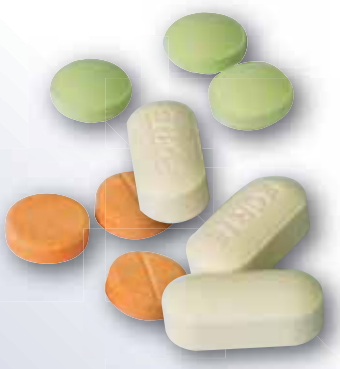
The State Institute for Drug Control

Slovak Republic

ANNUAL REPORT

2005



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Preface

Dear ladies and gentlemen,
I have the pleasure of presenting you the Annual Report 2005 of State Institute for Drug Control. Recently SIDC has passed through a long way of the approximation of the national legislation with EU legislation related to the pharmaceutical testing, pharmacologically-toxicological testing, clinical trials of medicines, manufacture and dispensing of medicinal products, package labelling, information duties and advertisement of medicinal products.

At the same time there have been on-going reforms in the health service in Slovak Republic. The key target is to reinforce the responsibility of citizens as well as the state institutions responsible for the realisation phase of the general health policy. The effort of SIDC is to increase the transparency of licence issuing processes for the medicinal products manufacturing, distribution of medicinal products, registration of human medicines, clinical trials and medical devices.

Currently the transformation of SIDC to the *Slovak Agency for Human Pharmacy* is being prepared. The draft of a new act results from the following basic targets:

- To strengthen the independence by appointing the conditions for handling with medicinal products and medical devices.
- To create the conditions in order to the market mechanism principles and thus ensure the access to licences for all legal and physical persons, which comply with the law provisions.
- To arrange the competencies between the Ministry of Health SR and the other state administration bodies, which will participate in the execution of the state administration in the field of human pharmacy.

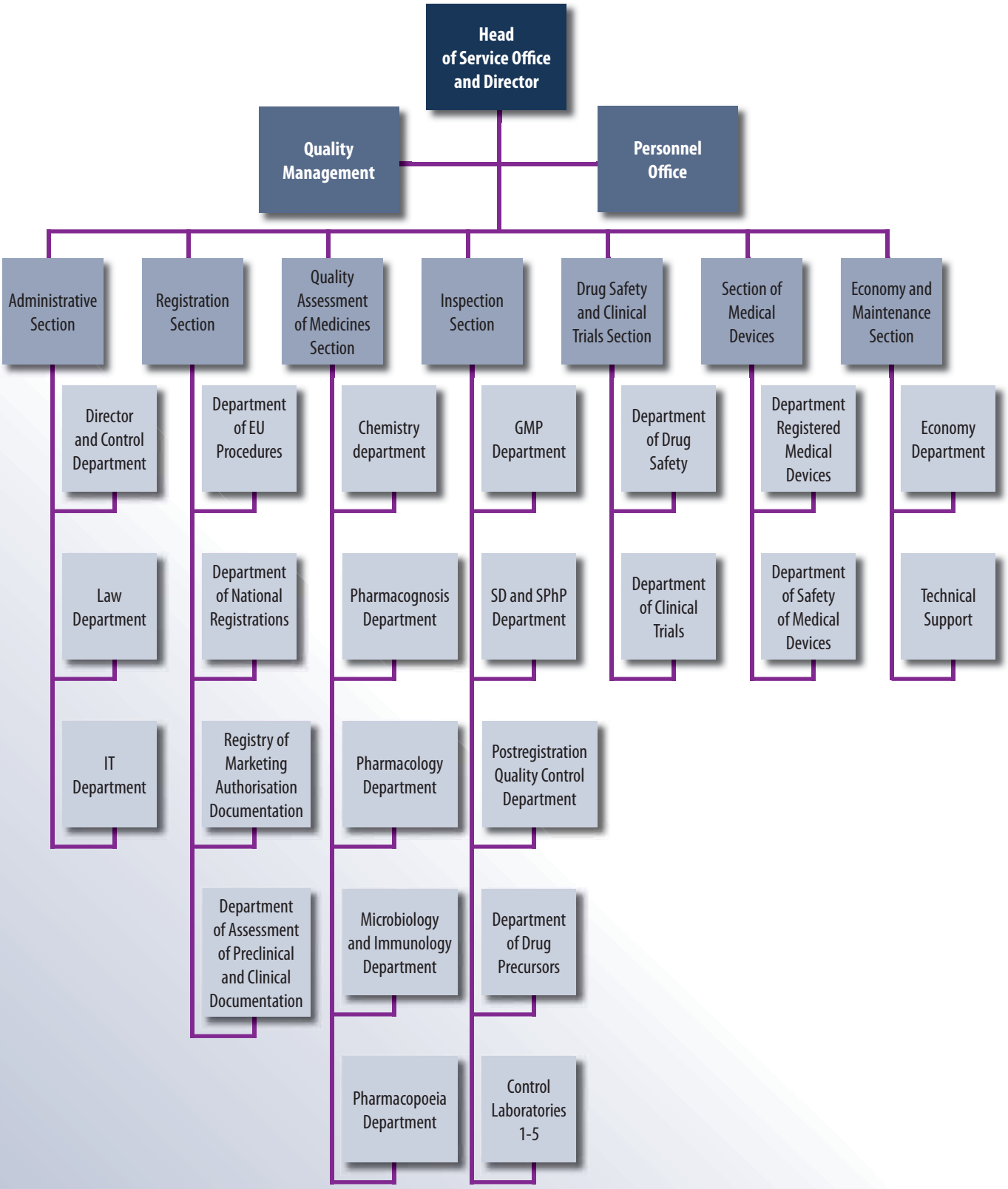
The new act on SAHP will establish conditions for utility, well-defined and transparent achievement of the state administration in the field of drug policy. We also expect that the new act will bring us new competecies and wider self-administration in decission making processes.

I would also like to inform you that in December 2005 the SIDC moved to the new building. Thereby we have adventageous working conditions and thus we can complay with important tasks and commitments arising from our membership in the EU.

Finally I would like to thank to all SIDC staff whose daily work ensured the patients to have the good quality, safety and effective medicines.

With regards,
PharmDr. Ján Mazag
Director of SIDC

Organizational Structure
State Institue for Drug Control



About SIDC

The State Institute of the Drug Control is according to the article 58 of the Act No 140/1998, Coll. on medicinal products and medical devices, on the amendment of the Act No 455/1991 Coll. on small trade business (Small Trade Business Act) in the vording of later rulings, and on the amendment and supplement of the Act of the National Council of the Slovak Republic No 220/1996 Coll. on advertising as amended, the authority of the state administration in the field of human pharmacy and drug precursors.

SIDC is a state budget organization directly governed by the Ministry of Health of the Slovak Republic. At the head of SIDC is a chief of Service Office and a director, appointed and recalled by the minister of health of the SR.

SIDC is an organization that ensures the state supervision and inspection of all pharmaceutical activities in the area of Good Manufacturing Practice, Good Distributing Practice, Good Laboratory Practice, Good Clinical Practice and Good Pharmacy Practice in the SR. The supervision over the quality, safety and efficacy, decisions making on registration of human medicines, issuing licences for activities with specified substances and registration of medical devices with the statement of compliance, registration of medical devices on the basis of CE certificates of the notified persons of EU, as well as the other activities following the current legislation is being a part of it.

1. The mission and perspective of SIDC

SIDC mission is the ensuring and control of the quality, efficacy and safety of medicinal products and medical devices, issuing the decisions of the registration of human medicines and issuing licences for activities with specified substances, performing the state supervision in the field of pharmacy, executing of state administration in the matters of drug precursors, the control of manufacture and wholesale distribution of medicinal products and medical devices and the cooperation with the EU organisations.In addition to above mentioned activities, SIDC carries out inspections of compliance with the principles of Good Manufacturing Practice, Good Clinical Practice, Good Laboratory Practice, Good Distributing Practice and Good Pharmacy Practice and to the observance of provisions of the Slovak Pharmacopoeia and the Slovak Pharmaceutical Codex in the process of preparation of the mass - and individually prepared medicines. Furthermore, SIDC compiles the Slovak Pharmacopoeia and the Slovak Pharmaceutical Codex (§45), imposes fines for shortcoming being disclosed and keeps the list of registered medicinal products and approved medical devices.

International cooperation is focused on the activities following the membership of the SR in the EU as well as on the development of the cooperation and the exchange of information with the member states of OECD.

Another important activity is the cooperation with the European Directorate for the Quality of Medicines in the view of the unified implementation of the quality system in the laboratories in the framework of the mutual recognition of the results, as well as the cooperation and the participation in the periodical sessions of the EMEA.

The nominated members participated in the regular sessions of the Working Groups and

Committees according to the requirements of the above mentioned organisations and agencies (EMEA, EDQM, OECD, and EC – Pharmacopoeia Committee).

No less important part is the Good Laboratory Practice. SIDC represents the SR in the Working Group for the GLP in the framework of OECD and in the Working Group in the EC. From this membership arise the implementation of the regulations and decisions and the coordination of the monitoring.

Within the international cooperation the special importance has the representation of the SIDC and SR by the expert lectures in the various international and domestic conferences, seminars and workshops, which are performed by the expert employees of SIDC.

In the framework of the mission and perspective SIDC is proposed to be the central agency of the state administration in the field of human pharmacy and drug antecedents with the new name "Slovak Agency for Human Pharmacy".

In this regard the Slovak Agency for Human Pharmacy apart of the competencies stated in the current legislation and the statute of SIDC should fulfil following tasks:

- preparing the draft proposals to the Government of the SR on principal direction and priorities of national pharmaceutical policy
- to issue Official publication of the Slovak Agency for Human Pharmacy
- to grant licenses for manufacture of medicinal products and medicinal products from blood, licences for wholesale distribution of medicinal products and medical devices and licenses for providing health care in hospital pharmacies
- to issue GMP certificates according to WHO resolution No. WHA 50.3. (Annex 2) of May 1997
- providing corresponding information and data in the pharmaceutical policy for the interested stakeholders
- publishing the Slovak Pharmacopoeia and other standard documents concerning the medicinal products and the policy in the area of medicinal products
- to cooperate with the European and other international organization functioning in the area of the quality assurance, efficacy, safety and control of human medicinal products and related activities.

2. Activities of SIDC

The main activities of SIDC are in the field of the quality management, registration of the medicinal products and medical devices, issuing licences for activities with specified substances, quality assessment of medicinal products, inspection activities, activities related to the safety of medicines and clinical trials. Another important role of SIDC also plays Administrative Section, which ensure fulfilling of tasks covering by their character the whole Institute.

Moreover for management and decision-making procces in particular fields of SIDC activities the following advisory bodies are established:

- Asembly for Drug Quality
- Pharmacopoeia Committee
- Committee for Drug Safety
- Committee for Medicinal Products
- Ethics Committee for Animal Testing

2.1 Quality Management

The international cooperation has been developed on the basis of collaboration and exchange of information between the member states of OECD according to the plan. The survey and assessment of the inspection activity "Annual Overview of GLP in Slovak Republic 2004" has been submitted according to the requirements to the Environment Directorate OECD, European Commission and consequently to the all member states according to the directions. This document was published at the website of Slovak National Accreditation Service www.snas.sk.

The reports on the activities and status of the Slovak Republic were presented at the 19th Meeting of Working Group on GLP OECD in Orlando, Florida. Generally the cooperation with the member states OECD was focused on the communication, exchange of information and making comments to the drafts of directives OECD.

The international cooperation with the EDQM, European Network of Official Control Laboratories was focused on the development of the cooperation, effort on implementation of the unified system of quality assurance and the exchange of information.

The international cooperation with the EMEA continued in the framework of the Benchmarking by the preparation of the assessment of the quality systems implementation – audits of particular agencies. The date of the Benchmarking audit was scheduled to 17th week 2006.

Within the international cooperation SIDC participated in the Twining Project with Turkey in the field of GLP. Two-year "Twining Project GLP Turkey" is financed and approved by EC. SIDC was accredited by EC as a "Mandated body". In the framework of the project the materials for the working plans of training were elaborated and the professional advisory activity was performed.

Controlled documents

In January 2005 was prepared and approved the amendment of Quality Policy, which has been published at the SIDC website. Controlled documents, internal directives, guidelines, internal guidelines were issued updated according to the requirements.

Summary of the issued controlled documents is presented in the table

Document	Issued in 2005	Total number
Quality Manuals	0	8
Internal Directives	4	32
Guidelines	3	20
Internal Guidelines	1	6
Standard Operating Procedures	15	720

Internal audits

In the months March-April was performed non-planned depth personal internal audit in all professional sections. Analysis outlined that the number of the employees in particular professional sections is not sufficient according to the tasks resulting from the Act No.140/1998

Coll. on medicinal products and medical devices as amended. Several redeployments were performed to strengthen the Registration section.

By reason of permanent changes in the personal field as well as changes in place moving there were not performed other audits according to the plan.

The Quality Managers were changed as well in some professional sections. The implementation of Quality Management System was slowed.

Inspection activity

GLP inspections in cooperation with Slovak Accreditation Service and entry audits on the basis of application for authorisation of subjects were performed according to the plan.

2.2 Administrative Affairs

Internal Control

On the basis of the plan of internal control activity 8 control actions were performed focused on:

- Property declarations of civil servants for the years 2002, 2003 and 2004
- Control of property declarations of public servants for the years 2002, 2003 and employees performing tasks in public interest for the year 2004.
- Control of corrective measures according to the EU Equivalency Report.
- Control of the work safety, health protection and civil deference.
- Control of the cash economy
- Control of travelling instructions
- Control of common expenses drawing
- Control of capital expenses drawing

By the performed control actions it was found that the checked activity sections obey the corresponding law provisions except the control of the work safety, health protection during the work and civil deference. The follow-up control indicated, that the corrective measures have been implemented.

The SIDC central registration of petitions and complaints received 11 complaints, 5 of them were assessed as justified, 3 as unjustified and in 3 cases the petitions were not assessed. The justified petitions pointed especially to the dispensing of incorrect medicinal product and the complaint procedure, size of letters in the package leaflets, package leaflet untranslated to Slovak language, change of medicinal product at dispensing in pharmacy. The corrective measures were taken, in one case have started the administrative proceeding with the proposal for suspension of the activity and the penalty was imposed. 2 anonymous petitions were received, justness of anonymous proposition was affirmed in none of them.

Public Relations & Communication

PR & Communication Division ensured the performing of the tasks resulting from the position of the division as the press body of the head of Service Office and director and continuously performed the monitoring of media. PR & Communication officer coordinated the communication of the SIDC to the public and media. There were executed 86 applications received from the media.

PR & Communication Division kept the evidence of applications submitted to the SIDC in terms of the Act No 211/2000 Coll. on the free access to informations. There were 216 applications

for information received and executed, in one case has been issued the decision about non-providing of the information.

Summary of the submitted applications for information

Number of the submitted applications for information	216
Number of provided information	215
Appeal for completion of the application	0
Issue of the decision about non-providing of information	1

EU Collaboration

The main activity of the EU Collaboration unit was focused on the activities connected with the implementation of the EU legislation.

The main action areas:

- updating of nominations of SIDC representatives and their alternates in particular advisory bodies of EMEA
- coordination of activities of SIDC representatives in the advisory bodies of EMEA, EC, EDQM, PIC/S Scheme, WHO, OECD and European associations in the field of human pharmacy
- translation of documents related to the duties resulting from the SIDC membership in the European structures
- technical realisation of the foreign official journeys of the nominated SIDC employees and external representatives

Metrology

Quality of measuring instruments and measuring equipment being in use in the Quality Assessment of Medicines Section has been ensured in particular in compliance with the requirements of Act No. 142/2000 Coll. as amended and with other related legislative standards of the Slovak Republic in the field of metrology as well as in compliance with the STN ISO standards for the demonstration of quality system operation in this area.

It has been prepared the proposal of SOP Activity of the Quality Manager MRK VS-O/001/05 which was submitted for comment and a new issue of metrology order is being prepared. The works on the revision of the other related control documents have started.

On deputy of the Quality Assurance Management the initial and follow-up audits have been performed in the company Labeko Ltd., Piešťany.

On the request of the Inspection Section the metrologist participated in 2 GMP inspections.

On the basis of agreement between SIDC and Slovak National Accreditation Service 4 GLP inspections were performed, two of them abroad.

There were performed 4 internal audits according to STN EN ISO 9001 in Administration Section.

In the framework of the co-operation with the Ministry of Health SR and Ministry of Economy SR the government regulations on the principles of Good Laboratory Practice and on performing of Good Laboratory Practice inspections as well as the proposal of the amendment of the Act No. 163/2001 Coll. on chemical substances and chemical preparations were commented.

SIDC metrologist regularly participated in the sessions of the Commission for certified reference materials, which is the advisory body of director of the Slovak metrological institute.

IT Support and Drug Database Maintenance

In terms of electronic processing of the registration documentation, the IT department was assigning SIDC codes (for the medicinal products registered by the national, centralised and MRP procedure) and preformed ongoing processing of the database of registered medicinal products.

The employees of the department cooperated with the Registration section in the field of further development of the programme for the processing of the registration documentation. The help was provided to the employees of the Registration section in the work with the mentioned programme according to their needs.

The continuous processing of the approved package leaflets and SPC from manufacturers proceeded.

On the basis of the PR & Communication details IT department continuously carried out the maintenance and updating of the SIDC website. The cooperation between SIDC and author of AISLP went on in the form of the mutual exchange of data.

The operation of the computer technology and photocopying machine of SIDC have been ensured.

The cooperation with the management of SIDC have been realised within the purchase of the computer technology and expendable supplies and the expert help to the users of the IT in the work with the installed programmes have been provided.The department developed simple programmes for internal purposes of the Institute. The data from distributors concerning the notifications of the consumption were processed.

Technical workers of the department cooperated with the external company during the reconstruction of the PC network and performed the installation of the PC technology in the new building of the Institute as well.

Law Affairs

In the Law Affairs department have been started administrative proceeding in 50 cases in the terms of the Act No 71/1967 Coll. on administrative proceedings in the full version and in the terms of this act totally 47 decisions on infliction of a fine for a breaking the Act No.140/1998 Coll. on medicinal products and medical devices in the full version, Act No.139/1998 Coll. on narcotic substances, psychotropic substances and preparations in the full version and for the breaking other current legislation. Total sum of the fine imposed is 1.095.000,- Slovak crowns.

Further in the assessed period 14 standpoints have been elaborated to the appeals of physical and legal persons, which in the terms of the Act No.71/1967 Coll. participated in the administrative proceeding and appealed against the SIDC decisions issued in the first stage proceeding. The standpoints together with the support documentation have been by reason of subject-matter venue transferred to the second stage administrative authority to the Ministry of Health SR for the purpose of the further proceeding and decision in the matter.

In addition to this activity the legal advices to the SIDC employees, physical and legal persons were provided complying with the principle and condition not to provide an information about the matters that are subject to confidentiality.

A part of the Law Affairs department is a control of the advertisement of the medicinal products. In the assessed period totally 265 advertisements of medicinal products, preparations of the soft food and following additional preparations have been monitored.

Further according to the provision of the Art.18 of the Act No,71/1967 Coll. on administrative

proceedings in the full version 3 administrative proceedings have started and according to the provision of the Art.46 of the Administrative order in connection with the Art.11 of the act on the advertisement in amendments 2 decisions about the advertisement prohibition have been issued and the penalties have been imposed in the sum 150 000 Slovak crowns.

1 standpoint to the appeal of the legal person have been processed – the participant of the administrative proceeding according to the Art.14 of administrative order, which was together with the support documentation have been by reason of subject-matter venue transferred to the second stage administrative authority to the Ministry of Health SR for the further proceeding and decision in the matter.

In addition to the mentioned activity the legal advices to the physical and legal persons were provided.

2.3 Registration of Medicines

Registration of medicinal products have been realised by the Registration section and its main targets and activities were determined especially by:

- progressive participation in the cooperation with the network of the medicines agencies EU in the field of the registration of medicinal products
- preparation for the implementation of the revised pharmaceutical EU legislation
- targeted work organisation focused on the elimination of the time delay in execution of registration applications from the past period

Among 43 employees of the section 21 are new this year.

It has been established a cooperation with the patient organisations and it has been created a space at the SIDC website regarding these questions.

For the purpose of skill increasing of the SIDC employees in connection with the registration of medicines and assessment of the registration documentation we have presented project Twinning Light Project to EC under the name "Strengthening of SIDC capacities for implementation of new EU legislation Directive 2001/83/EC and Directive 2004/27/EC."

Committee for medicinal products

On the sessions there were discussed **271** applications, among them:

- recommended **261** applications
- suspended **6** applications
- not recommended **1** application
- stopped the registration proceeding **3** applications

National registrations

The activity was especially focused on the continuous execution of the agenda and on the elimination of the time delay in the dates of applications execution.

National registrations

Type of registration	received 2005	executed 2005
new	110	67
notifications	1789	540
variations	2784	2192
extensions	632	387
cancellations		173
rejections		31
Assessments for boundary products		9
TOTALLY	5315	3399

EU procedures

EU procedures – i.e.procedures of mutual recognition, decentralised procedures, centralised procedures and arbitration proceedings were realised by the EU procedures department. The activity was focused mainly on:

- coordination process of the registration, variations and extensions in the procedure of mutual recognition and decentralised procedure,
- checking of the translations correctness of SPC, PIL and package labelling according to QRD models of medicinal products registered by centralised procedure (CP), participating in the process of new registrations, variations, extensions and annual re-assessments
- cooperation with European Medicines Agency in dissolving of arbitration proceedings in EU and coordination of the decisions on registrations of "national registrations" of medicines in connection with the conclusions of the Decision of European Commission concerning the arbitrations
- making comments of EU guidelines and directives in connection with the responsibilities following the membership in particular EU working groups and committees.

EU procedures

Type of application	received 2005	executed 2005
MRP new	540	387
MRP notifications	885	200
MRP variations	859	426
MRP extensions	37	4
DCP new	30	In process
CMD(h) referrals	5	In process
Referrals	84	39
CP-QRD n		100%
COMP-QRD		100%

Reception of registration documentation

In terms of optimalization of process organisation have been in the second half of 2005 established department of reception of registration documentation, which ensures especially the reception of registration applications and archiving of registration documentations and decisions.

2.4 Quality Assessment of Medicines

The quality assessment of medicines was realised by the Quality Assessment of Medicines Section (formerly Laboratory Control Section). The new name is more complex and apposite to express the contents and function of section, i.e. quality assessment of medicinal product in the registration process and control of the declared quality of medicinal product after its placing on market.

Quality Assessment of Medicines Section is the executive expert section of the state institute. It is divided into 5 departments:

- Department of chemistry
- Department of pharmacognosis
- Department of pharmacology
- Department of microbiology and immunology
- Pharmacopoeia department

One of the most important activities was the quality assessment of medicinal products in the various types of registration processes. The results of this assessment were the Assessor Reports on the chemical, pharmaceutical and biological part of the registration documentation. Assessors elaborated the assessments to the national procedures and MRP procedures.

They performed the laboratory analysis of the medicines samples and substances for the manufacture of medicines as well.

In the framework of the international cooperation the section as the OMCL SR participated in 2 PTS studies organised by EDQM. In **PTS 073** has been reached an excellent result, z-score =0,67, the second study **PTS 077** is in-process.

OMCL participated in MSS study **(MSS 030)** as a laboratory which provided the greatest amount of results of 20 concerned laboratories.The task was to chose medicinal products in solid uniformity of dosage units form with the drug content 2 -25 mg from the market and check up the dosage.

In the scheme Collaborative studies **(CS)** of European pharmacopoeia the OMCL participated in the analysis of 2 reference materials: **fludarabine phosphate** and **claritromycine.**

In the frame of EDQM programme focused on the analysis of centrally registered medicinal products (CAP) the OMCL performed full analysis of 3 batches of CIALIS 20 mg tbl.

Lecture activity was realised in cooperation with the Slovak Health University.

The pharmacopoeia department processed data for the preparation of the complete edition of all 7 volumes of Slovak Pharmacopoeia 1 in electronical version CD-ROM. The revisions and translations of Ph.Eur.5 monographs continued. In 2005 were processed 350 monographs (940 pages), 27 general chapters (120 pages), 82 pages of pharmacopoeia forms, 32 pages of homeopathics, totally 1174 pages. The international cooperation with EDQM proceeded in the field of comments on document about reference substances, translations of the reference terms of pharmaceutical dosage forms.

The works on 60 monographs for magistral and officinal formulas of Slovak Pharmaceutical Codex were being finished.

Per order were in the pharmacology department performed lots of analysis on bacterial endotoxines.

In the microbiology and immunology department the control of medicines prepared from human blood and plasma, vaccines of domestic and foreign production was performed and the microbiology quality of medicines in the frame of complaints was assessed.

In terms of the Act No.140/1998 Coll. were from external subjects collected and depreciated 38 litres, 3 288 g and 67 900 shred pharmaceutical forms with content of narcotic and psychotropic substances after expiration.

Two public pandering passed, on dissolution tester and UV/VIS spectrophotometer.

Totally **868** samples (tab.1) and **3 551** assessment reports (tab.2) were processed. Among the analysed samples 12 were nonconforming in the view of appearance, proteins content, viscosity, content. Activity of the section expressed financially represents 16. 745 289,- Slovak crowns.

Tab. 1

Number of samples	Chemistry department	Pharmacognosis department	Pharmacology department	Microbiology and Immunology department
Foreign registration	1	2	-	-
Domestic registration	-	-	-	-
Obligatory control	51	1	-	14
Import	38	7	-	15
Domestic manufacture	-	4	-	1
Ordered	52	5	551	32
Clinical complaint	9	-	-	5
Reclamation	2	6	-	1
Internal needs (QA)	21	19	-	21
PTS/MSS/CS	2/1/2	-	-	-
Others	6	-	-	-

Tab. 2

Number of Assessment Reports	Chemistry department	Pharmacognosis department	Pharmacology department	Microbiology and Immunology department
Foreign registrations	392	213	55	31
Domestic registrations	3	8	6	3
Variations	1084	552	271	273
Clinical batches	-	-		-
Analytical certificates	46	43	-	222
Assessments and reviews	38	25	-	-
„Upgrade“	173	46	6	26
Others	1	-	-	31

2.5 Inspection

The main part of the Inspection section activity was the performing of inspections focused on the compliance with the principles of the good manufacturing pracice, good pharmacy practice, good distribution practice, good practice of preparation transfusive medicines and the provisions of the Slovak Pharmacopoeia in the terms of the valid legislation.

By approving the Act No.331/2005 Coll.on the state administration bodies in the matters of drug precursors and on the variation and amendment of certain acts, which came into force on 18.8.2005, the competency for drug precursors questions was transferred from the Ministry of Health SR to SIDC, the drug precursors department.

In connection with the result of the international audit of EC at SIDC (September 2004) focused on the control of the activity of national inspection authority in the field of Good Manufacturing Practice, was the activity of the Inspection section aimed to the ensuring realisation of the elimination of the deficiences assigned in the Final Equivalency Report of European Commission.

Good Manufacturing Practice

The main tasks in the field of good manufacturing practice ensured the GMP department. They were focused especially on solving the tasks connected with the results of EC audit.

All essential comments concerning the implementation of EU legislation were harmonised with the requirements of EU in cooperation with the Ministry of Health SR and implemented

into national legislation SR. Other legislative and law requirements following from the novelised EU legislation ensures the Inspection section continuously.

Important activity has been the assessment of the GMP status of the manufacturers of medicinal products according to the reqiurements of the Registration section (MRP procedures, registration variations).

GMP inspectors actively participated in the activities organised by the international bodies and institutions, especially EC, EMEA, PIC/S, EDQM and WHO.

From the side of the GMP department was ensured the participation of the inspectors at all the most important working meetings, congresses and seminars organised especially by EMEA and PIC/S. The important information and requirements from these actions were ensured continuously.

It has been elaborated the revision of the PIC/S document Aide Memoire for the performing the GMP inspection in laboratories for the quality control of the pharmaceutical manufacturers. This material was agreed by PIC/S Committee.

In the framework of approved Slovak-Bavarian cooperation was realised the expert seminar focused on the activity of the national inspectorates and GMP inspection. The expert seminar took place 30.11. – 2.12.2005 at SIDC.

The lecturing and publishing activity was ensured by the GMP inspectors.

Total number of GMP inspections of domestic manufacturers of medicinal products was 13. 5 inspections of the importers from third countries – batch release and 7 GMP inspections of foreign manufacturers of medicinal products were performed.

Good Distribution Practice and Good Pharmacy Practice

State supervision and control of the compliance with the principles of the Good Pharmacy Practice and Good Distribution Practice in health facilities was performed by the GDP and GPhP department. The state supervision and control of non-health facilities, as an opticians, poppy producers etc., was performed as well.

It was registered a significant increase of focused inspections performed on suggestion of MH SR and other authorities of state administration and the patients as well. In the case of justified suggestion the proposal for further proceeding was submitted to the relevant bodies MH SR, Reginal Office, Law Affairs department of SIDC (administrative proceeding). Total number of the focused inspections was 10.

In the framework of the proceeding 2 proposals for suspension of the activity by the relevant state control body were submitted.

In connection with the amendment of the Act No. 140/1998 Coll., which allowed the propriety of pharmacies also to legal persons, non-pharmacists, it was registered the increase of the inspection activity by the reason of the raising of new pharmacies (c.100 in 2005), as well as by the reason of changing the legal form of existing pharmacies. Total number of entry inspections was 63.

With the change in legistation was connected also the increase of entry inspections in opticians, where 23 inspections were performed.

The inspection activity is in detail presented in Annex No.2 according to the type of facility and type of inspection.

Post-marketing surveillance

The activity was focused on the control of the medicinal products imported from third countries, control of certificates of vaccines and blood derivates distributed in the territory of SR, reception and transmission of information on quality defects of medicinal products, which were subsequently the subject of the sessions of the Assembly for Drug Quality.

The Assembly for Drug Quality discussed 135 cases, 19 medicinal products and 18 medical devices were recalled from the market. The activity of the Assembly covers also the reception of the international RAPID ALERTs – fast recalls of the medicinal products from the market within EMEA, PIC/S and WHO. 105 notifications from the international agencies were received, 4 of them covered the recall of medicinal products in the Slovak Republic and 1 notification was iniciated by SIDC for the other states participating in the system of Rapid Alert.

The Reports on Drug Quality 43-46/2005 were published at a website. Moreover, they were distributed through the database of e-mail and post addresses. The quality information is continuously published monthly in "The Health News Paper" and in the annex of the magazine "The Pharmacist".

In January 2005 the department actively participated in the sampling of the centrally registered medicinal product INSULATARD inj in cooperation with EDQM, Strassbourg, France and the marketing authorisation holder NovoNordisk, Denmark.

In September – December 2005 the department was sampling the medicinal product CIALIS tbl in the framework of the international control after the appearance of its counterfeits in the territory of EU. Analysis is performed by the English agency MHRA on the authority of OMCL. 6 batches of the medicinal product CIALIS in two strengths were transferred.

The summary of the received and processed analytical certificates and samples is in the annex No 1.

Drug precursors

SIDC activity in the field of drug precursors is in compliance with the Act No.331/2005 Coll. and the Regulations (EC) No.273/2004 of the European Parliament and the Council on the drug precursors, the Council Regulation (EC) No.111/2005 which determines the rules of monitoring the market with the drug precursors between the Community and the third countries and with the Comission Regulation (EC) No. 1277/2005 which determines the executing rules for the Regulation of the European Parliament and the Council (EC) No.273/2004 on drug antecedents and for the Council Regulation (EC) No. 111/2005, which determines the rules of monitoring the market with the drug antecedents between the Community and the third countries. It has been issued:

- 130 special licences for handling with the determined substances of 1 cathegory;
- 2 registrations of determined substances of cathegory 2 and 3;
- 10 variations in the special licences, licences and registrations.

In this connection, according to the Act No.145/1995 Coll. on administrative fees can be the benefit to the state budget for this activity expressed in the sum 167 000,- Slovak crowns.

Control laboratories 1 – 5

The activity of control laboratories 1-5 was focused on the inspection, control-analytical and other expert activity.

Inspection activity

- in the facilities providing pharmacy care
- in the distribution organisations
- in other organisations

Total number of inspections: 762
Total number of samples taken: 241

Control-analytical activity was focused on:
- chemical and microbiological control of the active substances and excipients on the basis of the order for distribution organisations and hospital pharmacies (issuing of analytical cerificates),
- chemical and microbiological control of medicinal preparations, purified water and packaging material in pharmacies on the basis of random choice,
- chemical and microbiological control of the purified water for pharmacies on the basis of the order

The most frequently found deficiencies were:
- incomplete labelling of medicinal preparations
- non-complying total amount of the sample
- incorrect content of the active substance
- non-complying quality of the purified water (conductivity, presence of the oxidable substances, ammonium, chlorides, nitrates, microbiological purity),
- non-complying miocrobiological purity of the medicinal preparations

Other expert activities:
- within the year the stability studies for the "Slovak Pharmaceutical Codex" were performed (Pharmacopoeia department),
- the new SOPs were elaborated and mutually commented by all control laboratories,
- in the control laboratories the expert training of employees (with university and secondary education) was ensured in the form of seminars according to the training plan,
- expert consultations were provided in the case of creation of new pharmacies (public and hospital), dispensaries of medical devices, opticians, wholesale distribution organisations, poppy producers and other organisations etc.,
- regular audits were performed by the quality managers
- the internal guideline of the head of Service Office and the director "Assessment criteria for the tolerable interval of the active substance content and total weights of the medicines prepared in pharmacies" was elaborated.

2.6 Drug Safety and Clinical Trials

Drug safety

Department of drug safety is a coordinating center for pharmacovigilance and monitoring of adverse drug reactions in Slovak republic. Its main task is identification, monitoring, analysis, assessment and evaluation of new information on safety of drugs (so called safety signals), as well as reports of adverse drug reaction to registered medical products for human use.

In 2005 we started to report spontaneous reports that we received from health care professionals to Eudravigilande database. We also started to prepare our own national database of adverse drug reactions based to E2B criteria and use of MedDra terminology.

Overview of activities

Reporting ICSR from Slovak republic (spontaneous)	1280
Expedited reporting of ADR (post-registration)	40 047
Clinical complaints requiring laboratory control	10
Submitted PSURs	551
Control of PSURs for renewal of registration	548
Published statements on drug safety	9
Reports from Slovakia submitted to Eudravigilance (year 2005)	129
Reports from Slovakia submitted to Eudravigilance (year 2004)	40
Public statements issued in 2005	9

One of the tasks of department is promotion of adverse reactions reporting. We use several means including direct posting of letters to physicians and lectures. Two issues of the bulletin "The Drug Risk" have been prepared and issued that are also available on our website. A guideline on reporting ADR (spontaneous, solicited and from literature resources) has been published on our website.

The Committee on safety of drugs that is advisory body met 2 times. The Committee evaluated reported cases of adverse reactions and evaluated signals and different kind of communication.

Clinical trials

Since May 1, 2005 directive No. 2001/20/EC on clinical trials has been implemented to our act No. 140/1998 Coll. Applications for Clinical trials of investigational medicinal products and of medical devices has to be assessed by SIDC and approved. Department ensures reviewing of applications for clinical trials and study protocols, issuing the decisions on approval of clinical trials, surveillance over its performance and approving of study centers. Tasks of department include inspection of GCP as well. We participate in the project of European database of clinical trials – EudraCT.

Overview of the activities

Activity	Number
Application for clinical trial	97
Authorization of clinical trials of drugs	99
Rejection of application for clinical trial	1
Application on approving of amendment to protocol	259
Application/notification on changes in Investigator's Brochure	170
Application on approving of a new study center	43
Submission of agreement of ethical committee	86
Notice on beginning of clinical trial	32
Notice on end of clinical trial	110
Annual report on process of a clinical trial	102
Report on adverse event from Slovak trial sites	155
Notice on adverse event from abroad	97
Own activity	81
Other	155
Application for clinical trial with medical device	3
Authorization of clinical trial with medical device	2
Inspection of GCP	12

2.7 Medical Devices

Medical Devices Section performs the function of the competent authority for medical devices and the tasks resulting from the Act No.140/1998 Coll. as amended, from the three Government Regulations (No 569/2001 Coll., No 570/2001 Coll. and 572/2001 Coll. as amended).

On the basis of free movement of certain products after the accession of SR to EU, most of the registrations were performed on the basis of the EC/CE certificates of manufacturers issued by the notified EU test rooms, the other registrations were accepted on the basis of CE Declaration of Conformity of the manufacturer. In this year was registered significant increase of submissions of variations in the original registrations of medical devices (218 cases). In most cases it was the prolongation of validity on the basis of new CE certificates, extension of range of the registered medical devices in the framework of the registered commodity and the change in the name of the manufacturer. The processing of the variations of the original registrations is more laborious and time-consuming.

The workers of the section follow and process the notifications of the manufacturers, competent EU authorities and distributors about adverse effects of medical devices and file registration formats of diagnostical medical devices in vitro sent by the manufacturers after the registration by the authorised person in the country of manufacture, resp. authorized

representatives in the EU.The registration form of active implantable medical devices according to the Act of National Council SR No.570/2001 Coll., are registered and processed, too (20 cases).

The amount of the notifications about adverse effects of medical devices and of the registration forms of diagnostical medical devices in vitro enormously increased in comparison to the year 2004. Registration of diagnostical medical devices in vitro comes more and more into the time delay because of the variety and severity of the formats processing.

The lists of manufacturers, abbreviations of manufacturers, or distributors of medical devices according to the requirements of MH SR and health facilities are processed as well. For the needs of health insurance companies is performed especially the verification of the compliance with the legislation norms for the exceptions on the reimbursement of the medical devices exceeding "List of medical devices fully or partially reimbursed on the basis of the public health insurance". The notifications from the distributors on the consumption of medical devices are transferred to MH SR quarterly.

Summary of the acivity of the Medical Devices section

Number of received registration forms of medical devices	1206
Reportsof accidents, malfunctions and failures of medical devices	365
New codes assigned	2654
Updated codes	5359
Inspections of the wholesale distributors	13
Repeated inspections of the wholesale distributors	8
Suggestions for the inspections of the wholesale distributors	1
Assessment reports for the wholesale distribution licence	22
Clinical complaints	6
Notification of the clinical trials	3
Comments on the drafts of new STN (Slovak Technical Norm)	1
New norms for medical devices included into the list	82
Personal and telephone consultations	200
Registration forms of the diagnostical medical devices in vitro from EU	491

3. Budget of SIDC

Budget of the Institute and its utilization in the year 2005

Budget classification	Budget Approved	Utilization adjusted	(In thousands SKK)
Incomes from the others SIDC activities	12 000	11 000	11 120
Incomes from registration	98 148		
Incomes of SIDC[1]	**109 268**		
Common expenses	96 182	98 338	98 333
Capital expenses	0	108 008	107 990
Expenses of SIDC[2]	**164 520**		

Development of selected budget indicators for the period of 2002 - 2005
(In thousands SKK[3])

	2002	2003	2004	2005
Incomes	**16 273**	**8 453**	**7 715**	**11 120**
Common expenses	**78 998**	**93 651**	**95 438**	**98 333**
Capital expenses	**16 273**	**43 226**	**69 082**	**107 990**

4. Personal Policy

Personnel Office provided exercising of Act No. 312/2001 Coll. on Civil Service and amendments to certain acts in their later amendments (hereafter called „Civil Service Act"), Act No 552/2003 Coll. on exercising the work in public interest in later amendments (hereafter only "public service"), Act No. 311/2001 Coll. Labour Code in later amendments and Act No. 553/2003 Coll. on remuneration of certain employees exercising the work in public interest in later amendments. The Personnel Office provided keeping of records and statistics related to the above mentioned activities which are submitted to the Statistical Office of SR, the Civil service Office, the MH SR and to the Institute of Health Information and Statistics according to their assignment.

In May after the SIDC internal audit the material have been prepared containing the increase of the number of employees – totally 46. In November 2005 we received 4 positions for state employees and 8 positions for the employees performing the work in public interest, i.e. the systemized number was 85 positions for state employees and 135 positions for the works in public interest at the end of the year 2005.

[1] total incomes which are not utilized by SIDC, they are going directly to the state budget
[2] total budget allocated from the Ministry of Health of Slovak Republic
[3] Exchange rate 1 EUR = 37,8 SKK

Number and structure of SIDC employees

Limit for SIDC employees and filling of capacity:

Indicator	Civil service	Public service	Total
Limit (modified from 1.11.2005)	**85**	**132**	**217**
Reality-physical persons	**79**	**132**	**211**
Average status counted to 31.12.2005	78,5	127	205,5

Underflow of the limit for the number of state employees was caused especially by the lengthy procedure in engaging the positions of state employees by the selection proceeding, several times enunciating of the selection proceeding on the engaging of position Head of the Registration section and Head of the Medical Devices section, and especially by the great fluctuation of state employees at the EU procedures department, where practically all employees during the year were changed.

Average age of employees: 47 years

Comparision of certain indicators from the personal work field in the last 3 years

Indicator	2002	2003	2004	2005
Average registered number of employees				
re-counted	194,76	192,42	195,48	205,5
in physical persons	199,26	198,00	205,00	211
Average month salary				
in Slovak crowns	14 674	15 677	16 177	16 412*

Employees fluctuation

Fluctuation is represented by 74 employees, that means 35% of the original number 205 employees.

The labour relation or civil service relation was terminated with 35 employees, thereof:

4 retirement
6 agreement
1 termination of temporary civil service
2 termination in trial period
4 termination of the certain period
16 termination of employment
1 termination of civil service relation in the terms of law
1 death

During the year 2005 the SIDC entered the labour relation or civil service relation with 39 employees, thereof:

17 in public service
22 appointed to state service

Selection proceedings and qualification examination of civil service employees

In 31enunciated selection proceedings 27 persons were engaged. The realisation of selection proceedings fully complied with the relevant law provisions on the civil service, the regulations and directives of the Office for civil service. Regarding the unsuccessful selection proceedings the SIDC always asked the Office for civil service for their repeated enunciation in legal 60-days time limit.

In 2005 were continuously performed the qualification examinations of civil service employees, which were appointed to the preliminary state service. Totally 15 employees passed the examination, 14 of them were successful and they were subsequently appointed to the standing state service.

Training of employees

According to the government decree of SR No 79/2004, which approved the Conception of education of state employees, was at the service office developed the Plan of education of the state employees for the year 2004. Regarding the emplyees performing the works in public interest, they had the plan of internal training as well and they also participated in external training according to the needs.

5. Aims and overview of their fulfilment

International cooperation was focused on the acivities resulting from the SR membership in the EU structures, further on the development of the cooperation and exchange of information between the member states OECD.

Another important task was the cooperation with EDQM and OMCL, in purpose of the unified implementation of the quality system in laboratories in the framework of the mutual recognition of the results as well as the cooperation and participation in the regular sessions EMEA.

The nominated representatives participated in the regular sessions of the working groups and commissions according to the rquirements of the European institutions (EMEA, EDQM, OECD, EC).

Legislative activity was realised within the cooperation with the health, environmental and economy department and the Center for chemical substances in the frame of the implementation of decisions and recommendations OECD and European Committee in the field of chemical substances.

The elaboration of controlled documents: quality manuals, guidelines and SOPs in the purpose of accreditation continued, as well as the publication of the 7th volume of the Slovak Pharmacopoeia I.

Quality Management was focused on the implementation of the effective system of the documents control in electronical form.

During the coordination of the tasks within the unified quality systems in the purpose of the mutual recognition of the results proceeded the cooperation with OMCL, EMEA, OECD. The supervision of the laboratories with the SIDC authorisation on the pharmaceutical and toxicologically-pharmacological testing was executed. At the same time the criteria of the quality systems were consequently applied..

Administrative section according to the plan of the control activity realised the control activity and ensured the complaints and petitions agenda in the term of valid legislation.

Moreover it was ensured the performing of the tasks in the field of the public relations, metrological activity, as well as in the field of fire protection, work safety and civil deference. Issuing of the decisions in the terms of the Act No.71/1967 Coll. when breaking the Act No. 140/1998 Coll. on the medicinal products and medical devices as amended. The SIDC supervised the advertising of medicinal products, infant food prearations and supplements.

Informatics - the processing of the registration documentation started in new programme. The updating of the database of registered medicinal products and assignation of SIDC codes was performed continuously.The work on the internal information system proceeded. The works related to the editorial activity were carried on.

Registration section and its activity was connected with the registration of medocines in the MRP procedure and mutual recognition. This required the organisational change. In the framework of the registration section were established: department of EU registrations, department of national registrations, reception of registration documentation department and the department of the assessment of the pre-clinical and clinical documentation.

In the framework of the laboratory control came to a change of the name of the section to the Quality Assessment of Medicines section, which ensured the assessment of the chemical, pharmaceutical and biological part of the registration documentation in the registration applications within the MRP procedure.

The Pharmacopoeia activity covered the translations of the paragraphs of PhEur.5 and the general revision of the Slovak Pharmacopoeia 1 volumes published by now. The work on the Pharmaceutical codex was carried on by theexperimental verification of the tests and stability tests started.

Inspection activity consisted in the ensuring os the preparation, coordination and realisation of the foreign MRA GMP audit from the side of the membergroup of international agreement. The coordinating sessions with the control laboratories were carried on. Controllaboratories 1 - 5 performed the inspection activity according to the valid legislation coordinated on the basis of the requirements of MH SR and in cooperation with the Inspection section. Analytical control activity was especially focused on monitoring of the of random samples of medicinal preparations, purified water and packages in the view of chemical and microbiological quality.

Monitoring of adverse effects of medicines was focused on stimulating of adverse effects reports and taking necessary measures. Cooperation with WHO at International Drug Monitoring project and involvement in EU system proceeded.

In the field of clinical testing of drugs and medical devices and Good Clinical Practice SIDC was providing the assessment of the applications for clinical testing, issuing of the decisions on clinical testing permissions, approving of work places and conducting supervision.

Medical devices section ensured the tasks connected with the preparation of the effective mode of resolving the adverse effects of medical devices withinthe enormous increase of the amount of the notifications about adverse effects within the EU. Another task is to solve the evidence of diagnostical medical devices in vitro notified in the EU.

Economy section ensured the activity of SIDC connected with the monitoring the expenses of the particular units and control laboratories, as well as the monitoring of the working schedule regarding the development and extension of SIDC to be in compliance with the termination date of building, which was reduced in 11 months in comparison with the original term. The extenstion has been put into operation on 1.12.2005. In the terms of the conclusions of the consultation with the minister the works on the building of the control laboratory 4 Žilina continued by the enunciation of the competitive bidding.

Personal Office – the main activity covered the realisation of the act on civil service and the act on works performed in public interest. It has been elaborated the internal guideline for the processing of descriptions of state employees positions and for the processing of the workloads.

6. Evaluation and analysis of SIDC development

In recent years, SIDC works on the improvement of the quality of its activities. Appropriate feedback is essential for development of the quality system. Therefore, it was performed regular annual research of information in the form of questionnaire (contmentment of client). The results of the research were published at the SIDC website.The results of the quanitative research confirm that SIDC activities have been evaluated very positively. SIDC decided to perform the research regularly, at least once a year. The repeated research will help to monitor trends in quality of services provided and to compare similar time periods. The results of the research will be used as one of the tools for improvement of the quality of SIDC acivities.

For effectivity assessment in the view of the quality targets was according to the plan performed Management Review with the purpose to reveal the deficiences and reserves and to avoid the same mistakes preventively.The adopted corrective actions are monitored with the purpose to improve the quality of services provided by SIDC.

For ensuring of the sophisticated tasks the Institute used the state budget resources divided into current and capital expenditures. The results of SIDC were regularly evaluated in the sessions of the director of SIDC. On the basis of these evaluations the following conclusions could be presented:

Drawings from the state budget for the particular items and subitems were from 1.1.2005 realised in the Information System of the State cash. Detail financial planning of the expenditures in the particular months and weeks increased the economical utilization of the vested resources.

Total current expenditures were drawn according to the approved actual budget, mainly for ensuring of the material, services, energy , postage and official journeys.

Capital expenditures were drawn in the volume 107 990 thousands Slovak crowns*. On 30.11.2005 was finished the investment action Extension of SIDC, for which was in the year 2005 invested 99 979 thousand Slovak crowns. By finishing of this action premises and technical equipment of the institute was resolved according tho the requirements of the EU. For the machines and equipment were drawn the shift in the volume 7 953 thousand Slovak crowns.

The income of the SIDC for the year 2005 reached 11 120 thousand Slovak crowns, which presents the budget excess in 120 thousand Slovak crowns. This was delivered to the state budget.

7. Target groups

External SIDC clients are:
- patients,
- physical and legal persons (pharmaceutical manufacturers, medical devices manufacturers, distributors of medicinal products and medical devices, pharmacies, dispensaries of medical devices),
- applicants for clinical testing
- Others (e.g. applicants for information, applicants for authorisation).

Services provided to the clients:
- registration of medicinal products and medical devices,
- issuing of binding opinions on the material, space and personal equipment
- issuing of permissions for clinical testing,
- Realisation of initial inspections at pharmacies and dispensaries of medical devices.

SIDC outputs are designed for and used by the Health Ministry of SR and wide range of users, in particular pharmaceutical manufacturers, wholesale distribution companies of medicinal products and medical devices, owners of public and hospital pharmacies, opticians, and dispensaries of medical devices as well as general public.

Particular sections and departments provide specialized advisory services and consultancy in the field of registration of medicinal products and medical devices, Slovak Pharmacopoeia and Pharmaceutical Codex issues and other specialized services.

Agenda related to Act No. 211/2000 Coll. on free access to Information is handled in the PR & Communication Division. Totally 216 requests for information were received (information provided 215-times, 1 decision on withholding information was issued in compliance with the act).

The editorial activity in the evaluated year was represented by quarterly publishing of the "Reports on Drug Quality" that are published for the benefit of general medical community. The reports inform about non-compliant medicinal products and measures resulting from it, and/or about products consequently released for medical use.

Database of registered medicinal products being used by the Ministry of Health of SR and health insurance companies represents an electronic form of the output. Partial outputs from the mentioned database are provided to the applicants for the registration and to the Ministry of finance for the purpose of the pricing of medicinal products.

8. Publication of the Annual Report

The Annual Report is published in two versions (Slovak and English language) and will be delivered to Ministry of Health of the SR, Slovak Medical University and to the other domestic and foreign institutions. The Annual Report is also published on SIDC's website www.sukl.sk.

Annex No. 1

Overview of analytical certificates and samples

Total number of analytical certificates submitted **265**
Total number of samples accepted for laboratory testing **980**
Total number of registrations and amendments in registration submitted **3959**
Number of updates of registration documents **2**
Number of samples for EDQM **5**

Analytical certificates	Complying	Non-complying	Pending	Total
Import	236	27	60	323
Domestic Producers	1	0	0	1
TOTAL	237	27	60	324

Samples in laboratory testing	Complying	Non-complying	Pending	Total
Imported drugs	40	1	19	60

Samples in laboratory testing	Complying	Non-complying	Pending	Total
MIS*, Pharmacies	222	28	59	309
IMUNA PHARM s.e.	4	0	0	4
ZENTIVA, s.e.	424	1	12	437
CHIRANA T. INJECTA, s.e.	3	0	0	3
VULM, j.s.c.	27	0	10	37
ADR**	20	0	3	20
Starting Substances	1	0	0	1
Complaints	5	4	1	10
Clinical Trials	0	0	0	0
Other Companies on Request	87	5	5	97
Center of Drug Dependences	3	0	0	3
Attests	3	0	0	3
Approval Decrees	220	0	0	220
PTS, CS Testing	7	0	1	8
Internal Testing	67	5	13	85
TOTAL	1093	43	101	1237

* MIS (Manufacture of infusion solutions)
** ADR (Laboratory Control due to Adverse Drug Reaction)

Annex No. 2

Overview of inspections GDP, GPhP and sample taking

Medical facilities	Inspections	Number
Public pharmacies and branches of public pharmacies	Entry inspections	384
	Targeted inspections	53
	Follow- up inspections	272
	Sample taking	238
Hospital pharmacies	Entry inspections	17
	Targeted inspections	1
	Follow- up inspections	0
	Sample taking	1
Dispensaries of medical devices	Entry inspections	36
	Targeted inspections	1
	Follow- up inspections	17
Distribution organizations	Entry inspections	25
	Targeted inspections	14
	Follow- up inspections	7
Opticians	Entry inspections	51
Other facilities	Entry inspections	9
	Targeted inspections	1
	Follow- up inspections	1
	NPS	12
	Sample taking	2
Producers of poppy	Entry inspections	12
TOTAL	Inspections	913
	Sample taking	241

* NPS - Narcotic and Psychotropic Substances

Abbreviations

ADR	Adverse Drug Reaction
CAP	Centrally Authorised Product
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedure (human)
COMP	Committee for Orphan Medicinal Products
CP	Centralised Procedure
CS	Collaborative Studies
DCP	Decentalised Procedure
EDQM	European Directorate for the Quality of Medicines
EMEA	European Medicines Agency
GCP	Good Clinical Practice
GDP	Good Distributing Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPhP	Good Pharmacy Practice
ICSR	Individual Case Safety Reports
MH SR	Ministry of Health of the Slovak Republic
MHRA	Medicines and Healthcare products Regulatory Agency
MRA	Mutual Recognition Agreement
MRP	Mutual Recognition Procedure
OECD	Organisation for Economic Co-operation and Development
OMCL	Official Medicines Control Laboratories
PIC/S Scheme	Pharmaceutical Inspection Convention Scheme
PIL	Patient Information Leaflet
PSUR	Periodical Safety Update Report
QRD	Quality Review Documents
SAHP	Slovak Agency for Human Pharmacy
SIDC	State Institute for Drug Control
SOPs	Standard Operating Procedures
SPC	Summary of Product Characteristic
STN ISO	Slovak Technical Norm
WHO	World Health Organisation
Ph.eur.	Pharmacopoea Europaea

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