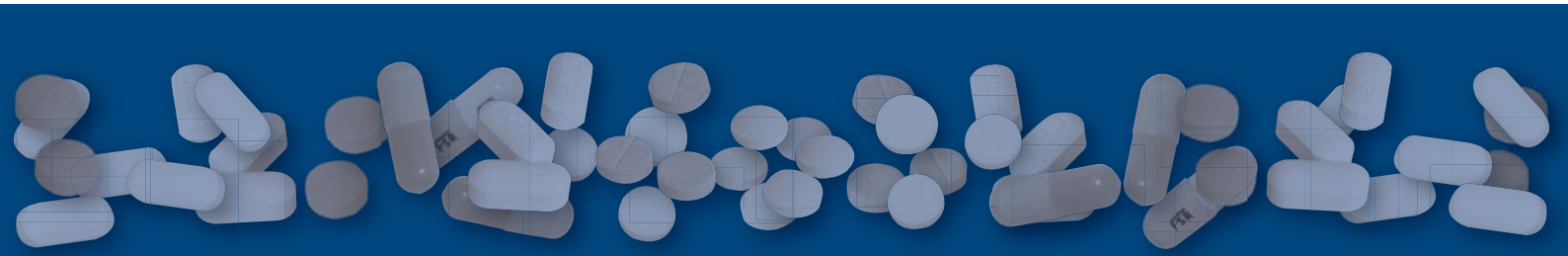
SIDC

STATE INSTITUTE FOR DRUG CONTROL

ANNUAL REPORT 2007



Content

Annexes

1. Identification of SIDC

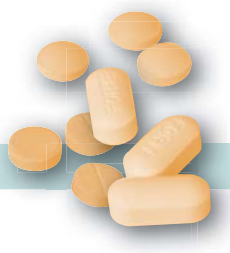
Name:	State Institute for Drug Control
Registered Office:	Kvetná 11, 825 05 Bratislava 26
Government Department:	Ministry of Health SR
Head of Office and Director:	PharmDr. Ján Mazag

Main activities:

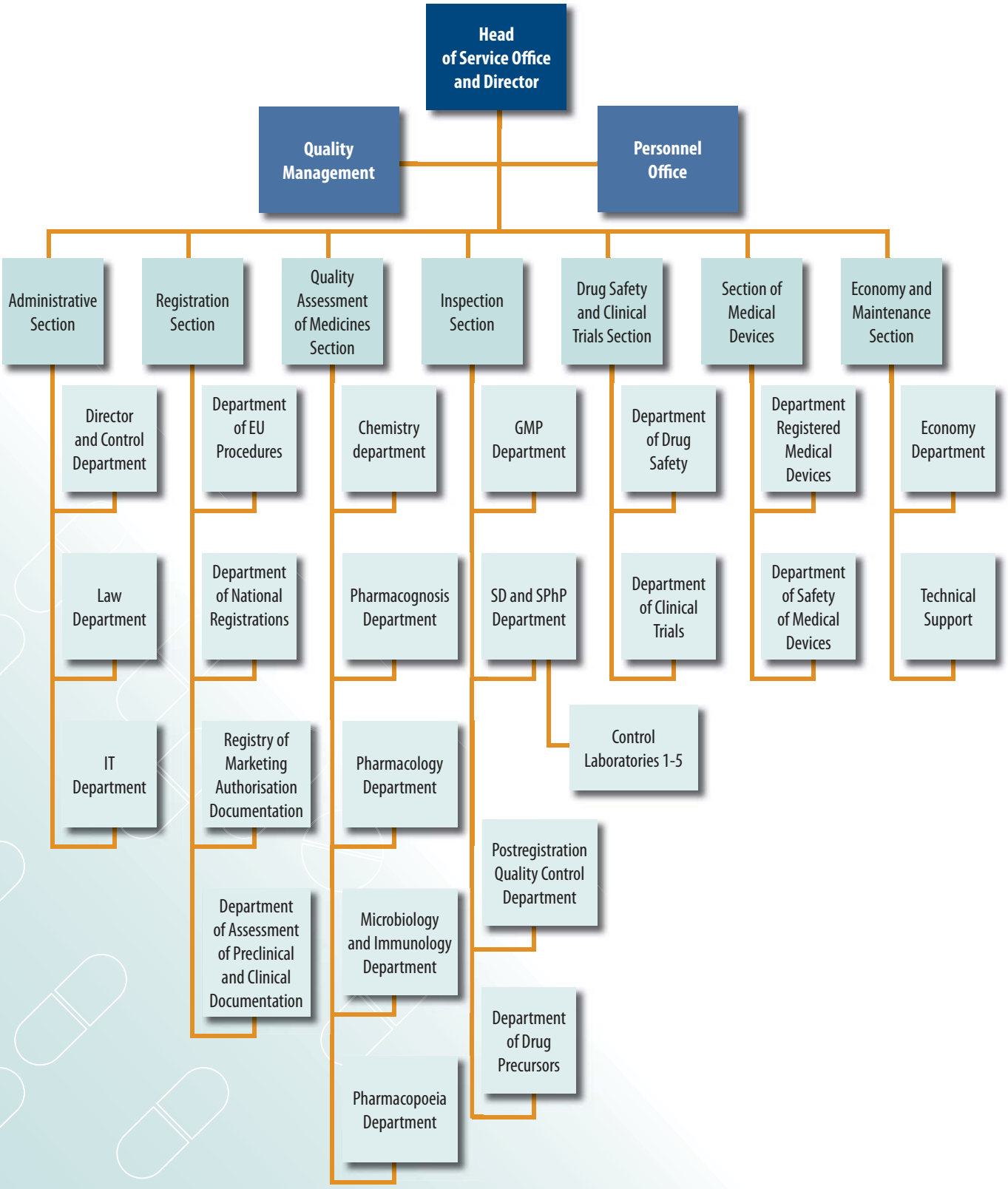
The State Institute for Drug Control is according to the article 58 of the Act No. 140/1998 Coll. on medicinal products and medical devices, on the amendment of the Act No. 455/1991 Coll. on small trade business (Small Trade Business Act) as amended, and on the amendment and supplement of the Act of the National Council SR 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 Head of service office and director, appointed and recalled by the minister of health of SR.

SIDC is an organization that ensures the state supervision and performs inspection of all pharmaceutical activities in the area of good manufacturing practice, good distributing practice, good laboratory practice, good clinical and good pharmacy practice in SR. The supervision over the quality, safety and efficacy, decisions making on registration of human medicines and registration of medical devices with the statement of compliance and since 1.5.2004 also registration of medical devices on the basis of CE certificates of the notified persons EU, as well as the other activities following the current legislation is being a part of it.

One of the main activities of the institute is the cooperation with the foreign organizations and institutions within Council of Europe, being a regular member of them, with the European Pharmacopoeia Commission, European Commission, in the frame of which we closely cooperate with the European Medicines Agency, London (EMEA), WHO, PIC/S Scheme (Pharmaceutical Inspection Convention), European network of pharmaceutical activities in the field of drugs and their monitoring, as well as within the activities related to the cooperation of OECD bodies in the field of good laboratory practice, where we are connected with cooperating bodies and organizations.



Detailed organizational structure is presented in the following overview:



2. Mission and Perspective of SIDC

The mission of SIDC in the health care system according to the act is executing of the state administration in the field of human pharmacy and drug precursors.

To the main tasks of SIDC belong the supervision over the quality, safety and efficacy of drugs, issuing of decisions on registrations of human medicines, issuing licenses for activities with specified substances, registration of medical devices, as well as the other activities following the current legislation.

Recently SIDC has passed through a long way of important tasks following from 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 labeling, information duties and advertisement of medicinal products.

The year 2007 is in sign of changes to ensure the work effectivity at particular divisions of activity. We managed to improve significantly the terms of processing the applications for registration of medicines in the terms of legal requirements. We entered the active cooperation in assessment of registration documentation (SIDC for the first time became the reference member state in the processing of assessment report in the medicines registration within EU.). We concentrated on the performing of state surveillance and inspections of all pharmaceutical activities in the field of good manufacturing practice, good distribution practice, good clinical practice and good pharmacy practice in SR, so that apart the inspection activity and eventual repressive actions we had effect preventative by pointing out the most frequently found defects among the particular representatives of medicines chain.

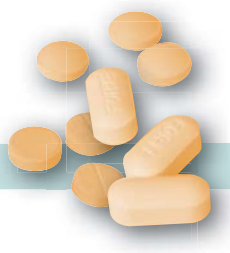
The year 2008 is the year of further necessary changes especially with the accent on the improvement of the work quality. We want to achieve this aim by the changes in the work management system, in the system of further electronization of activity in receiving the applications for medicines registration, in the system of clear determination of competencies among the responsible workers and following of their fulfillment. In the last period among the new tasks accrued the tasks in the field of pediatrics, in the field of monitoring and evaluation of medicines safety in therapeutic practice, in the inspection area and in the area of chemical analysis of medicines.

Within the perspective the effort of SIDC henceforth is to increase the transparency of proceedings forgoing the issuing of the licenses for manufacturing and wholesale distribution of medicinal products, registration of human medicines, clinical trials of medicinal products and medical devices, as well as the decisions on suspension of release of medicinal products and medical devices.

From the view of membership of SR in European Union one of our priorities is the cooperation with the European organizations and institutions in the framework of Council of Europe, cooperation with the European Medicines Agency (EMEA), European Pharmacopoeia Committee, European Commission, European network of official control laboratories (OMCL network), OECD in the field of good laboratory practice and other medicines agencies of EU member states. In the worldwide context SIDC collaborates with WHO and PIC/S scheme, too.

In the next period the ambition of SIDC is to increase the transparency towards all of the participants in the medicines chain - i.e. towards the manufacturer, distributor, pharmacist, physician, professional physician associations, as well as the patient himself and the patient organizations.

The steps we undertake in this area are necessary and correct, because by managing of new tasks following from the new legislation in the field of medicines in SR and EU we will ensure the correct health care in the field of medicines policy for the inhabitants of the Slovak Republic.



3.1. Quality Management

The international activities have 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 the Slovak Republic 2006" has been elaborated and submitted to the Environment Directorate OECD, European Commission and consequently to the all member states according to the directions.

The background report was elaborated for the standing mission SR near OECD according to the requirements and the evaluation of OECD activities in the field of GLP according to the requirements of the MH SR. Generally the cooperation, communication and exchange of information with the member states OECD continued, draft documents were annotated – OECD guidelines. It was ensured active participation at the sessions of the working group for GLP OECD as well as the working group GLP near EC.

In the framework of benchmarking continued the international cooperation with EMEA. On the basis of the evaluation of course and results of BEMA I (assessment of the quality systems implementation of particular agencies according to ISO 9004, ISO 19011 extended by specific chapters PERF III) within EMEA has been agreed three-year periodical evaluation of each agency. The preparation for BEMA II has been performed according to the plan. Following the EMEA requirement it was elaborated BEMA II profile of the institute and it was ensured the active participation at 2 training seminars for BEMA II, which is planned in 2008.

Within the international cooperation SIDC continued in activities connected with the Twinning projects with Turkey in the field of GLP and medical devices. Two-year „Twinning project Turkey" for GLP and project for medical devices is financed and approved by EC. The institute accredited by European Commission as "Mandate Body" acted by its experts in Turkey, where the expert consultancy and lecture activity was performed (Šidlíková, Tarábková for GLP and Gibala for medical devices).

The activity was focused on the implementation of the quality system according to STN EN ISO 9000:2000 and STN EN ISO/17025 in laboratories and on performance of corrective measures following from audit BEMA I., from management review and from questionnaires on client's satisfaction.

Results of the survey on client's satisfaction are presented at the website of the institute.

On the basis of the actualization of the system for documentation administration all data in the software EISOD have been revised and the database of employees, database of documents and the approach of employees to documents have been updated.

Within the administration of controlled documents were:

- prepared the plan of revisions of internal directives
- updated 2 internal directives and 2 guidelines
- annotated, approved and issued controlled documents of the institute according to topicality.

Survey of issued (new, updated) controlled documents in 2007 and their total number

Controlled document (CD)	Issued in 2007	Total number of CD
Quality Manuals		8
Internal Directives (ID)	10	34
Guidelines	3	23
Internal Guidelines (ID)		12
Standard Operating Procedures (SOPs)	62	717
Total number of controlled documents		**794**

During the year were performed 3 sessions of quality managers, where the procedure and implementation of quality systems have been discussed. Quality managers gave an accounts on each performed audit at their organizational division according to the plan. Activity of quality managers was monitored and the problems were discussed.

Each half year the level of performance of their duties has been evaluated.

Except the performance of accepted tasks have been with the quality managers discussed the requirements and tasks following from the benchmarking within the European medicines agencies. Internal audits were performed at the Inspection Section, Drug Safety and Clinical Trials Section and special audit at the Pharmacology department – experimental menagerie was performed by the request of the head of section.

At present 9 laboratories are registered with permission to perform pharmaceutical and pharmacologically-toxicological testing. Their survey has been regularly updated and published at the website of the institute and in the magazine „The Pharmacist". In the frame of supervision over these laboratories the inspections were performed according to the plan.

3.2. Administrative Section

Director and Control Department

Control division

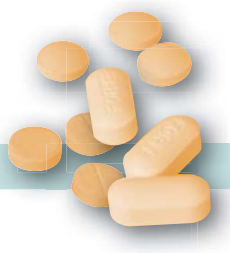
Internal controls

In the year 2007 were internal controls performed on the basis of the Plan of control activity of SIDC, approved by HSO and director. The following control actions were carried out:

1. Control of observance of the Internal Directive No.5/2006 – Personnel Training of SIDC
2. Control of observance of the Internal Directive No.6/2006 – Preparing Personnel on Recruitment
3. Control of observance of the provisions of the Act No. 124/2006 Coll. on the work safety and health protection and on amendment and supplement of certain acts
4. Control of observance of the provisions of the Act No. 314/2001 Coll. on fire protection
5. Control of observance of provisions of §29 art.3 of the Act No. 431/2002 Coll. on accounting concerning the financial resources, as well as the control of handling with valuables (soup tickets)
6. Control of observance of the provisions of the Act No. 81/2005 Coll. on travelling reimbursements
7. Control of utilization of common expenses
8. Control of utilization of capital expenses
9. Control of amount outstanding
10. Control of residual time delay in processing of the registration applications

Handling of petitions and complaints

In 2007 we registered 20 complaints. Petitions were not received. Justness of the complaints was confirmed in 5 cases. The administrative proceeding was initiated and the fine was imposed. Only one complaint we registered against the SIDC employee – this complaint was unjustified (In 2006 we registered 18 complaints).



Public Relations & Communication

PR&Communication unit ensured the performing of tasks resulting from the position of division as the press body of the head of Service Office and director and continuously performed the monitoring of media. PR&Communication unit coordinated the communication of SIDC with media. There were executed 110 applications for information received from print and electronic media.

In cooperation with other sections of institute the unit participated in realization of annual report on the activity of institute, coordinated activities connected with translation and ensured works related to the publishing of English version of Annual Report. In cooperation with the informatics department the unit regularly updated internet and intranet websites of institute on the basis of requirements of expert sections. Furthermore the unit monitored internet websites of the important institutions in the field of medicines policy and legislation.

PR&Communication unit coordinated cooperation between SIDC and external companies in the development of the new website. Similarly the unit cooperated in the development of new logo of SIDC and in elaboration of Design Manual of SIDC.

Provision of information

The unit kept records and executed agenda related to all applications registered at SIDC according to the Act No.211/2000 Coll. on free access to information. There were registered and executed 350 requests for information.

Survey of registered requests for information	
Number of registered requests for information	350
Number of provided information	350
Appeal for completion of request	3
Issuing of decision about non-providing of information	0

EU collaboration

The main activity of the EU Collaboration unit was focused on the connection of SIDC to the European structures in the field of human pharmacy.

The main action areas of the EU Collaboration unit:

- coordination of transfer of actual information and tasks of SIDC, following from the connection of SIDC to EU structures in the field of human pharmacy (membership in advisory bodies of EC and EMEA), SIDC representation in international organizations (PIC/S – Pharmaceutical Inspection Scheme, EDQM – European Directorate for the Quality of Medicines, OECD for good laboratory practice, WHO
- updating of nominations of SIDC representatives and their alternates within the particular advisory bodies of EMEA and EC
- coordination of activities of SIDC representatives in advisory bodies of EMEA, EC, EDQM, PIC/S Scheme, WHO, OECD and European Associations in the field of human pharmacy
- technical realization 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 and documents for quality assurance EDQM for OMCL.

The basic controlled document has been revised: ID 36/2006 System of measurements control. Revision of the other controlled documents is in-process.

On deputy of the Quality Management the external audit as supervision was performed at the authorized workplace LABEKO, Ltd., located in Piešťany.

On the basis of agreement between SIDC and SNAS four GLP inspections were performed.

At the Informatics department – Administrative Section three internal audits of second level were performed according to STN EN ISO 9001.

Since 1.10.2007 the metrologist performs also the function of quality manager of the Quality Assessment of Medicines section.

Metrologist of the institute regularly participated in the session of the Commission for certified reference materials, which is the advisory body of director of the Slovak Metrological Institute.

In the framework of cooperation agreement between ÚNMS SR (Office for Standards, Metrology and Testing) and SIDC the metrologist of institute participates in „Twinning Project TR/2004/IB/EC/06, Strengthening the ministries of health, environment and forests, and agriculture and rural affairs to harmonize and implement legislation in the field of Good laboratory practice for non-clinical health and environmental protection“ for Turkey.

IT Department

Activity of IT department was focused on:

- continuous electronic processing of the registration documentation (national procedure, centralized procedure, MRP) and amending of the database of medicinal products
- consulting in processing of the database of companies, list of drug forms, list of components and ATC list
- cooperation in further development of internal information system on medicinal products and medical devices
- collecting and processing of the package leaflets information and SPC and scanning of documentation
- updating of data at the internet page of the institute
- technical support of the development of the new institute webpage
- cooperation between SIDC and authors of AISLP
- cooperation between SIDC and operator of webportal NOBEL.sk
- operation, maintenance and purchase of the computer equipment
- development of several software for the internal use of the institute

Within the electronic processing of the registration documentation the IT department closely cooperated with the Registration Section. The department made out the identification lists, which are the integral part of each decision on registration of human medicinal product and decision on the variation in registration. The department assigned SIDC codes for the medicinal products registered by the national and European procedures. Workers of the department continuously updated the database of registered medicinal products by filling up the card of decision and the card of medicinal product by necessary data.

Department workers performed consulting for the relevant institute workplace in the maintenance

and amending of the database of companies (manufacturers, holders...), in the development of the list of dosage forms, list of active and auxiliary substances and in maintenance of ATC groups according to the WHO data.

The working meetings with company MCR and Registration Section were realized, regarding the further development of the information system on medicines and medical devices and the workers from time to time performed the training, advisory and consultancy activity for the workers of the Registration Section in processing of data.

The works were performed connected with the maintenance and updating of SIDC website, with receiving, classifying and sending of electronic mail.

Technical workers of department actively participated in the development of the new internet page of the institute.

The cooperation between SIDC and authors of AISLP proceeds in the form of the mutual exchange of data.

On the basis of contract between SIDC and authors of webportal NOBEL is performed regular supplying of required data from the information system of medicinal products and there are solved the remarks supplied by the authors of webportal NOBEL.

The department ensured operating and service of computer technology of SIDC. Minor defects at the presented technology were resolved by department itself. At the occurrence of major defects the department ensured the service at the selected service companies.

Technicians, programmers of SIDC worked on the development of simple software for internal use of the institute.

Law Department

Unit for administrative proceedings

At the unit for administrative proceedings were in the year 2007 registered 49 files. From the mentioned number was in terms of the art.18 of the Act No. 71/1967 Coll. on administrative proceedings in the full version started administrative proceeding in 39 cases. In 9 cases of the started administrative proceeding the decision was issued on suspension of administrative proceeding. In the terms of art.46 of the act on administrative proceedings were in mentioned period issued 35 decisions imposing fines to physical persons and legal persons in total sum 590 thousand SKK. By the reason of the material competence 1 file was ceded for execution to the Ministry of Health SR.

On 31.12.2007 was lawfully terminated 29 cases and the volume of sanctions paid in the form of imposed fines was 380 thousand SKK. On this date remained 10 cases of proposals for starting of administrative proceeding, which were ceded for execution to the Law department from the Inspection Section.

Further internal agenda of the Law department was connected with the providing of opinions and law support to all workplaces. Along this line the cooperation was intensified with the Inspection Section, Control laboratories and the Registration Section.

Continuously the legal advices and information were provided to various physical and legal persons under the observance of conditions determined by the act on free access to information.

Unit for the supervision of the medicines advertisement

The unit for the supervision of the medicines advertisement registered 1 379 notifications of prepared advertisement by holders of decisions on registration of medicinal product according to the provision of §8 art. 22 letter b) of the Act No. 147/2001 Coll. on advertisement as amended.

The unit started 12 proceedings on potential breaking of the provisions of the act on advertisement.

In 2 cases the administrative proceeding was stopped and it was issued 1 decision on prohibition of advertisement distributing. The volume of imposed fines was 245 thousand SKK.

In addition to this activity the information was provided according to the Act No. 211/2000 Coll. on free access to information and on amendment and supplement of some acts and legal advices were provided to the physical and legal persons.

Furthermore the unit provided information according to the Act No.211/2000 Coll. and legal consulting to the Registration Section.

3.3. Registration Section

Activity of the Registration Section was focused especially on the following actions:

- personnel stabilization of the section and workers motivation
- implementation of the requirements of the revised pharmaceutical legislation EU in SR
- increasing of quality and rationalization of the procedures concerning the registration applications processing, especially the variations IA and IB and the deepening of the coordinated cooperation with the internal partners
- increasing of work quality of the Committee for medicinal products, introduction of the "peer review" system
- deepening of the assessor activity: first procedures with SR as a reference state, systematical approach to CMDh referrals, issue of bioavailability and bioequivalence.

Section employees actively participated in cooperation in the framework of EU medicines agencies network in several committees and working groups (Coordinating group, Herbal Medicinal Working Group, e-TIG, EWP, Standing Committee, Pharmaceutical Committee).

In the purpose of expertness increasing of SIDC employees in connection with the registration of medicinal products and evaluation of registration documentation we coordinated Twinning Light Project "Strengthening of SIDC capacities for implementation of new EU legislation Directive 2001/83/EC and Directive 2004/27/EC", in which 17 Dutch and about 90 Slovak experts participated.

We lectured on several international conferences dedicated to partners in state institutions (Croatia, Netherlands), as well as to applicants for registration of medicinal products (DIA Euromeeting).

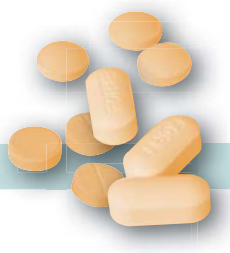
Registry of Marketing Authorization Documentation

Registry of Marketing Authorization Documentation ensures all initial, supporting administrative, accounting and distributing processes for Registration Section.

Department activities:

- reception of applications regarding medicinal products
- revision of administrative fees
- registration of applications in the computer system
- primary revision of the documentation inclusiveness in all types of applications
- archiving of registration documentation and decisions
- coordination of documentation allocation to the processers
- putting the decisions into validity
- keeping and handling the medicines files

Department has received 11 969 applications concerning the medicines registrations.



Department of National Registrations

Department activity was focused on:

- coordination of national registrations, variations, extensions and transfers
- organization of consultations, approvals of SPC, PIL and package labeling in printed form with sequential conversion to full processing in QRD format
- harmonization of medicines registrations with the status in other member states of EU
- implementation of new provisions of the act on medicinal products and medical devices
- sequential elimination of time delay in processing of applications received to the Department of National Registrations

Activities extent of the Department of National Registrations:

Type of application	Status to 1.1.2007 (not processed)	Received 2007	Processed 2007	Cancellation 2007
New registrations	413	58	21	114
Extensions	543	215	4	91
Transfers	138	176	227	8
Variations	677	832	11	202
Variations IA	1 274	3 023	3 588	124
Variations IB	818	1 318	1 606	43

Department of EU Procedures

Activity of department was focused mainly to processing of applications submitted by mutual recognition procedure and decentralized procedure, with the effort to deepen the quality of SIDC accession in the role of concerned member state and at the same time to initiate the SIDC progress in the role of reference member state.

Abreast of HMPC the state institute actively participated in the tasks designed to this Committee, during this time SIDC asked for the role of rapporteur in elaborating of monograph and assessment report to the concrete drug.

Activity extent of Department of EU procedures for the year 2007:

SR as CMS	Received	Processed
DCP new registrations	594	199
MRP new registrations	275	287
MRP extensions	106	54
MRP variations – type II	825	678
MRP variations – type IB	1105	1007
MRP variations – type IA	2086	2050
Transfers	54	51

SR as RMS	Received	Processed
DCP new registrations	0	0
MRP new registrations	3	1
MRP extensions	0	0
MRP variations – type II	4	4
MRP variations – type IB	0	0
MRP variations – type IA	0	0
Transfers	0	0

Committee for Medicinal Products

Committee for Medicinal Products came together for 11 times, during which time it assessed the new applications for registration, CMDh referrals, registration extensions, variations in registration and changes in the form of medicines dispensing.

At the sessions there were discussed 644 applications, thereof:
- 169 applications for clinical testing
- 55 applications in coordinating group EU (CMD(h) referrals)
- 20 applications for new registration of generic medicinal product
- 17 applications for extension of the medicinal product sequence, by new drug form or strength
- 14 applications for change in the form of dispensing
- 369 applications for the change of the information about medicinal product

Subcommittee for phytopharmacs and homeopathics came together for 3 times.

At the sessions there were discussed 12 applications, thereof:
- 7 applications for variation
- 3 applications for registrations and completing of information to 1 application for registration

3.4. Quality Assessment of Medicines Section

Quality Assessment of Medicines Section is an executive expert division of the institute. The section is divided into 4 departments:
- Pharmacopoeia department
- Biology department
- Pharmacognosis department
- Chemistry department

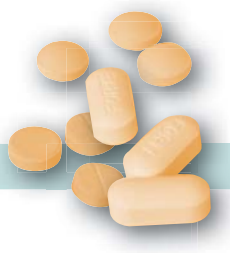
Since 1.7.2007 the Quality Assessment of medicines Section changed its structure. By joining of the Pharmacology department and Microbiology and immunology department arose the Biology department equipped with the experimental menagerie.

The status of personnel was during the year reduced by 2 assessors, 1 laboratory assistant, 1 washer of laboratory glassware and two animal tenders in experimental menagerie. 1 post of assessor was occupied again through the selection procedure by young employee and the second is occupied temporarily.

The present status of personnel on 31.12.2007 at the Quality Assessment of Medicines Section is as follows:

Number of assessors:
- 7 experienced (2 ML)
- 4 in qualification
- 4 managers of departments
- head of section

Number of laboratory assistants: 16
Service employee: 1
Washers of laboratory glassware: 3
Tender of laboratory animals: 1



At the Pharmacopoeia department work 2 expert employees, manager of department and 1 service employee. At the section are engaged totally 43 employees.

Metrologist integrated in the SIDC structure into Administrative Section is since 1.10.2007 nominated to a post of quality manager of section.

Within the cooperation of the member states EU in the field of European legislation 2 assessors of QAMS annotated the draft of the new EC ordinance on the variations in registration.

One of the important activities of the institute is the cooperation with the European Pharmacopoeia Commission of CE, in which the Slovak Republic through SIDC as a competent authority has the member representation in terms of Agreement CE No.50. Pharmacopoeia department continued in the translations of the new articles and adjustment of the modified ones of Ph.Eur. 5th edition and annexes. In 2007 were revised 630 pharmacopoeia monographs and control methods and translated 56 new ones; there were processed 47 pages of new reagents and were revised 315 pages of regents. At the request of EDQM were prepared 2 opinions and answers for regular questionnaires within the working programme of the commission.

The works on the Slovak Pharmaceutical Code were finalized. Complete text in 609 pages was submitted to the expert review and to three readings. It was passed to the MH SR in the purpose of interdepartmental marking up proceeding.

Assessors were trained by Dutch experts in writing of "Assessment Report" during the "Twinning project".

At the section there were elaborated two Assessment Reports in English for MRP proceeding of the registration of medicinal product Mucosin tbl, Zentiva Inc., CZ and Halea tbl 50 mg and 100 mg, Belupo, Croatia.

Whereas the priority of the state institute in the past year was the reduction of time delay in assessment of applications for national registrations, the assessors didn't elaborate the assessments from the position of one of concerned member states in registration proceedings MRP and DCP and thus did not contribute to the fulfillment of common tasks of the member states of EU. After the processing of the time delay will be necessary to consider again the participation of Slovakia in assessment in European proceedings.

In the area of quality control of the medicines at the market on 31.12.2007 remain to assess 148 certificates to batches of medicinal products at the market and samples supplied for the laboratory analysis. In the past year within the systematical control of vaccines and blood derivates there were executed 288 certificate assessments of manufacturing documentations. The survey on performed analysis and other assessed certificates is in the table (see below).

In the menagerie there were executed 21 tests on pyrogens and 2 tests on innocuity.

It was performed the training on operating of the equipment AAS – spectrophotometer at the Chemistry department.

In the framework of international collaboration the section as an OMCL SR entered 2 PTS studies **(PTS086 and PTS090)** organized by EDQM in Strassbourg. We received the results of PTS studies from the plan for the year 2006. In **PTS 084** (determination of drug content and impurities by HPLC method) was achieved an excellent result, z-score = -0,11 and 1,89 in determination of two components of the drug ivermectin. In determination of impurities the laboratory achieved z-score -2,90 and -0,87. Z-score between -2,0 and +2,0 is acceptable, from ±2,0 – 3,0 is disputable and above 3,0 is unacceptable. In study **PTS 085** (Microbiological content of antibiotics) the laboratory reached good result z-score 1,3 for both of the analyzed samples. In study **PTS086** (content determination by UV-spectrophotometry method and drying loss) the laboratory achieved very good z-score -0,65. PTS090 (Dissolution test) is in-process.

In the past year OMCL started the updating of the Quality Manual, hence it did not participate

at the laboratory analysis of **MRP products** registered by procedure of mutual recognition and of those sent for analysis from other member states.

Similarly in the year 2007 OMCL didn't participate in the scheme of European cooperation **Collaborative studies (CS)** of European pharmacopoeia, which is the mean of the quality appointment (potency) and declaration of the substance as the reference material Ph.Eur.

The reason of the lower level of cooperation with EU was the determination of the section priority, namely the revision of the Quality Manual according to the new ISO/EN standard 17 025:2005 and revision of SOP.

Within the EDQM programme focused on the analysis of centrally registered medicinal products (CAP) OMCL performed the complex analysis of three samples (A,B,C) and of CTS sample of medicinal product KIVEXA, 600/300 mg, tbl flm (abacavir/lamivudin), GlaxoSmithKline. In cooperation with the Slovak Health University the experts of section lectured 9 lectures. Section employees participated in relevant seminars.

One employee of the section cooperated in the working group for the System of early warning against the new synthetic drugs near the National monitoring center for drugs.

27 assessments were elaborated for the boundary products between the medicinal product and food supplement or cosmetics for the Office of public health.

At the end of 2007 the section got "online" access to Ph.Eur. for 14 users. Since 1.1.2008, when the 6th edition of Ph.Eur. came into force, each assessor has the "online" access.

Totally **335** samples (tab. 1) and **4 187** assessments (tab.2) were processed.10 of the analyzed samples were unacceptable from the view of average weight of tablets, packaging, content of drug and purity, conductivity, microbial purity and low efficacy.

The activity of section expressed financially represents **15 857 291,- SKK.**

Table No. 1

Number of samples	Biology department	Pharmacognosis department	Chemistry department
Foreign registration	-	-	-
Domestic registration	-	-	-
Systematic control	-		12
Obligatory control	-		-
Import	17	3	90
Domestic manufacture	-		1
Ordered	135	3	6
Clinical complaint	9	1	6
Reclamation	1		9
Internal testing	12	2	10
PTS/MSS/CS	2/0/0	1/0/0	0/1/0
CAP	-		4
Others	-		9
Unacceptable	1		4
TOTALLY	**176**	**11**	**148**

Total number of samples for section: 335
Financial value: 2 575 946,- SKK

Table No. 2

Number of Assessment Reports	Biology department	Pharmacognosis department	Chemistry department
Foreign registrations N/MRP/DCP	2/7	23/1/0	38/4/4/5
Variations	298	1 176	2 212
Clinical batches	-	-	-
Analytical certificates**	300**	26	9
Assessments and reviews	-	27	-
„UP“	-	-	24
Others	2	-	-
Opinions	8	-	-
Marking up	21	-	-
Unacceptable	23(22 certificates, 1 national registration)	-	11
TOTALLY	**638**	**1 253**	**2 296**

AC – 300 certificates of imported medicinal products, hereof 288 systematic control of vaccines and blood derivates certificates and 12 certificates of medicinal products imported from third countries.

Total number of Assessment Reports for QAMS: 4 187
Financial value: 13 281 345 SKK
TOTAL FINANCIAL VALUE: 15 857 291 SKK

3.5. Inspection Section

The main focus of Inspection Section activity was performing of various types of inspections (entry, concurrent, targeted), focused on the inspection of material, space and personnel equipment and the compliance with the principles of good manufacturing practice, good pharmacy practice, good distribution practice and good practice of transfusive medicines preparation. Inspections were carried out in all types of health facilities.

Number of particular facilities on 31.12.2007 is in the following table:

Facility	Number
Public pharmacies and their branches	1 658
Hospital pharmacies	74
Distribution companies	133
Dispensaries of medical devices	206
Opticians	487
Carriers	10
Salvage service	118
Manufacturers	24
Transfusiological facilities	50
Other facilities (schools, institutes, hospice)	45
Total number of facilities	2 805

The activities connected with the preparation of the international MRA audit of the Canadian inspectorate continued.

Department of good manufacturing practice and good distribution practice

The department carried out entry, follow-up, concurrent and targeted inspections in health facilities, i.e. manufacture of medicinal products, wholesale distribution of medicinal products and medical devices and transfusiological workplaces and on the basis of request inspections of foreign manufacturers in the purpose of issuing GMP certificate.

Inspection activity of department is presented in the table, structured according to the type of facility and type of inspection:

Type of inspection	Manufacture		Wholesale distribution	Transfusiology	Totally
	Domestic	Foreign			
entry	11	0	29	3	**44**
follow-up	0	0	1	1	**1**
concurrent	9	6	1	12	**28**
targeted	0	0	1	2	**3**
totally	**20**	**6**	**32**	**18**	**76**

Output documents of inspections are the opinions on the material, space and personnel equipment – number of issued – 35, GMP certificates – number of issued 7, confirmation on following the principles of good practice in preparation of transfusive medicines – number of issued 3 and the inspection reports.

Department of good pharmacy practice

Inspection activity was performed:

- in facilities providing the pharmacy care
- in dispensaries of medical devices
- in distribution organizations

and in other facilities:

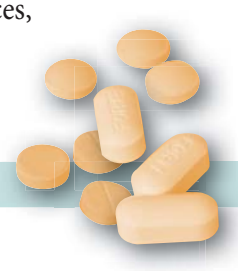
- opticians, poppy producers, fast health aid stations, fast medical aid stations and other non-state health facilities

Total number of inspections: 812
Total number of performed takings of samples: 316

The number of targeted inspections is year after year higher and from their results there have been suggested the starting of the administrative proceeding in the matter of imposing fine in terms of the Act No.140/1998 Coll. and it have been suggested to Regional Office the suspension of permission to provide the pharmacy care.

Other organizations

The number of entry inspections in other health facilities in the purpose of issuing the Report of SIDC in the terms of the Act No.139/1998 Coll. and issuing the Opinion of SIDC in the terms of the Act No.331/2005 Coll. increases. It concerns the fast medical services, fast health services, hospices, one-day medical care.



The value of inspections charged:	**2 526 686,-SKK**
The survey of inspections and takings of samples is presented in Annex No.6	
Control-analytical activity	
Total value of analyses:	**8 739 988,-SKK**
hereof invoiced:	**2 304 733,-SKK**

Control of samples on the basis of random choice – was focused on the monitoring of chemical and microbiological quality of randomly taken samples of medical preparations and purified water.

Control of samples on the basis of request – was performed by request of state and non-state health facilities from the view of chemical and microbiological quality, evaluated according to Slovak Pharmacopoeia 1 and valid SOP. In CL 3 was performed microbiological control of medical preparations, manufactured in the company Galvex B.Bystrica. On the request of pharmacies there was performed chemical and microbiological control of purified water according to Slovak Pharmacopoeia 1.

Other expert activity

- consulting activity – comments on the layout of pharmacies, hospital pharmacies, wholesale distribution organizations and other organizations
- elaboration and updating of SOPs for CL activities, updating of the Quality Manual
- works on the stability studies of testing and volumetric solutions continued
- marking up of SOP among CL 1-5
- training of employees in the form of internal and external courses
- regular audits performed by quality managers of CL on the basis of elaborated plan, the quality of measuring instruments and measuring equipment was ensured according to the elaborated schedule of metrological assurance of measuring instruments by the metrologists of laboratories

Post-marketing surveillance department

The activity of post-marketing surveillance department was focused on the control of medicinal products imported in the territory of SR, reception and transmission of information on quality defects of medicinal products, which are subsequently the subject of the session of the Assembly for Drug Quality.

In 2007 the Assembly for Drug Quality held session on March 28, June 21, September 20 and December 6, 2007. The members of Assembly discussed 200 cases, hereof 14 medicinal products were recalled from the market, 1 medicinal product was suspended in release and use and 7 medical devices were recalled from the market. Information on counterfeit medicines were 19.

Between the sessions of the Assembly for Drug Quality 17 interventions were performed, hereof 14 interventions by fax and 3 interventions by letter. The recall of medicinal product in 14 cases, release into market was notified in 2 cases, fast information on medicinal products in 1 case. Other interventions were performed through the Reports on Drug Quality.

In 2007 the post-marketing surveillance department actively participated in the sampling of centrally registered medicinal products Velcade 3,5 mg power for injection, Mimpara 30 mg film coated tablets and Adipra 100U/ml solution for injection in collaboration with EDQM, Strassbourg, France.

Drug precursors department

Activity of the department was focused on the enforcement of the community legislation of EU for drug precursors in conditions of SR. Drug precursors department in this activity closely

cooperated with the relevant authorities ME SR, MHA SR and Customs directorate SR, which are competent to act according to the Act No.331/2005 Coll. on the state administrative bodies in the matters of drug precursors and on amendment and supplement of certain acts.

Type of decision	Number of decisions	Administrative fee (SKK)	Totally SKK
Special permissions and permissions	400	1000,0	400 000,0
registrations	2	1000,0	2 000,0
changes	85	500,0	42 500,0
cancellations	98	0	0
TOTALLY	**585**		**444 500,0**

Increased number of cancellations of special permissions for public pharmacies was connected especially with the transmission of proprietary relations from physical person to legal person.

3.6. Drug Safety and Clinical Trials Section

Department of drug safety

Department of drug safety is a coordinating centre for pharmacovigilance, drug surveillance and monitoring of adverse drug reactions in Slovak republic and surveillance of registered medicinal products for human use. 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 reactions to registered medical products for human use.

In 2007 we continued to report spontaneous reports that we received from health care professionals to Eudravigilande database. We continued in development of our own national database of adverse drug reactions eSkadra for recording, archiving and transmission of reports to Eudravigilance database.

Overview of activities in 2007:	
Reporting ICSR from Slovak republic (spontaneous)	1205
Expedited reporting of ADR (post-registration)	23 819
Laboratory control of the batch due to ADR	5
Submitted PSURs	1231
Control of PSURs for renewal of registration	103
Published statements on drug safety	26
Reports from Slovakia submitted to Eudravigilance (year 2007)	119
Public statements issued in 2007	9
Assessment requests on OTC status	4
Assessment of type II. variations	156
Exchange of information with EU countries - non-urgent requests - alerts - other request on information	 44 2 48
Drug bulletin	2
Other activities – assessment Dear Doctor/Health Professional Letter „education activities“ as part of Risk mineralisation plans Risk minimisation plan	 16 2 3

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

The Committee on safety of drugs that is advisory body met 5 times. The Committee evaluated reported cases of adverse reactions and evaluated signals applications for switch to OTC status and different kind of communication with health care professionals and public.

Department participates to the activities of Pharmacovigilance Working Group and all over activities of Pharmacovigilance in EU.

Department of clinical trials

Department ensures processing of applications and notifications for clinical trials of investigational medicinal products, reviewing study protocols, issuing the decisions on approval of clinical trials, surveillance over its performance and approving of study centres. Tasks of department include inspection of Good clinical practice (GCP) as well.

We participate in the project of European database of all clinical trials in European Union– EudraCT.

Overview of the activities for the year 2007 in comparison with the year 2006:

Activity	2006	2007
Application for clinical trial	151	154
Authorization of clinical trials of drugs	128	131
Rejection of application for clinical trial	2	10
Application on approving of amendment to protocol	242	231
Application/notification on changes in Investigator's Brochure	151	176
Application on approving of a new study centre	19	38
Submission of agreement of ethical committee	135	70
Notice on beginning of clinical trial	38	60
Notice on end of clinical trial	87	113
Annual report on process of a clinical trial	103	83
Report on adverse event from Slovak trial sites	301	140
Notice on adverse event from abroad	5856	3141
Own activity	69	1
Iné	387	857
Meetings of committee	11	11
Application for clinical trial with medical device	3	2
Authorization of clinical trial with medical device	3	2

3.7. Section of Medical Devices

Section of Medical Devices SIDC as a competent authority for medical devices (MD) in the Slovak Republic fulfills the tasks resulting from the Act No.140/1998 Coll. as amended and the Government Regulations SR (No.569/2001 Coll., No.570/2001 Coll. and No.572/2001 Coll. as amended) and in a broad context cooperates with EC bodies as a representative of the member state in the field of

medical devices. MD Section is divided into two departments: department of registered medical devices and department of safety of medical devices.

Department of registered medical devices

Department performs evidence of all medical devices put on the market or put into operation in the Slovak Republic and the registration of manufacturers of MD with location in SR. In consequence of the free movement of goods within the EU countries most of MD registrations have been performed on the basis of EC/CE certificates of manufacturers issued by the notified persons in any member state of EU.MD registrations of class I. were accepted on the basis of the ES declaration on conformity of manufacturer. Problems in the registration process of manufacturers and medical devices are caused mainly by insufficient and ambiguous handling of MD issue in the Act No.140/1998 Coll. as amended and in three above mentioned Government regulations, which are the executive provisions of the act No.264/1999 Coll. on assessment of conformity as amended and at the same time they are the implementation of the three European directives into the Slovak legal system. Ever more important becomes the need of the separate act on medical devices.

In the evaluated period it was noticed the increase of all indicators (number of new registrations by 284, number of codes assigned by 1942). In addition to registration of new manufacturers and MD the department especially deals with prolongation of validity on the basis of new EC/CE certificates, extension of line of the registered medical devices in the framework of the registered group of MD and the change in the name of manufacturer, which is very time-consuming.

Regarding the extensity of SIDC codes database and severity of database administration of registered MD the institute management decided to join both of the databases by external IT company to one database, which should enable more operative exploitation of existing data. The company was chosen with experience in similar software solutions at other SIDC sections. Databases were joined, but during the use appeared great amount of mistakes, debugging of which is in progress up to this day. Since September the section works in the new database, which the employees continuously correct and at the same time they perform the registrations in it. Database of registered MD is updated weekly at the internet page of the institute.

MD Section continuously cooperates with MH SR in the categorization process of MD. 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 by health insurance companies exceeding the categorization list.

The notifications of distributors on the consumption of MD are processed quarterly and the final list of MD consumption is regularly transferred to MH SR.

In summer months within the marking up proceeding we annotated the statutory text of the Act No.140/1998 Coll. as amended and Act No.577/2004 Coll.

Department of safety of medical devices processed the notifications of manufacturers, competent authorities EU, advisory bodies EU, distributors, hospitals, hospital pharmacies and doctors on adverse effects of MD and monitored the process of solving. The amount of adverse effects notifications is approximately the same as in the last year. Department workers at the same time solved the great amount of recalls of MD from the market of the Slovak Republic.

During the year 2007 it was recorded one clinical complaint on MD and at the end of the year it was received one announcement on the starting of clinical trial of MD, performing of which is coordinated with the Drug Safety and Clinical Trials Section.

Two workers of the section participated in the sessions of working groups near EC (MDEG and MDEG-vigilance) and in the meetings of the competent authorities for MD (CA meeting).

Whereas many new working groups rise within EU, in which SR is not actively represented

and it is required active cooperation of each member state, it is necessary to solve this problem by personnel measures.

Moreover the section carried out the entry and repeated inspections of wholesale distribution companies following from the Act No.140/1998 Coll. as amended and also inspections required by MH SR.

Regularly we participated at the sessions of the Assembly for Drug and MD Quality.

The Head of Section periodically participated at the sessions of Categorization Commission for medical devices MH SR, from which he was on 1.12.2007 recalled by minister and at the same time on this date he was nominated to Categorization Council for MD at MH SR.

Quality manager of MD Section regularly performed internal quality audits within the quality management system following the standard STN EN ISO 9004/2000.

Survey of the MD Section activity

– number of received forms for the registration of MD	1390
– codes assigned	5035
– notifications on adverse effects of MD	527
– clinical complaints	
– assessment reports for the permission of wholesale distribution activity	8
– entry inspections of wholesale distribution companies	4
– repeated inspections of wholesale distribution companies	4
– announcement on starting of the clinical testing of MD	1

4. Budget of SIDC

Act on the state budget for the year 2007 No.681/2006 Coll. was approved on 12.12.2006. In connection with approved budget the Ministry of Health SR itemized to the Institute through the information system of Exchequer **common expenses for the year 2007 in the volume 129 621 thousand SKK**, hereof wages and salaries 49 696 thousand SKK, insurance and contribution to insurance companies 17 369 thousand SKK, commodities and services 61 500 SKK and common transfers 1 056 thousand SKK.

During the year 2007 several adjustments of budget were realized, during which time the actual budget of common expenses by the end of 2007 was **133 862 thousand SKK.**

Capital expenses for the year 2007 were not itemized on 1.1.2007. After the adjustments performed by budget measures from the side of MF SR was the budget of capital expenses on 31.12.2007 in the volume **4 117 thousand SKK**.

State institute for drug control ensured according to the preliminary data from the information system of Exchequer on 31.12.2007 the following utilization of the budget:

in thousand SKK

Economical classification	Original budget on 1.1.2007	Actual budget on 31.12.2007	Utilization on 31.12. 2007	% utilization
200 Non-taxable incomes	**15 000**	**9 500**	**9 757**	**102,71**
600 Common expenses	**129 621**	**133 862**	**133 860**	**99,99**
hereof:				
610 Wages, salaries	49 696	51 016	51 016	100,00
620 Insurance and contribution to insurance companies	17 369	17 133	17 133	100,00
630 Commodities and services	61 500	65 240	65 238	99,99
640 Common transfers	1 056	473	473	100,00
700 Capital expenses	**0**	**4 117**	**4 117**	**100,00**
hereof:				
Reconstruction of CL Žilina	0	3 707	3 707	100,00
Reconstruction of CL Košice	0	0	0	0
Reconstruction of the object of archive Malacky	0	410	410	100,00

Incomes

The institute obtained in 2007 incomes in the total amount 10 502 thousand SKK, that is in comparison with the adjusted breakdown by 1 002 thousand SKK more. It involves incomes for the provided services, e.g. inspections of pharmacies, attests of medicines, water and fines.

Incomes from registrations totally:		number 120 884 thousand SKK
hereof:		
issuing the decision on registration	609	45 675 thousand SKK
extension of registration	324	16 200 thousand SKK
variation in registration	2 077	41 540 thousand SKK
MRP	252	15 120 thousand SKK
others	252	2 349 thousand SKK
Incomes of institute totally		**131 386 thousand SKK**

Incomes from the registration are not budgeted. Applicants for registration pay the administrative fee, which is through the tax bureau derived to the state budget.

Common expenses

Common expenses in 2007 were utilized according to the budget, which was adjusted by the last budget measurement MH SR to 133 862 thousand SKK. Slight non-utilization of the budget by 2 thousand SKK was by the reason of lower account of the fees in the information system of Exchequer than it was assumed. According to preliminary data on 31.12.2007 the institute itemized unpaid liabilities towards the suppliers in the sum 1 066 thousand SKK. It involves the invoices delivered in the last days of 2007 repayable in January 2008.

Capital expenses

Capital expenses were utilized only for mounted investment actions Reconstruction of CL Žilina and Reconstruction of the object of archive Malacky in total volume 4 117 thousand SKK.

Development of selected budget indicators for the period 2005-2007

	year 2005	year 2006	year 2007
210 Incomes	**7 715**	**9 655**	**10 502**
600 Common expenses	**95 438**	**124 103**	**133 860**
hereof:			
610 Wages and salaries	37 949	49 837	51 016
620 Insurance and contribution to insurance companies	12 724	16 724	17 133
631 Travelling reimbursements	4 995	3 457	3 837
632 Energy, water and communications	6 702	8 712	9 929
633 Material	8 742	14 243	12 372
634 Transporting charges	1 573	1 506	1 849
635 Routine and standard maintenance	2 612	4 757	6 814
636 Rentage for rent	3 482	1 959	4 552
637 Services	15 925	22 364	25 880
700 Capital expenses	**112 172**	**22 109**	**4 117**

Incomes

Incomes of the institute results from the providing of services for fees. In comparison with the year 2006 the incomes were increased by 11 039 thousand SKK, especially because of the increase of the number of registrations, as well as the increase of the inspection activity inland and its extension to abroad. The activity of the institute was intensified also in the recovery of debts.

Travelling reimbursements

78% from total volume of the travelling expenses represent reimbursements for foreign official journeys, which were in 2007 utilized in the volume 3 010 thousand SKK. SIDC actively cooperated with the institutions within the World Health Organization and integration groupings, with the institutions of the Council of Europe, European Pharmacopoeia Commission and others. For the development of these activities the realization of official journeys of institute employees abroad was necessary. Reimbursements for domestic official journeys were utilized in the volume 827 thousand SKK and were connected mainly with the inspection activity.

Capital expenses

On the basis of budget measurement No.1/2007 were according to the Art.8 of the Act No.523/2004 Coll. transferred to the budget year 2007 unutilized resources for capital expenses of the year 2005 and 2006 in the volume 16 177 thousand SKK for the three investment actions:

- Reconstruction of CL Žilina — 3 707 thousand SKK
- Reconstruction of CL Košice — 812 thousand SKK
- Reconstruction of the object of archive Malacky — 11 658 thousand SKK

MH SR increased by the budget measurement the volume of capital expenses for the Reconstruction of the object of archive in Malacky by 1 842 thousand SKK, whereby the budget expenses of this building were covered.

Capital expenses for the realization of the above mentioned actions were utilized only for the building Reconstruction of CL Žilina in the volume 3 707 thousand SKK and Reconstruction of the object of archive in the volume 410 thousand SKK.

5. Personnel policy

Personnel Office standardly provided exercising all of the valid acts on civil service, on exercising the work in public interest, as well as on renumeration of certain employees exercising the work in public interest. The office provided keeping of records and statistics related to the above mentioned activities which are submitted to the Statistical Office of SR, the Ministry of Health and the National Center of Health Information.

We actively participated in organizational changes at the Quality Assessment of Medicines Section and Inspection Section with the aim of increasing the effectivity of their activity. The changes proved effective. Regarding the permanent increase of competencies following from the acts amending and the increasing need of changes with respect to EU legislation SIDC permanently encounter with the lack in number of employees.

During the year 2007 we decreased the number of employees by 9 in two phases in the term of government decree on decreasing of employees in state administration. For the year 2008 the number of establishment posts is 203, consequently we had to proceed to further reduction to fulfill the specified number of employees. At the same time in connection with the government decree No. 1054 from 12.12.2007 on the strategy of the medicines policy to the year 2010 we asked for the increase of the number of employees at the divisions of medicines registration and inspections by 10 employees with the relevant financial resources, material and technical equipment.

Number and structure of SIDC employees

Determined limit of employees for the year 2007	**223**
Adjustment – I. phase of decreasing in I.half 2007	-6
Adjustment – II. phase of decreasing in II.half 2007	-3
Limit of employees for the year 2007	**214**

Employees fluctuation

During the year 2007 the labour relation or civil service relation was terminated with 38 employees

and 29 employees entered the job. Fluctuation is represented by 67 employees, that means 31,3% of the original number 214 employees.

Average salary including off-budget resources

Civil service	**average salary**	**27 221,-SKK**
Public interest	**average salary**	**16 265,-SKK**
Totally	**average salary**	**20 735,-SKK**

Selection procedures

In 2007 totally there were put 24 selection procedures for occupation of 26 free civil service posts.

Totally to selection procedures applied 50 candidates, thereof in selection procedure participated 30 candidates.20 applicants were successful and 16 successful applicants were appointed to civil service. Many selection procedures were repeated because the participants did not register, resp. the registered participants did not fulfill the conditions.

Training of employees

Like every year at the Service Office there was compiled the Training plan of state employees for the year 2007, where they were trained in the form of internal seminars. Employees are trained in external form, too.

At the second half 2007 there was ensured the teaching of English language in the own space. The course was performed in 4 groups, depending on the level of language knowledge and the need of language for the performing of job. Totally 58 employees were integrated to the course.

6. Aims and overview of their fulfillment

We intensified the participation of the state institute in the cooperation of European medicines agencies network, with the priority focus on the mutual recognition procedure, decentralized procedure and activity in the coordination group. In three procedures we figured as a reference member state, we actively participated in the work of Coordination group, CMDh and the Committee for herbal medicines, HMPC as coordinators in the preparation of documents, rapporteurs and delegates in other working groups (CHMP Working group for cooperation with the organizations of patients and customers, PCWP).

We continued the work in the rational implementation of the requirements of the Act No. 342/2006 Coll. (amendment of the act on medicines) in the field of medicines registration, especially in the patent issue.

We improved the effectivity of administration of registration documentation reception and its further flow to assessors internal and external. Electronic assigning of registration numbers and payment automation are in the phase of testing before implementation. We support the reception of documentation by post.

Remaining backlog in the applications processing was significantly decreased

Quality procedures of applications assessment in SR according to EU procedures we have ensured by training (six months twinning project), by control and individual guidance of new workers.

We supported the activity of Commission for human medicines so that it could provide quality opinions for national decisions on registration of medicinal product in exacting time frame of EU procedures. We introduced the system peer review, systematically for CMDh referrals.

Within the deepening of work quality we identified the need of reorganization of Registration Section. We prepared and discussed possible models with the workers.

7. Target groups

External SIDC clients are:

a) Patients
b) Legal persons (pharmaceutical manufacturers, medical devices manufacturers, distributors of medicinal products and medical devices)
c) Physical persons (pharmacies, dispensaries of medical devices)
d) Applicants for clinical testing
e) Others (e.g. applicants for information, applicants for authorization)

Services provided to the clients:

- issuing of decisions on registration of medicinal products
- issuing of opinions on the material, space and personnel equipment to the applicant for permission on handling with medicinal products
- keeping a register of medical devices manufacturers and a list of MD put on the market in SR
- issuing of permissions for clinical testing
- realization of entry inspections for pharmacies and dispensaries of medical devices

SIDC outputs are designed for and used by the Ministry of Health SR and wide range of users, especially 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 the general public.

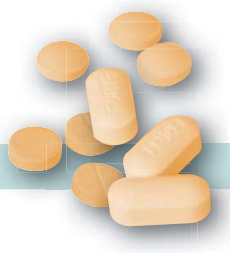
The specialized advisory services and consultancy in the field of registration of medicinal products and medical devices, issues related to Slovak Pharmacopoeia and Slovak Pharmaceutical Code and other specialized services are provided by the particular sections and departments of SIDC.

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 public. The reports inform about non-compliant preparations and the measures resulting from it, eventually about products consequently released for medical use.

Electronic form of output is represented by the database of registered medicinal products being used especially by the Ministry of Health SR and health insurance companies. Partial outputs from the mentioned database are provided to the applicants for the registration and to the Ministry of Finance SR for the purpose of pricing of medicines.

8. Publication of the Annual Report

Publication of the Annual Report is realized in two ways, by written form in Slovak and English language, which are delivered to the founder, i.e. MH SR, Slovak Medical University and to the other domestic and foreign interested institutions. The second way is the publication at the SIDC webpage – www.sukl.sk .



Annex 1:

OVERVIEW OF ANALYTICAL CERTIFICATES AND SAMPLES

Total number of analytical certificates accepted **380**
Total number of applications for registration and variation in registration accepted **2.230**
Total number of accepted preparations submitted for updating according to G 5/2002 **0,**
Total number of samples accepted for laboratory testing **649**
Total number of registered PTS, CS – international tests **9**

Analytical certificates	Complying	Non-complying	Pending	TOTAL
Imported medicines	279	14	107	400
Domestic producers	0	0	0	0
TOTAL	**279**	**14**	**107**	**400**
Samples assessed by laboratory testing	**Complying**	**Non-complying**	**Pending**	**TOTAL**
Imported medicines	107	0	54	**161**
Samples assessed by laboratory testing	**Complying**	**Non-complying**	**Pending**	**TOTAL**
MIS*, Pharmacies	459	49	54	562
IMUNA PHARM HOLDING, Inc.	9	0	0	9
ZENTIVA, Inc.	0	0	0	0
CHIRANA T. INJECTA, Inc.	0	0	0	0
VULM, Inc.	0	0	0	0
Clinical complaint	11	0	3	14
Starting substances	2	0	0	2
Complaints	5	3	0	8
GALVEX, Ltd.	2	1	0	3
EL, Ltd. S.N.Ves	0	0	0	0
Clinical batch	0	0	0	0
Other companies	10	0	6	16
Center for Drug Dependences	0	0	0	0
Attests	0	0	0	0
UP – G 5/2002	0	0	0	0
PTS, CS tests	9	0	1	10
Internal testing	13	3	1	17
TOTAL	**520**	**56**	**65**	**641**

*MIS (Manufacture of infusion solutions)

Annex 2:

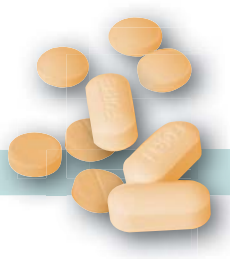
OVERVIEW OF INSPECTIONS AND SAMPLES TAKING AT GPhP DEPARTMENT IN 2007

Medical facilities	Inspections	Number
Public pharmacies	Entry inspections Act No. 140/1998, 139/1998, 331/2005 Targeted inspections Concurrent–obligatory inspections Taking of samples	**230** **48** **345** **303**
Branches of public pharmacies	Entry inspections Act No. 140/1998, 139/1998, 331/2005 Concurrent-obligatory inspections Taking of samples	**29** **21** **5**
Hospital pharmacies	Entry inspections Act No. 140/1998, 139/1998, 331/2005 Concurrent-obligatory inspections Taking of samples	**2** **5** **6**
Dispensaries of medical devices	Entry inspections Act No. 140/1998 Concurrent-obligatory inspections	**23** **5**
Distribution organizations	Entry inspections Act No. 140/1998, 139/1998, 331/2005 Concurrent-obligatory inspections Targeted inspections	**10** **4** **1**
Opticians	Entry inspections	**38**
Other facilities RZS,RLS,Medical jurisprudence,Hospice, Children Faculty Hospital, Center for Drug Dependences, Hospital with Policlinic	Entry inspections Act No. 139/1998, 331/2005 Targeted inspections	**34** **3**
HAMELN rds Ltd. Modra	Taking of samples	**2**
Poppy producers	Entry inspections	**14**
	Inspections	**812**
TOTAL	**Taking of samples**	**316**

List of Abbreviations

AMS	Association of the Medicines Suppliers
WS&HP	Work safety & Health protection
CAP	Centrally Authorized Products
CE	Full Quality System / Complex system of quality assurance assigned and certified by European testing room (Notify Body)
CMS	Concerned Member State
CD	Civil deference
CP	Centralized Procedure
CRF	record cards
CS	Collaborative studies
CTD	Common Technical Document
EDQM	European Directorate for the Quality of Medicines
EC	European Commission
EMEA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
GLP	Good Laboratory Practice
IG	internal guideline
CL	Control laboratory
ML	maternity leave
MF SR	Ministry of Finance SR
ME SR	Ministry of Economy SR
MHRA	Medicines and Healthcare products Regulatory Agency (London)
MLSS&F	Ministry of Labor, Social Security and Family
QM	Quality Management
MRP	Mutual Recognition Procedure
MHA SR	Ministry of Home Affairs SR
MH SR	Ministry of Health SR
DO	District Office
OECD	Organisation for Economic Co-operation and Development
NS	narcotic substances
OMCL	European network of Official Medicines Control Laboratories
FP	Fire protection
ID	Internal Directive
Ph.Eur.	Pharmacopoeia Europaea
PIC/S	Pharmaceutical Inspection Convention/ Scheme
PIL	Patient Information Leaflet
PS	psychotropic substances
QRD	Quality Review Documents
CD	Controlled document
PR&C	Public Relations & Communication
SAPhS	Slovak Association of pharmaceutical Societies
SIDC	State Institute for Drug Control

GCP	Good Clinical Practice
GPhP	Good Pharmacy Practice
GLP	Good Laboratory Practice
SNAS	Slovak National Accreditation Service
SPC	Summary of Product Characteristic
QAMS	Quality Assessment of Medicines Section
SR	Slovak Republic
STN EN ISO	Slovak Technical Norm
GMP	Good Manufacturing Practice
SZO	World Health Organization
SMD	Section of Medical Devices
SHU	Slovak Health University
SOP	Standard Operating Procedure
HSO	Head of Service Office
WHO	World Health Organization
MD	Medical device



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