenary
PharmDr. P. Potúček

20 - 23/04/2009, London/England
CHMP Plenary
PharmDr. J. Mazag

26 - 28/04/2009, Paris/France
4th PIC/ S Expert Circle Meeting on Quality Risk Management
Mgr. T. Ottinger

28 - 30/04/2009, Prague/Czech Republic
Homeopathic Medicinal Products Working Group
PharmDr. A. Liščáková

04 - 06/05/2009, Geneva/Switzerland
Meeting of the PIC/S Committee
RNDr. J. Rašková

12 - 14/05/2009, London/England
HMPC
Prof. Ing. Milan Nagy, PhD.

11 - 12/05/2009, London/England
AD HOC Expert Meeting on Vedrop
PharmDr. J. Mazag

12 - 14/05/2009, Paris/France

Working Group for Good Laboratory Practice
PharmDr. I. Šidlíková

13 - 15/05/2009, London/England
CAT
Prof. MUDr. Peter Turčáni CSc.

17 - 19/05/2009, Mariánske Lázne/Czech Republic
HMA
PharmDr. J. Mazag

17 - 20/05/2009, London/England
GMP/ GDP Inspectors Working Group
Ing. M. Nádaská

25 - 26/05/2009, Leiden/Netherlands
Modelling and simulation Workshop - Concepts
PharmDr. P. Ochodnícky

25 - 28/05/2009, London/England
CHMP Pharmacovigilance
MUDr. P. Gibala

25 - 28/05/2009, London/England
CMD (h)
PharmDr. D. Stará

25 - 28/05/2009, Austria/Vienna
OMCL ANNUAL MEETING
Mgr.M. Mlynárová

25 - 29/05/2009, Austria/Vienna
OMCL ANNUAL MEETING OCABR Vaccine Session
PharmDr. I. Nováková

25 - 29/05/2009, Austria/Vienna
OMCL ANNUAL MEETING OCABR Blood Session
PharmDr. Z. Čemická

26 - 29/05/2009, London/England
CHMP
PharmDr. J. Mazag

27 - 29/05/2009, London/England
TIGes
PharmDr. Z. Nouzovský

27 - 29/05/2009, Leiden/Netherlands
Modelling and simulation Workshop- Applications
PharmDr. P. Potúček

01 - 05/06/2009, London/England
CHMP/CVMP Joint Quality WP
Mgr. M. Mlynárová

02/06/2009, Vienna/Austria
PHIS Hospital Pharma meeting
PharmDr. J. Mazag

02/06/2009, Vienna/Austria
PHIS Hospital Pharma meeting
Ing. B. Bilančíková

02 - 05/06/2009, London/England
COMP
PharmDr. T. Foltánová

03 - 05/06/2009, Prague/Czech Republic
Emacolex
Mgr.E. Siminská

07 - 09/06/2009, Luxembourg
2nd PHIS NETWORK Meeting
PharmDr. J. Mazag

07 - 09/06/2009, Luxembourg
2nd PHIS NETWORK Meeting
Ing. B. Bilančíková

07 - 09/06/2009, Luxembourg
2nd PHIS NETWORK Meeting
PharmDr. P. Púčať

08 - 09/06/2009, London/England
Joint PCWP/ HCP WG meeting
PharmDr. D. Stará

08 - 09/06/2009, London/England
EWP
PharmDr. A. Adameová

08 - 09/06/2009, London/England
Eudravigilance TIG
RNDr. T. Magálová

14 - 15/06/2009, Prague/Czech Republic
Working Group of Quality Managers
PharmDr. I. Šidlíková

15 - 17/06/2009, London/England
Quality of Documents
Ing. M. Polláková

17 - 18/06/2009, London/England
EudraGMP Database Sub-working Group
RNDr. M. Baková

17 - 20/06/2009, London/England
CAT
Doc. MUDr.Mikuláš Hrubiško,CSc.

18 - 19/06/2009, London/England

HMPC Assessors Training - New Regulation to Quality Assessment
Mgr. M. Mlynárová

21 - 24/06/2009, London/England
CHMP Pharmacovigilance
MUDr. P. Gibala

21 - 24/06/2009, London/England
CMD(h)
PharmDr. D. Stará

22 - 25/06/2009, London/England
CHMP Plenary
PharmDr. J. Mazag

24/06/2009, London/England
PSUR Work Sharing Working Group
RNDr. T. Magálová

24 - 25/06/2009, London/England
EudraNet TIG
Ing. K. Blšák

25 - 26/06/2009, London/England
Assessors Training
MUDr. P. Gibala

25 - 26/06/2009, London/England
Assessors Training
RNDr. T. Magálová

29/06 - 01/07/2009, Strasbourg/France
134$^{th}$ Meeting of the European Pharmacopoeia Commission
PharmDr. R. Martincová

29/06 - 02/07/2009, Como/Italy
4th EUSTITE course for tissue establishment
Ing. R. Baďurová

30/06 - 02/07/2009, Litvínov, Dečín/Czech Republic
Inspection of GMP
Ing. J. Rašková

01/07/2009, London/England
CMD(h) Assessors Workshop on Paediatrics Regulation
MUDr. V. Jankó

01 - 03/07/2009, Uppsala/Sweden
Meeting of the Competent Authorities for Medical Devices
MUDr. M. Slávik

05 - 07/07/2009, Strasbourg/France
Training Session/ The European Pharmacopoeia 6th Edition
RNDr. J. Jánošková

05 - 07/07/2009, Strasbourg/France
Training Session/ The European Pharmacopoeia 6th Edition
Mgr. V. Návojová

06 - 08/07/2009, Stockholm/Sweden
HMA
PharmDr. J. Mazag

06 - 09/07/2009, London/England
COMP
PharmDr. T. Foltánová

12 - 16/07/2009, London/England
HMPC Working Party on Monographs/List + HPMC Plenary
Prof. Ing. Milan Nagy, PhD.

15 - 17/07/2009, London/England
CAT
Doc. MUDr.Mikuláš Hrubiško,CSc.

19 - 22/07/2009, London/England
CHMP Pharmacovigilance
MUDr. P. Gibala

20 - 23/07/2009, London/England
CHMP
PharmDr. J. Mazag

24/07/2009, Vienna/Austria
PHIS meeting
PharmDr. J. Mazag

24/07/2009, Vienna/Austria
PHIS meeting
Ing. B. Bilančíková

17 - 18/08/2009, Prague/Czech Republic
Pharmaceutical seminar
Ing.E. Malcherová

17 - 18/08/2009, Prague/Czech Republic
Pharmaceutical seminar
P. Beňová

31/08 - 03/09/2009, London/England
COMP
PharmDr. T. Foltánová

01 - 02/09/2009, London/England
Eudravigilance TIG
MUDr. R. Kamenská

06 - 09/09/2009, London/England
GMP/GDP Inspectors Working Group
Ing. M. Nádaská

08 - 11/09/2009, London/England
CHMP/CVMP Joint Quality Working Party
RNDr. L. Potúčková

09 - 11/09/2009, Uppsala/Sweden
Emacolex
Mgr. E. Siminská

09 - 11/09/2009, London/England
TIGes
PharmDr. Z. Nouzovský

09 - 11/09/2009, London/England
CAT
Prof. MUDr. Peter Turčáni CSc.

13 - 15/09/2009, Uppsala/Sweden
Meeting of the Informal Pharmacovigilance Working Party
MUDr. P. Gibala

13 - 17/09/2009, London/England
HMPC Working Party on Monographs/List + HPMC Plenary
Prof. Ing. Milan Nagy, PhD.

16 - 18/09/2009, London/England
Quality of Documents
Ing. M. Polláková

17 - 18/09/2009, London/England
ENCePP Plenary Meeting
Prof. M. Kriška

20 - 23/09/2009, London/England
CMD (h)
PharmDr. D. Stará

20 - 23/09/2009, London/England
CHMP Pharmacovigilance
MUDr. P. Gibala

21 - 25/09/2009, Copenhagen/Denmark
16th PIC/S Expert Circle on Human Blood and Tissue
Ing. R. Baďurová

21 - 25/09/2009, Copenhagen/Denmark
16th PIC/S Expert Circle on Human Blood and Tissue
RNDr. M. Baková

21 - 24/09/2009, London/England
CHMP
PharmDr. J. Mazag

22 - 23/09/2009, London/England
Eudranet TIG meeting

Ing. K. Blšák

25/09/2009, Vienna/Austria
PHIS meeting
PharmDr. J. Mazag

25/09/2009, Vienna/Austria
PHIS meeting
Ing. B. Bilančíková

28/09/2009, Brussels/Belgium
Meeting of the competent authorities for blood and blood preparations
Ing. R. Baďurová

28 - 29/09/2009, London/England
EWP
PharmDr. A. Adameová

30/09 - 01/10/2009, London/England
Management Board
PharmDr. J. Mazag

30/09 - 02/10/2009, Stockholm/Sweden
Informal COMP Meeting
PharmDr. T. Foltánová

04 - 06/10/2009, Uppsala/Sweden
CMD(h) Informal
PharmDr. D. Stará

05 - 08/10/2009, London/England
COMP
PharmDr. T. Foltánová

06 - 09/10/2009, London/England
Meeting of Experts on Product Quality Defect and Rapid Alerts
Mgr. T. Ottinger

08/10/2009, London/England
BEMA assessors
PharmDr. I. Šidlíková

11 - 15/10/2009, London/England
EV Datawarehouse Training
MUDr. P. Gibala

11 - 15/10/2009, London/England
EV Datawarehouse Training
RNDr. T. Magálová

11 - 15/10/2009, London/England
EV Datawarehouse Training
MUDr. R. Kamenská

12 - 14/10/2009, Berlin/Germany
PDA/ EMEA Joint Conference-Ensuring Patient Safety through Supply Chain Control and GMP
Ing. M. Nádaská

13 - 14/10/2009, Strasbourg/France
MRP/ DCP Database Training
Mgr. M. Mlynárová

14 - 16/10/2009, London/England
CAT
Prof. MUDr. Peter Turčáni CSc.

14 - 16/10/2009, Brno/Czech Republic
Process validation and optimation
Mgr. T. Ottinger

14 - 16/10/2009, Brno/Czech Republic
Process validation and optimation
Ing. K. Repaská

14 - 16/10/2009, Brno/Czech Republic
Process validation and optimation
RNDr. J.Rašková

18 - 20/10/2009, Brussels/Belgium
CTFG meeting
MUDr. P. Gibala

18 - 21/10/2009, London/England
CHMP Pharmacovigilance
RNDr. T. Magálová

18 - 22/10/2009, London/England
CMD (h)
PharmDr. D. Stará

25 - 27/10/2009, London/England
Quality Assessors Trainig
Mgr. M. Mlynárová

25 - 28/10/2009, Uppsala/Sweden
HMA WGEO
Mgr. Ľ. Bašová

28 - 29/10/2009, London/England
EUTCT NCA Info Day
RNDr. M.Baková

28 - 29/10/2009, London/England
EUTCT NCA Info Day
PharmDr. Z. Nouzovský

28 - 29/10/2009, London/England
EUTCT NCA Info Day
MUDr. R. Kamenská

27 - 28/10/2009, Uppsala/Sweden
HMA
PharmDr. J. Mazag

27 - 30/10/2009, Oslo/Norway
Case Study
M. Pastuchová

27 - 30/10/2009, Oslo/Norway
Case Study
Ing. B. Bilančíková

29 - 30/10/2009, Oslo/Norway
Case Study
PharmDr. J. Mazag

01 - 03/11/2009, Rome/Italy
MRP/ DCP Session, CAP Annual Meeting
Mgr.M. Mlynárová

03 - 05/11/2009, London/England
COMP
PharmDr. T. Foltánová

01 - 06/11/2009, Uppsala/Sweden
PIC/ S Seminar
Ing. M. Nádaská

08 - 10/11/2009, Prague/Czech Republic
Training - Medicinal Product Quality Assessment/DIA
Mgr. V. Návojová

08 - 10/11/2009, Prague/Czech Republic
Training - Medicinal Product Quality Assessment/DIA
Ing. L. Majerčíková

08 - 12/11/2009, London/England
Eudravigilance-Electronic Reporting of ICSRs
PharmDr. A. Harčárová

09 - 10/11/2009, London/England
Quality of Documents
Ing. M.Polláková

10 - 12/11/2009, London/England
HMPC Plenary
Prof. Ing. Milan Nagy, PhD.

11 - 14/11/2009, London/England
CAT
Doc. MUDr.Mikuláš Hrubiško,CSc.

12 - 13/11/2009, Prague/Czech Republic
Visit at the SIDC Prague
Mgr. M. Mlynárová

12 - 13/11/2009, Prague/Czech Republic
Visit at the SIDC Prague
RNDr. L. Potúčková

15 - 18/11/2009, London/England

CMD(h)
PharmDr. D. Stará

15 - 18/11/2009, London/England
CHMP Pharmacovigilance
RNDr. T. Magálová

16 - 19/11/2009, London/England
CHMP
PharmDr. J. Mazag

20/11/2009, Vienna/Austria
PHIS meeting
PharmDr. J. Mazag

20/11/2009, Vienna/Austria
PHIS meeting
Ing. B. Bilančíková

22 - 23/11/2009, London/England
HMPC Assessors Training
PharmDr. P. Potúček

23 - 26/11/2009, London/England
CHMP/ CVMP Joint Quality WP
RNDr. L. Potúčková

26/11/2009, Vienna/Austria
PPRI Network Meeting
PharmDr. J. Mazag

27/11/2009, Vienna/Austria
PPRI Network Meeting
PharmDr. J. Mazag

30/11 – 01/12/2009, Brussels/Belgium
Medical Device Expert Group
MUDr. M. Slávik

30/11 - 01/12/2009, London/England
Eudravigilance TIG
PharmDr. A.Harčárová

30/11 - 02/12/2009, Strasbourg/France
135$^{th}$ Meeting of the European Pharmacopoeia Commission
PharmDr. R. Martincová

30/11 - 02/12/2009, Strasbourg/France
135$^{th}$ Meeting of the European Pharmacopoeia Commission
PharmDr. M. Benková

30/11 - 03/12/2009, London/England
GMP/ GDP Inspectors WG
Ing. M. Nádaská

01 - 03/12/2009, London/England
COMP
PharmDr. T. Foltánová

02/12/2009, Czech Republic
EISOD Training
PharmDr. I. Šidlíková

02/12/2009, Czech Republic
EISOD Training
O. Vojteková

02 - 04/12/2009, London/England
CAT
Prof. MUDr. Peter Turčáni CSc.

07 - 08/12/2009, London/England
Annual PCWP plenary meeting
PharmDr. D. Stará

07 - 09/12/2009, London/England
Safety Working Party
PharmDr. A. Kováč

07 - 13/12/2009, Uppsala/Sweden
HMPWG
PharmDr. A. Liščáková

09 - 10/12/2009, London/England
Management Board
PharmDr. J. Mazag

10 - 11/12/2009, London/England
ENCePP Meeting
Prof. M. Kriška

10 - 11/12/2009, Uppsala/Sweden
Informal Meeting of the Herbal Medicinal Products Committee
PharmDr. P. Potúček

13 - 16/12/2009, London/England
CMD (h)
PharmDr. D. Stará

13 - 16/12/2009, London/England
CHMP Pharmacovigilance
RNDr. T. Magálová

13 - 18/12/2009, Koprivnica/Croatia
Inspection
Ing. K. Repaská

13 - 18/12/2009, Koprivnica/Croatia
Inspection
RNDr. J. Rašková

14 - 17/12/2009, London/England

CHMP
PharmDr. J. Mazag

16 - 17/12/2009, London/England
Eudranet TIG
Ing. K. Blšák

**Annex No. 3**

**Table No.1: Assessment Activity**

| | Number of assessment reports |
|---|---|
| | |
| **registration N/DCP- CMS** | 269/47 |
| **registration MRP/DCP- RMS** | 1/6 |
| **for variations IB/II** | 821/574 |
| **Not recommended** | |
| **UP** | 130 |
| **Other** | - |
| **TOTAL:** | 1,848 |
| | |
| **opinions for media and national institutions** | 25 |
| **questionnaires, opinions, Annual Reports for EDQM and EMEA** | 18 |
| | |
| **Total number of assessment reports per SMPQA:** | 1,891 |
| **Financial value:** | €459,399.60 |

**Table No. 2: Analytical Activity**

| | Number of samples | Number of certificates |
|---|---|---|
| | | |
| **for foreign registration** | 9 | - |
| **for national registration** | 1 | - |
| **vaccine and blood derivate batch release** | - | 468 |
| **market control: import** | 37 | 72 |
| **on order** | 107 | - |
| **for clinical complaint** | 1 | - |
| **for complaint** | 2 | - |
| **internal testing** | 24 | - |
| **PTS/MSS/CS** | 5/0/1 | - |
| **CAP** | - | - |
| **other** | - | - |
| **Total number per SMPQA:** | 187 | 540 |
| **whereof non-compliant** | 12 | 17 |
| **Financial value:** | **€44,102.42** | |

**Table No.3: Non-Compliant Samples**

| Non-Compliant Samples | | | |
|---|---|---|---|
| Medicinal Product Name | Batch | Holder | Defect |
| Aqua purificata (water stability study and applicability time for HPLC – 4x) | batch 280909 | room no. 130 | High conductivity |
| Aqua purificata (water stability study and applicability time for HPLC – 3x) | batch 280909 | room no. 15 | High conductivity |
| HYDROCHLÓROTHIAZID Léčiva, tbl | batch 5010108 | Léčiva a.s, CZ | Weight homogeneity of half tablets |
| GLIMEPIRID MYLAN 2 mg, tbl | batch 07852 | Generics Ltd, GB | Incorrect registration number specified on secondary packaging |
| PANADOL RAPID tbl flm | batch 080839 | Glaxosmithkline Belgium | Dissolution of respective tablets not homogenous, 3 tablets released less than prescribed in specifications |
| Dr. THEISS SCHWEDENBITTER sol | batch 01028 | Dr. Theiss Naturwarwn | Low ethanol content |
| BRIMONAL 0,2% int opo | batch 370308 | UnimedPharma sro, Bratislava | Incorrect registration number specified on secondary packaging |

**Annex No. 4**

**Summary of Inspections and Sample Collections at the Department of Good Pharmacy Practice per 2009**

| **Facilities** | Inspections | **Number of** |
|---|---|---|
| **Public pharmacies** | entry - Act No. 140/1998, no. 139/1998 and no. 331/2005 Coll. | **172** |
| | running | **394** |
| | targeted | **130** |
| | follow-up | **1** |
| | sample collection | **254** |
| **Public pharmacies branches** | entry - Act No. 140/1998, no. 139/1998 and no. 331/2005 Coll. | **14** |
| | running | **35** |
| | targeted | **4** |
| | sample collection | **8** |
| **Hospital pharmacies** | entry - Act No. 140/11998, no. 139/1998 and no. 331/2005 Coll. | **5** |
| | running | **10** |
| | targeted | **2** |
| | sample collection | **5** |
| **Dispensaries of medical devices** | entry - Act No. 140/1998 Coll. | **23** |
| | running | **17** |
| | targeted | **6** |
| | sample collection | **1** |
| **Opticians** | entry - Act No. 140/1998 Coll. | **38** |
| **Poppy-seed growers** | entry - Act No. 139/1998 Coll. | **4** |
| **Other facilities** | entry - Act No. 139/1998 and no. 331/2005 Coll. | **6** |
| | running | **0** |
| | targeted | **18** |
| | sample collection | **2** |
| **Total** | **Inspections** | **879** |
| | **Sample collection** | **270** |

**Annex No. 5**

**Evaluation of Control Activity at the Department of Good Pharmacy Practice, Chemical Control Section per 2009**

| Control | Total number of samples | Compliant | Non-Compliant |
|---|---|---|---|
| **Control of samples on order - charged** | | | |
| ***Supply organisations*** | | | |
| GALVEX spol. s r.o., B. Bystrica | 4 | 2 | 2 |
| TAMDA, a.s., Olomouc | 52 | 52 | 0 |
| *Hospital pharmacies* | | | |
| Purified water | 38 | 33 | 5 |
| Infusion solutions | 8 | 7 | 1 |
| ***Public pharmacies*** | | | |
| Purified water | 138 | 117 | 21 |
| Medicines and auxiliary substances | 2 | 2 | 0 |
| *Total samples on order* | ***242*** | ***213*** | ***29*** |
| *Percentage* | | ***88.0 %*** | ***12.0 %*** |
| **Random sample control - not charged** | | | |
| ***Hospital pharmacies*** | | | |
| Purified water | 10 | 8 | 2 |
| Medicines prepared in pharmacy | 33 | 32 | 1 |
| Eye preparations prepared in pharmacy | 1 | 1 | 0 |
| Infusion solutions | 3 | 3 | 0 |
| ***Public pharmacies*** | | | |
| Purified water | 223 | 163 | 60 |
| Medicines prepared in pharmacy | 662 | 584 | 78 |
| ***Other analyses*** | | | |
| Other samples | 45 | 42 | 3 |
| *Total - random control* | ***977*** | ***833*** | ***144*** |
| *Percentage* | | ***85.3%*** | ***14.7 %*** |
| | | | |
| **Total samples** | **1,219** | **1,046** | **173** |
| **Percentage** | | **85.8 %** | **14.2 %** |

**Annex No. 6**

**Evaluation of control activity at the Department of Good Pharmacy Practice, Chemical Control Section per 2009**

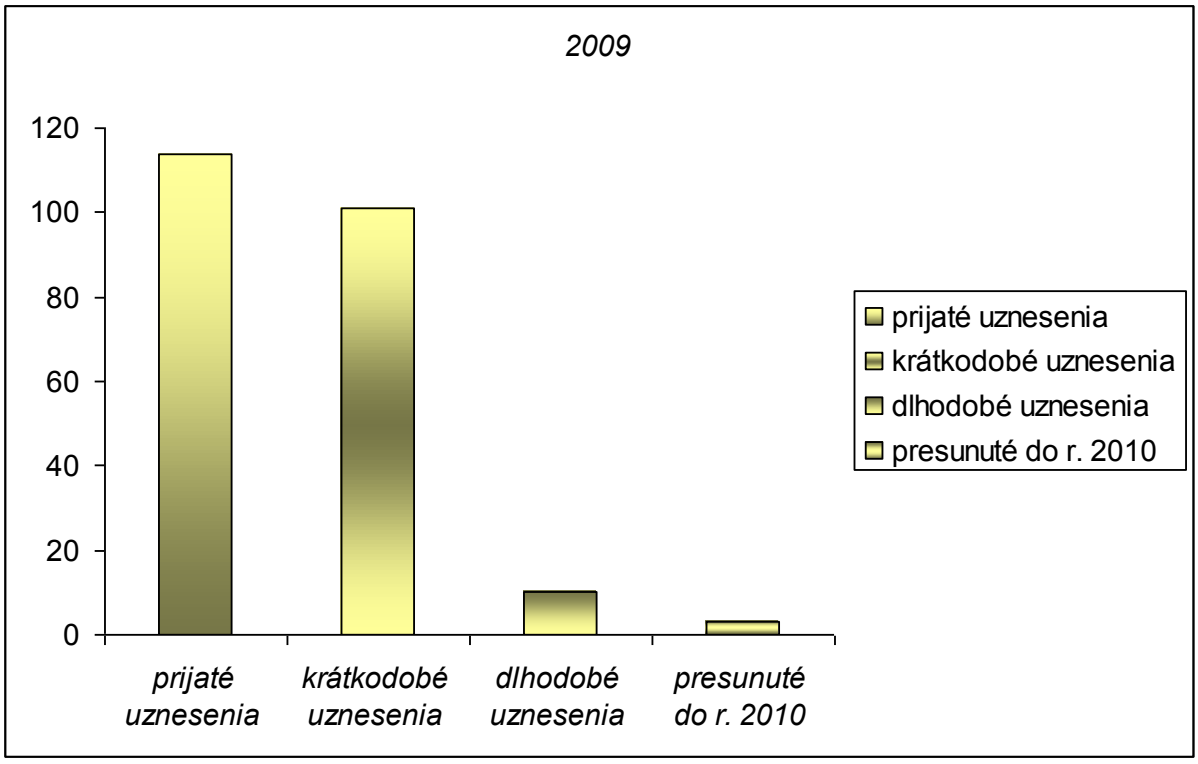
| Control | Total number of samples | Compliant | Non-Compliant |
|---|---|---|---|
| **Control of samples on order - charged** | | | |
| ***Supply organisations*** | | | |
| GALVEX spol. s r.o., B. Bystrica | 0 | 0 | 0 |
| TAMDA, a.s., Olomouc | 0 | 0 | 0 |
| *Hospital pharmacies* | | | |
| Purified water | 31 | 31 | 0 |
| Infusion solutions | 0 | 0 | 0 |
| *Public pharmacies* | | | |
| Purified water | 98 | 97 | 1 |
| Medicines and auxiliary substances | 0 | 0 | 0 |
| *Total samples on order* | ***129*** | ***128*** | ***1*** |
| *Percentage* | | ***99,2 %*** | ***0,8 %*** |
| **Random sample control - not charged** | | | |
| ***Hospital pharmacies*** | | | |
| Purified water | 11 | 9 | 2 |
| Medicines prepared in pharmacy | 6 | 6 | 0 |
| Eye preparations prepared in pharmacy | 0 | 0 | 0 |
| Infusion solutions | 0 | 0 | 0 |
| *Public pharmacies* | | | |
| Purified water | 343 | 274 | 69 |
| Medicines prepared in pharmacy | 155 | 150 | 5 |
| *Other analyses* | | | |
| Other samples | 117 | 115 | 2 |
| *Total - random control* | ***632*** | ***554*** | ***78*** |
| *Percentage* | | ***87,7 %*** | ***12,3 %*** |
| | | | |
| **Total samples** | **761** | **682** | **79** |
| **Percentage** | | **89,6 %** | **10,4 %** |

**Annex No. 7**

**TASKMAN**

Number of resolutions adopted in 2009: 114.
Number of long-term resolutions: 10, deadline: 31 December 2009.
Number of long-term resolutions: 101.
Number of resolutions postponed for 2010: 3.

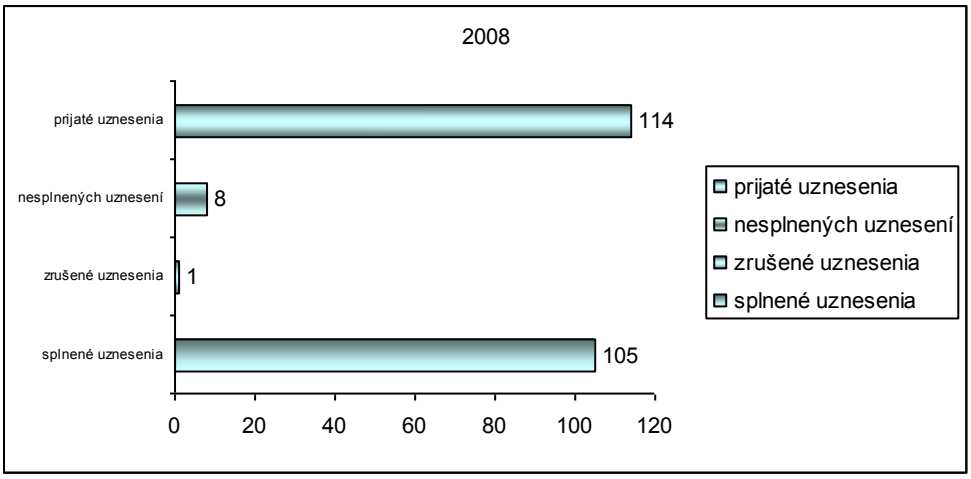
| year | 2009 |
|---|---|
| adopted resolutions | 114 |
| short-term resolutions | 101 |
| long-term resolutions | 10 |
| postponed for 2010 | 3 |




adopted resolutions
short-term resolutions
long-term resolutions
postponed for 2010

Summary of discharged resolutions per 2009

| Summary of resolutions | 2009 |
|---|---|
| discharged resolutions | 105 |
| cancelled resolutions | 1 |
| not discharged resolutions | 8 |
| adopted resolutions | 114 |




discharged resolutions
cancelled resolutions
not discharged resolutions
adopted resolutions

Comparison with 2008

In comparison with 2008, the number of adopted resolutions in 2009 dropped by 36 resolutions, i.e. by 24 % and the number of resolutions not discharged increased by 6, i.e. by 75 %. The structure of short-term and long-term resolutions has not changed.

**Annex No. 8**

**Summary of the Number of Selection Procedures (SP) – 2009**

| Ref. No. | Selection Procedure No. | SP Announcement Date | Application Submission Date | Structural Unit/Vacancy | Number of Positions | SP Date | Number of Registered Applicants | Number of Attending Applicants | Number of Successful Applicants | Number of Appointed Civil Servants | Civil Service Start Date |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | 36/2009 | 10/02/2009 | 04/03/2009 | Section of MD/Chief Counsellor | 1 | 02/04/2009 | 2 | 1 | - | - | - |
| 2. | 37/2009 | 10/02/2009 | 04/03/2009 | Registration Section/Chief Counsellor | 1 | 02/04/2009 | 7 | 3 | 1 | 1 | Mgr. Ševčeková - 02/04/2009 |
| 3. | 38/2009 | 10/02/2009 | 04/03/2009 | Inspection Section/Chief Counsellor | 1 | 02/04/2009 | 3 | 2 | 1 | 1 | Dr. Michalová – 02/04/2009 |
| 4. | 39/2009 | 10/02/2009 | 04/03/2009 | Inspection Section/Chief Counsellor | 1 | 02/04/2009 | 3 | 2 | 1 | 1 | Mgr. Bašová – 02/04/2009 |
| 5. | 61/2009 | 07/04/2009 | 29/04/2009 | Chief Counsellor - CL 3 Zvolen | 1 | 27/05/2009 | 5 | 2 | 1 | 1 | Mgr., Ing. Hradská 01/07/2009 |
| 6. | 62/2009 | 07/04/2009 | 29/04/2009 | Chief Counsellor/Administrative Section | 1 | 27/05/2009 | 2 | 2 | 1 | 1 | Ing.Bi-lančíková-01/06/2009 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 7. | 64/2009 | 07/04/2009 | 29/04/2009 | Chief Counsellor-Head/CL 3 Zvolen | 1 | 27/05/2009 | 1 | 1 | 1 | 1 | Dr. Berčík - 01/06/2009 |
| | | | | | 7 | | 23 | 13 | 6 | 6 | |