2007

ANNUAL REPORT

On the activities of the Institute for State Control of Veterinary Biologicals and Medicaments in Brno

Basic information about ISCVBM, position of ISCVBM

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CONTENT **page**

Introduction

Institute for State Control of Veterinary Biologicals and Medicaments lay before the general and scientific public, governing bodies and in terms of administered quality assurance system and clients and partners its Annual report with a view to inform all these subject about activities which are ensured by the Institute not only within the Czech Republic, where is naturally a center of its interest and operation, but also in international domain which is concerning involvement of Czech republic into international acitivities and concerning the nature and structure of pharmaceutical control system more remarkable.
From submitted report the accrument of general claims posed to the Institute and the growth of scientific claims put before the activity of Institute has to be apparent. In spite of the claim accrument the Institute is confronted by the political development in the Czech Republic, namely in relation to measures aimed at slenderizing machinery of state administration and further by the development of economic situation in CR, here namely in relation to decreasing rate of unemployment, increasing demand for qualified manpower and increasing wages in business branch which is for the sphere of state administration still more serious competitor in the matter of rivalship relating to human resources.
It is necessary to say that despite of all difficulties, which government´s economy measures bring to the Institute, the ISCVBM understands these measures and it adopted approaches in 2007 which fully met demands of Ministry of Agriculture in this matter. This measures coerce the Institute to considerations and to take its own measures in the sphere of structure of the Institute, effective exploitation of employees, increases in professional and administrative qualification of employees, growth of labour productivity, major expoitation of modern information and communication technologies and facilities, curtail an activities which are realized by the Institure ultra vires the responsibilities provided by the law as is e.g. issue relating to the assessment of biocides, and finally despite of the all accompanying difficulties, to further cooperation starting with other authorities or institutions as well. From these views it is possible to perceive government´s measures as a stimulant and contributive.
Nevertheless, the Institute has to emphasise in this phase that if the range of activities required by the regulations and by control mechanisms should be kept as they are currently set in the sphere of medicinal products within the EU, it is not possible to realize further economy measures without solid analysis of procedures and needs in future.
Concerning acivities of the Institute in connection with EU, nowadays it is not already possible to realize the tasks given to the Institute from sources, which are available for the Institute from the state budget. Extra budget resources have the essential influence on maintenance and development of special acitivities of the Institute. The Institute obtains these resources as a cost compensations for activities carried out by request in compliance with Medicine Act. It is possible to suppose, that the importance of these resources will encrease during oncoming period. The system of extra budget exploitation enables e.g. flexible manpower exploitation, opens the motivation possibilities for employees of the Institute and allows to respond to changing requirements – consequently changing numbers of submitted applications. Implementation of effective system of external experts exploitation remains down to full exploitation of these advantages, which is one of spheres that the Institute will have to be concerned with during the oncoming period.

I trust that the Institute remained fair and responsible partner for its customers and partners all the year 2007 round and it was possible to reckon on all its activities. I would like to make all concerned parties sure that your satifaction with our work is my principal priority.
Prof. MVDr. Alfred Hera, CSc.
Director

1. The quality assurance system and organisation structure of the Institute

Regarding steps ordered by Ministry of Agriculture the Institute accepted organizing arrangements and altered its organisation structure in compliance with its organisation manual at the end of the year 2007. (see Annex No. 1)

2. Activities and active co-operation with national, european and other international organisations

HMA

Among the most important spheres of international co-operation in which the Institute is involved belongs HMA Meeting (HMA – Heads of Medicines Agencies – www.hma.eu).

The meeting is organised by the presidential country and it take place twice during every presidency.

The main objective of the meeting is preparation and solution of conceptual questions in the sphere of VMP regulation, searching for answers and solutions concerning actual problems in VMP regulation, procedure harmonisations of member states, dialogue with concerned parties and other.

During the year 2007 the attention was focused on solving of following spheres:

- Functioning of Coordination Group for Mutual Recognition and Decentralised Procedures with a view to ensure
  - smooth start of recently implemented decentralised procedure
  - solving conflictful positions leading to arbitrations abreast Committee for Medicinal Products for Veterinary Use (CVMP)
  - solving problems of border preparations including biocides
  - solving problems of package labelling
- work-sharing in the sphere of pharmacovigilance – problems of PSURs assessment
- inspectional and supervisory activity in the sphere of VMP counterfeits
- the quality assurance systems and benchmarking exercise of medicines agencies
- some practical questions linked with marketing authorisation of VMP – problems regarding conditions of vaccine diluent marketing

The Council – Working party for veterinary experts – public health

In the first half-year of 2007 and from the half year 2007 experts from the Institute (Dr. Pokludová, Rejtharová MSc, Dr. Bureš) were participating actively and regularly together with State Veterinary Administration deputies in meetings of Working Party for Veterinary Experts – Public Health (F 21.a), where new legislative regulation suggestions were discussed namely the proposal of EP regulation relating to EC approach to residue limit determination of pharmacologically active substances in food of animal origin and annulling the regulation No. 2377/90/EC and further the proposal of Directive of the European Parliament and of the Council, which amended the Directive 96/22/EC on prohibition of some substances with hormonal or thyreostatic use and beta-agonists in the animal husbandry. The proposal of Directive 96/22/EC amendment was in terms of special group closed and passed on for approval by parliamentary mechanism. Negotiations relating to proposal of regulation supplying the present regulation No. 2377/90/EC will also continue in 2008 and employees of

the Institute regularly prepare the opinions sent on behalf of the Czech Republic to Secretariat of the Council and representing actual positions to submitted proposals.

3.1 Preparing and amending of legal provisions

Year 2007 brought considerable demands on the Institute activity in the sphere of suggestions and opionions preparing and new legislation remarking namely new Medicine Act and its implementing regulations.

Since the beginning of 2007 new Medicine Act had been progressively approved on the level of Czech government and consequently it was submitted to Chamber of Deputies of CR Parliament for discussion. In terms of new Medicine Act draft discussion on the level of government the number of important changes was made. It was equal with terms of discussion in Chamber of Deputies. Athought most of changes were related to human medicinal products, some important changes were made even in regulations managing the sphere of veterinary medicinal products.

In consideration of progress in a new Medicine Act proposal discussion the Institute in cooperation with State Institute for Drug Control prepared proposals of implementing legal regulations, namely these decrees proposals (remark: These are not exact name quotations, but factual definition of implementing legal regulations):

- decree regarding using of pharmaceuticals when the veterinary care is provided; recently includes the conditions relating to import of the VMP authorised in other EU countries and not authorised in CR
- decree regarding marketing authorisation of VMP
- good clinical practice decree
- decree regarding reimbursement range of professional operations provided by the State Institute for Drug Control and ISCVBM
- good manufacturing and distributions practice decree
- good pharmaceutical practice decree
- decree regarding VMP prescription which newly with reference to provision of VMP Distribution Act towards breeder determines the groups of VMP which can not be prescribed by veterinarians ad hoc
- decree regarding GDP of designated VMP
- decree regarding registry of active ingredients and excipients which can be used for VMP preparation

2.1 Ministry of Agriculture, State Veterinary Administration and other parters of the Istitute in the CR

3.2.1 Ministry of Agriculture

During 2007 the Institute and Ministry of Agriculture (MA) were cooperating intensively on the preparation of legislation – namely on Medicine Act preparation and its implementing regulations.

The Institure was preparing opinions and suggestions for Ministry of Agriculture in the terms of draft law discussing both on the level of government and on the level of discussion by Parliament.

Simultaneously the Institute prepared for the Ministry of Agriculture suggestions for new implementing decrees, including the decree passed by the Ministry of Agriculture itself and where questions of using pharmaceuticals when the veterinary care is provided, records of VMP use, release and prescription, problems with substances and preparations treatment (notices and records of moving tracked substances and preparations), conditions for guest veterinary surgeons and finally conditions for distribution of medicinal products authorised in other member state, which can recently be used in terms of „cascade“ even with veterinary care provision in CR.

Next sphere which pertained to preferred domains of professional cooperation with Ministry of Agriculture was the preparation for control system in Cross compliance (C-C) mode. In 2007 in terms of preliminary activities coordinated by MA the plan for control provision according to Directive 96/22/EC, which will be realised both by the Institute, regarding limited capacity of the Institute, and by Regional Veterinary Administrations. Background papers for informational interface creation between the Ministry and State Veterinary Administration/ Institute were prepared.

In 2007 pursuant to Ministry requirements provisions regarding the number of employees reduction were realised at the Institute. Pursuant to Ministry instruction the Institute was obliged to drop the number of employees by 6 persons and further to decrease the current capital expences by 10% till March 2008.Over all accompanying difficulties these steps were fully realized by the Institute.

The next domain in which the cooperation between the Institute and the Ministry took place was the preparation for the presidency. The Institute frequently prepared and submitted to the Ministry the schedule of activities which the Czech republic will have to ensure in terms of the presidency of the Council so that the Ministry will be informed in advance. In compliance with submitted information it will namely deal with necessity to ensure in terms of presidency two meetings with Heads of Medicines Agencies, which will be organised in conjunction with Ministry of Health department and Ministry of Agriculture department and informal meeting of CVMP and CMDv.

Committee on Genetically Modified Organisms and Products Treatment in the Department of Ministry of Agriculture

GMO Committee was established as a advisory body of Ministry of Agriculture and it participates on the preparation and examination in sponsorship of plant commodities department in the sphere of GMO utilization in agriculture.
Pursuant to submitted documentation the GMO committee assessed applications for GMO release into environment, eventually into circulation and announcements of reserved GMO treatment and rendered opinions to it.
During the year 2007 the Committee statute and rules of procedure were restored because the updating was needed from both formal and relevant point of view. Commissioners also suggested the Ministry of Agriculture opinion proposal to GMO problems and participated on its final formulation. The opinion regarding exploitation of resistance against antibiotics genes in transgenic materials was processed for Scientific Committee for Genetically Modified Food and Feedingstuff (npt II).
Committee was expressing its opinion of proposed changes in the provision of Agriculture Act No. 252/1997 Coll. as amended by the subsequent acts regarding GMO crops cultivation. Actual problems regarding GMO were also discussed.
Also from now on the quality, safety and efficacy of genetically modified VMPs are supported by European Medicines Agency (EMEA) by the regime of „Centralised procedure“ and GMO identification is ensured by State Veterinary Institute Jihlava.
One employee from the Institute works in the Comittee.

3.2.2 State Veterinary Administration and Regional Veterinary Administrations

Regarding cooperation with State Veterinary Administration the year 2007 can be characterised as a year of preparation for controls realization in terms of Cross-Compliance system, as they are required according to regulation 1782/2003.

Institute for State Control of Veterinary Biologicals and Medicaments is responsible for preparation of demand control methodics as stated in the Directive 96/22/EEC, as amended by the subsequent regulations. Hence except the control methodics the submission for information connection provision of State Veterinary Administration, ISCVBM and Ministry of Agriculture was prepared in terms of on-coming informational system. Proper realization of informational system project will realize during the year 2008.

In 2008 the ISCVBM counts with the provision of workshop for Regional Veterinary Administrations aimed at problems of demand control as stated in the Directive 96/22/EEC and control according to new Medicine Act, which expands competences of State Veterinary Administration and Regional Veterinary Administrations.

In 2007 the cooperation between ISCVBM and State Veterinary Administration was proceeded among others in the sphere of legal regulations preparation and suggestions, in the sphere of organizational steps and in a number of special issues.

Regarding special issues, it is essential to emphasize namely monitoring of extraneous substances residues and especially collaboration in the sphere of investigation of chloramphenicol residues finding exceeding the limit in live animals and animal products and furhter questions associated with safety and efficacy of VMP (vaccines). Object of information exchange among ISCVBM and State Veterinary Administration/Regional Veterinary Administrations was – traditionally again – also question regarding mass medication.

On January 2007 the ISCVBM organized meeting with SVA/RVA themed check on medicaments application, mass medication and medicated feedingstuff manufacturing.

The next scientific issue at what the Institute and State Veterinary Administration were cooperating in 2007 was the problem related to residues of anticoccidic – nicarbazine – in eggs. The Institute prepared for State Veterinary Administration skilled perspectives namely both issues concerning toxicological assessment of nicarbazine residues and approach of selected member states to this matter. Discussion ended in the common proceedings of SVA deputies, Central Institute for Supervising and Testing in Agriculture deputies and deputies of ISCVBM and in participation of this supplementary ingredient manufacturer deputies and feedingstuff manufacturer deputies. The conclusion of this discussion was that in present state of legal regulations it is not possible to set the national limits for measures and that in the area of feedingstuff manufacturers and layer breeders it is necessary to take such measures, by which will be guaranteed, that nicarbazine residues which appears in the feedingstuffs for layers due to residues transfer from mixtures made on manufacturing line before them, will be on such a level which will ensure that in eggs there will be no residues which would be determinable by analytical methods that are validated and fulfill the standards of concerned EC reference laboratory for nicarbazine residues determination in eggs. This conclusion will be revised in connection with findings of EFSA which as expected will publish the opinion to nicarbazine residues transfer in feedingstuff manufactory as in case of lasalocide and narasine substances.

3.2.3 State Institute for Drug Control

The cooperation between ISCVBM and State Institute for Drug Control (SIDC) was proceeded – as in former times – in quite a number of spheres.

Regarding exacting requirements related to legislative operations in second halfyear of 2007 the most intense cooperation was in progress just at this sphere. Except opinions formulation regarding perspectives and conceptions in the sphere of drug regulation which should reflect in legal regulations administering this area, the collaboration in the sphere of factual suggestions and opinions preparation related to both Medicine Act proposal during its approval process in individual levels and implementing legal relulations preparation.

The next area of cooperation which is essential to emphasize in SIDC-ISCVBM relationship was the cooperation in the sphere of Heads of Medicines Agencies Meeting.

Further is necessary to mention cooperation in the sphere of Pharmacopoeial Committee activity, collaboration in the drug laboratory control area, information exchange relating legal questions concerning Medicine Act and the preparation for CR presidency of the Council, when the the collaboration issue of both institutions will be needful.

Finally, the Institute coupled with ISCVBM participated in organization of OMCL (Official Medicines Control Laboratories) annual session.

Cooperation was further proceeded also on technical level. Within the cooperation with State Institute for Drug Control there were exercised two controls over the good manufacturing practice sphere, together with SIDC the ISCVBM Guidelines were elaborated in connection with the reformatting of manufacturing permisson and GMP certificate and further EUDRA GMP database loading.

With SIDC there were 6 controls exercised over the GDP sphere.

3.2.4 Central Institute for Supervising and Testing in Agriculture

The cooperation with Central Institute for Supervising and Testing in Agriculture (CISTA) proceeded in 2007 within well-established connections of both institutions when the cooperation took place namely with the feedingstuff department of CISTA.

The subject which required special attention of both institutions was the foreign preparations and their organising from the regulation requirement acpects. This issue was solved on the common session of ISCVBM and CISTA deputies. On the basis of this session the decission tree for classification of individual product types was elaborated.

Then with this issue a number of factual communications came through between the Institute and CISTA during the year 2007.

On April 2007 the seminary was organized by ČMSOZZN (Association of Organisations for Agriculture Supply and Marketing in Bohemia and Moravia) with attendance of medicated feedingstuff manufacturer deputies and CISTA deputies. The issue related to „farm“ manufacturers of medicated feedingstuffs was discussed on this seminary.

The next activity very important in principle in which both institutes met in 2007 was the issue related to supplementary substance nicarbazine in eggs. SVA of CR organised the workshop related to this issue in November 2007 whose deputies of following institutions participated: CISTA, ISCVBM, ELANCO company, which is a manufacturer of this supplementary substance and feedingstuff manufacturers deputies. (see also section 3.2.2).

3.2.5 Ministry of Health

Pharmacopoeia Committee – activities of the Institute for Pharmacopoeia in 2007

In 2007 the ISCVBM participated in pharmacopoeial activity in accordance with duties which are administered by Medicine Act.
Among these main tasks pertained the participation in activities of Pharmacopoeia Committee of the Ministry of Health CR (Prof. A. Hera DVM PhD as a vicechairman and as members Prof. Šimůnek DVM and J. Jeřábková DVM afterwards) and the Veterinary Imunologicals and Pharmaceuticals Section activities and the Expert Group of European Pharmacopoeia Committee activities (J. Jeřábková DVM).
In the year 2007 analogous to previous years the crux of the work consisted in the translation and translation revisions of the articles and sections designed for the new Pharmacopoeia Bohemica impression – Addendum 2007.

The pharmacopoeial activity was mediated and coordinated by the ISCVBM Veterinary Imunologicals and Pharmaceuticals Section of Pharmacopoeia Committee. The ISCVBM is official administrative place of the Pharmacopoeia Committee of the Ministry of Health CR. The Institute ensured its leadership by the employee on parcial duty which was as external employee Prof. Šimůnek DVM, and hereafter J. Jeřábková DVM as a ISCVBM employee and head of pharmacopoeia department on ISCVBM got a commission. In the ISCVBM Veterinary Imunologicals and Pharmaceuticals Section of Pharmacopoeia Committee of MH

CR 6 employees were working in 2007 and 9 other members from other workplaces, the total number of members was 15 in 2007.
The external employee considerably took part on translations and translation revisions of the pharmacopoeial articles with which the Institute made a work contract.
J. Jeřábková DVM as a member of the Expert Group of European Pharmacopoeia Comittee took active part in this Committee including the participation in negotiations in Strasbourg.
Another employee of the Institute - J. Maxa, PharmDr., PhD joined the Expert Group of European Pharmacopoeia Committee in November 2007.
D. Pivodova DVM, the head of Laboratory Control Section remains the member of Antibiotic Section of Pharmacopoeia Committee of MH CR.

3.2.6 Chamber of Veterinary Surgeons of the Czech Republic

The cooperation of the Institute with Veterinary Chamber in 2007 consisted namely in notifying of new Medicine Act preparation. The Institute informed the veterinary community within accompanying programme along the Veterinary Chamber Congress and traditionally again the Institute deputy took part in periodic seminars organised by Veterinary Chamber in several CR regions.

The Institute further published the information from the veterinary pharmaceutical sphere in the Veterinary Chamber Bulletin.

3.2.7 Central Committee for Animal Protection

The activity of Expert Committee for Animal Protection

During the 2007 the Committee was ensuring all the activity of the ISCVBM experimental plant provided by the act related to protection against animal tortment No. 246/1992 Coll. as amended.
The Expert Committee expressed its opinion of four experimental projects with examination of aims, study benefits, methodics and animal care provision in compliance with the law. Persuant to data stated in the experimental project the Expert Committee approved the performance of all submitted experiments.

1/2007	Safety assessment of autogenous vaccines in terms of undesirable, extraneous contamination
2/2007	Efficacy, safety and contribution to animal production efficiency evaluation of IMPROVAC, VMP used in boars
3/2007	Study of chloramphenicol kinetics
4/2007	Efficacy evaluation of live vaccines used for Newcastle disease imunoprophylaxis

Regarding experiment 4/2007 submission at the end of year 2007, in the meantime only the experiments 1/07, 2/07, 3/07 have been approved by the relevant state agency although in project of experiment 04/07 the positive opinion is expected as well.
The Expert Committee has 5 members, one employee was replaced this year. Ten ISCVBM employees has qualification provided by law according to article 17 of the act No. 246/1992 Coll. related to protection against animal tortment and 6 employees passed the required course for laboratory assisstents, technicians and tenders, re-examination of professional qualifications regarding animal maintainance, also provided by the law.

The committee checked the approved experiment process, checked and ensured welfare of tested animals and checked and ensured required data records.
In the control investigation protocol there was no fault detected by governing body i.e. Regional Veterinary Administration inspectorate for South Moravia region (from day 23. 5. 2007).
Welfare of experimental animals after attended time was again ensured by trained and professional employees from the Institute.
The Summary Report for civil year was elaborated by the Committee including statistical tables for the Ministry of Agriculture. The numbers of used experimental animals in 2007 had upward trend in comparison with the last year, which was caused especially by the standartisation of the test for antirabies vaccines efficacy.

Numbers of used animals:

Animal category	Year 2006	Year 2007
mice	1310	3949
guinea pigs	17	12
rabbits	22	7
birds	109	4
dogs	9	-
cats	4	-
Total	**1471**	**3972**

The disposal of cadavers and contaminated materials after finishing the experiments is ensured by contract with these companies – AGRIS s.r.o. Medlov and SITA Brno.

3.3 EU organisations and other foreign partners

3.3.1 European Medicines Agency (EMEA)

European Medicines Agency steadily belongs to the most important partners of the Institute. Except the particular technical guidelines administering the claims on submitted documentation with applications for marketing authorisation of the VMP the Agency and her scientific committees, working parties and other working formations prepares number of fundamental policies, positions, opinions and rules, which makes provisions for conditions of VMP marketing authorisation in all EC. Lately the importance of the Agency increases not only as a body coordinating the activities of national medicines agencies, but the regulation No. 726/2004/EC gives to the Agency a number of specific tasks and thus the EMEA undertakes a number of active tasks, e.g. it is the central administration place of entire VMP adverse effects reporting in EC (Eurdra Vigilance system), administers the database of all human and veterinary medicinal products authorised in EC (EudraPharm project), keeps the records of all GMP certificates issued by inspectorates of member states (project EudraGMP database).

Beyond that development the main responsibility for special opinions formulation remains on the medicines agencies of member states. Active approach to work within the framwork of EMEA is therefore permanent priority for the Institute.

Activity in the Scientific Committe of the EMEA and its Working parties

Committee for Veterinary Medicinal Products (CVMP) sessions are held once a month. In 2007 the CVMP sat eleven-times (the Committee did not sat on August).

The CVMP was dicussing 8 marketing authorisation applications of VMP and 3 applications regarding MRL determination for pharmacologically active substances contained in VMP.
Further sphere of activity ensured by the CVMP which lately gains the importance considerably is the sphere of special opinion formulation in the scope of so called referral procedure. In 2007 the CVMP formulated the opinion in 7 cases.

The Czech Republic participates actively in the CVMP activities. Prof. Hera worked as a co-rapporteur, i.e. ensured the special assessment of applications for MRL determination of lectin isolated from red beans.

Except the centralised procedure applications approving and MRL determination applications the activity of the CVMP consists in coordination of regulatory activities within the whole EC and in preparation of particular guidelines in the sphere of VMP quality, safety and efficacy and pharmacovigilance. The proposals of these guidelines are elaborated by individual working parties of Committee (see below).

The following documents and regulatory guideline were prepared by the Committee and consequently published in 2007:

- Reflection paper – the use of the 3rd and 4th generation cephalosporins in food animals in EC. Resistency development and impact on human and animal health.
- Revised requirements on SPC of antimicrobial preparations.

- Reflection paper – the assessment of adujvants and preserving agents according to regulation No. 2377/90/EC
- The guideline concerning requirements on MA dossier of oncological VMP
- Guideline concerning VMP risk and benefit evaluation
- Guideline concerning Environmental Risk Assessment of VMP
- Revised requirements on SPC of anthelmintics
- Other guidelines in the sphere of VMP quality, safety and efficacy, pharmacovigilance and more general format documents

Joint CHMP/CVMP Quality working party (QWP)

Joint CHMP/CVMP Quality working party (QWP) is concerned with the quality of human and veterinary medicinal products met four times in 2007 (from that one meeting was shared with GMP working party and one meeting with industry deputies). Within the scope of working party the revisions of current guidelines were discussed relating to VMP quality, new guidelines elaboration, cooperation QWP with EDQM, ICH and VICH and solving of quality problems in specific preparations mainly authorised by centralised procedure.
In the sphere of VMP quality the revision of guideline relating to stability studies and the development of new guideline relating to spon-on preparations. Together with other working parties (SWP(v) and EWP(v)) the preparation of guideline on oncological preparations and the revision of guideline relating to bioequivalence studies requirements.

Safety Working Party

Working party for safety and residues of VMP meets regularly four times a year. The working party is focused on safety problems solving and its task is firstly the preparation of guidelines on authorisation of VMP intended for food animals, further preparing of opinions and comments for CVMP and also discussion of special VMP safety issues.
In the year 2007 the following guidelines were solved and prepared:
- Guideline on alternative limits for MRL determination
- Guideline on assessment whether the substance is pharmacologically active
- Guideline on pharmacological/pharmacokinetic data assessment regarding the pharmacological ADI determination
- Documentation requirements in oncological preparations
- Revision of guideline on microbiological ADI determination
- Revision of guideline on bioequivalency

Problems of VICH guideline proposals were commented relating to metabolism and kinetics assessment study for residues of VMP intended for food animals.

The following problems were discussed :
- Alternative reference limits and exposure assessment (TTC, ARfD)
- Injection site residue assessment
- New data relevant for assessment of amoxicillin safety factor
- User Safety Assessment guideline
- New template for MRL Summary Reports
- The carcinogenity of N-methylpyrollidone (NMP)
- Faecal binding studies

SWP also prepared the background papers for Codex Alimentarius session and informed about the conclusions from the 17th session of Codex Committee on Residues of Veterinary Drugs in Foods.

Efficacy Working Party

The working party works on elaboration of new guidelines for the efficacy substantiation, its suggesting and implementation. Cooperates with other working parties on common issues. In the year 2007 the EWP met four times in two days meetings where the following actual problems were solved:

- Revision of guideline on pharmaceutical fixed combination products, the guideline was implemented on June 2007
- Discussion of guideline proposal relating to prudent use of anthelmintics concerning possible resistance occurance and to guideline on SPC in anthelmintics, which was implemented on February 2008
- Discussion of guideline proposal on documentation requirements in oncological preparations
- Discussion of guideline proposal on documentation requirements in bibliographic applications
- Discussion of guideline proposal relating to alternative tests made on animals
- Discussion of guideline proposal relating to VMP efficacy in aquacultures
- Revision of guideline on efficacy testing and assessment of antiparasitic substances intended to treatment flea and tick infestations in dogs and cats
- Revision of guideline on SPC for pharmaceuticals
- Revision of guideline on Bioequivalency studies for VMP
- Implementation of guideline on MUMS in January 2007

Immunological Working Party

The working party met three times in the year 2004. J. Jeřábková DVM took part in the IWP negotiations on behalf of the Institute.
The following current problems were solved in IWP negotiations:

- The guideline on imunological VMP requirements intended for MUMS was finalised
- The guideline on the safe use of imunological VMP was finalized
- The proposal for guideline relating to registration documentation requirements for more vaccination strains was prepared, the working party was established which will continue on elaborating of this guideline
- the guideline relating to the necessity of required data proving the impact of maternal antibodies on very young animals vaccination was prepared and discussed
- working on the guideline „The preparation of master seeds to replace established master seeds already used in authorised immunological VMP.“ was proceeded
- the revision of guideline relating to attainment of veterinary vaccines conformity with corresponding to European Pharmacopoeia monographs was approved
- the working on VICH guideline continues: Safety test of live and inactivated vaccines in target species of animals
- the working on VICH guideline continues: Safety test in target animals, live vaccines testing for virulence recovery absence in target animals

Pharmacovigilance Working Party

Pharmacovigilance Working Party worked with new mandate in 2007 which was approved at the turn of 2006/2007 and which means that except the opinion preparations relating to VMP and resposibility concerning CVMP the Pharmacovigilance Working Party is also resposible for HMA concerns and also prepares the opinions on questions of VMP authorised by other procedures.
Thus the most considerable activity in 2007 was the issue relating to cooperation of medicine agencies on periodic safery update reports (PSURs) assessment – „PSUR work sharing. During the year 2007 the Pharmacovigilance Working Party together with European Surveillance Strategy Group (ESS) which works under the HMA, were preparing conceptual documents and rule outline according to which the cooperation should be realised.
In year 2007 the working meetings on this subject with industry were held, the list of active ingredients was prepared, which should be the subject of the pilot phase of the project and the list of marketing authorisation holders was prepared. The pilot phase will be initiated at the beginning of the year 2008 and the phase should pass on into the standard mode.

Further the Pharmacovigilance Working Party prepared in 2007 the guideline by which the PSUR assessment by medicinal agencies is administered, prepared number of opinions to the actual pharmacovigilant issues (including issues circulated by RAS system and NUIS system).
Finally the Pharmacovigilance Working Party was concerned with the preparation of EudraVigilance data analysis and signal detection from the data included in this electronic database of adverse effect reporting which is administered by EMEA.

Environmental Risk Assessment Working Party (formerly ad hoc)

The party works on the elaboration of new guideline relating to ERA approach simplification, provides specialists for specific issues associated with environmental risk assessment of VMP in actual way of using, cooperates with other working groups in common topics. It cooperates with OECD and SETAC. ERA Working Party meets irregularly, three meeting were held in 2007 and the following actual issues were solved:
- explanatory guideline for easier use of GL 6 and GL38 VICH guidelines on environmental risk assessment
- the possibility of individual active ingredient monograph elaboration that would describe the risk of its use
- in cooperation with EMEA and European Commission it elaborates the interpretation of ERA solutions for various types marketing authorisation applications, according to actual legislation rules

- the point of view on environmental risk assessment of the oncological preparations was supplemented into guideline on oncological preparations proposal
- bioaccumulative rate of substances reconsideration
- discussion on guideline proposals in cooperation with OECD relating to tests on dung beetle larvae and dung flies

Further the ERA Working Party gives the consultations for IFAH and for other external clients, the consultations are directed by EMEA.

Other activities of the Institute within the scope of EMEA

Ad Hoc Meeting of GMP Inspection Services – GMP/GDP Inspector Working Group

In the scope of procedures and approaches harmonisation in the sphere of pharmaceutical manufacturers inspections the Ad Hoc Meeting of GMP Inspection Services is organised on the ground of EMEA. The meeting is designated as GMP and GDP Inspector Working Group (GMDP IWG) from the mid-2007. The rename and change of mandate describes the periodical meetings of the inspector group (the 49th meeting passed at the end of 2007) and the extension of mandate concerning the GDP sphere. This GMP/GDP Inspector Working Group meets regularly four times a year. Members of the group are the deputies of EC/EEA inspectorates, beholders are the deputies of EDQM, countries joining the EC and third countries with concluded agreement on certificates approval and inspection results (MRA). During the regular meetings the new and revised chapters and addenda of GMP guidelines, documents relating to MRA agreements, the impact of new legislation in the sphere of active ingredient manufacturers inspections, documents for harmonisation of inspection procedures and the area of cooperation with other working groups and also other organisations as PIC/S, EDQM, PDA, ISPE are being discussed. After several suggestion go-arounds and public discussion the revision of pivotal addendum for GMP No. 1 – the manufacturing of sterile medicinal products was approved in 2007. J. Holý MSc (three times) and J. Kyllarová DVM (once) took part in these meetings in the year 2007. In terms of EMEA activity among others actions there were organised two seminars in the sphere of GMP and international audits in 2007 of which the inspectors of the Inspection Section took part (J. Holý, MSc and P. Müllerová DVM). In terms of Joint Audit Program the evaluation of French Veterinary Agency was assigned to the Institute in 2007. This assessment will be finished in 2008 simultaneously with the application of French Veterinary Agency for the PIC/S membership, which was also assigned to the Institute.

Scientific Advisory Group on Antimicrobials (SAGAM)

The group held three negotiations during the year 2007. Its task is to provide the expert opinions relating to marketing authorisation and the use of animicrobial medicinal products to the CVMP. SAGAM submits to the CVMP the evaluation of new antimicrobial medicinal products authorised via the centralised procedure with consideraiton of the possibility and the spread of the resistance and the importance of use in human medicine, introducing int the ATM group with the warning „prudent use“.

The Institute will not participate in this group anymore with reference to the membership termination of V. Billová DVM and to the fact that the group expressed the requirement on expert recruiting from the number of clinical practice specialists and experts with molecular biology approval. In consequence of guideline themes relating to the use of fluoroquinolones in food animals in EC considering the resistance development and the impact on the human

and animal health the information to IFAH were submitted as a reaction to „prudent use“ defined in the reflection paper concerning quinolones. The material informing about the mechanisms of quinolones resistance transfer via the plasmides was submitted. Following the quideline on using 3th and 4th generation cephalosporins these themes were elaborated from the view of susceptibility of pathogens occuring in mammary gland diseases and the information about the MRSA strains in animals was presented. The guideline on SPC for antimicrobial preparations and VICH guideline on pre-authorisation studies to assess the potential for resistance resulting from the use of antimicrobial VMP were revised, the guideline on monitoring of resistance development in marketed medicinal products is being prepared.
At the end of the year the group together with EWP organised the training for assessors on the topic relating to model cases of macrolide and cephalosporine antimicrobic preparations and the assessment of studies aimed at resistance evidence, strictly speaking the resistace and clinical efficacy of this preparations. E. Vernerová DVM and L. Pokludová Dr. took part in the proceeding.

Telematic Implementation Group (TIG)

Within the scope of TIG the Institute occupied only the meeting of Working Group on EudraPharm system preparation with regard to limited personal capacity. In EudraPharm Working Group the revised reference data model for EudraPharm database was prepared which will be taken into account next year within the continuation of informational system preparation in the Institute. The Institute should also launch the data transfer from its database to the EudraPharm database in compliance with given regulations during the year 2008.

QRD

The Quality Review of Documents (QRD) Working Group consists of the national agencies deputies of EC member states, EC deputies and EMEA deputies. The main aim of the group is to ensure intelligibility, conformity and accuracy of the information on medicinal products (summary of product characteristics – SPC, package leaflet and labelling) and its traslation, which is enclosed to opinions of the committees. In 2007 all SPC, PL and labelling translations for VMP whose marketing authorisation expired during this year were revised. Also in cases of the approved variations and marketing authorisation renewals when changes in these texts happens the accuracy was checked.
During the first half-year the texts to 5 new marketing authorisations, to a marketing authorisation extension, to 2 marketing authorisation renewals, to 6 type II variations and to 1 refferal procedure were revised. During the second half-year 2007 the texts to 3 new marketing authorisations, to 8 renewals, 15 type II variations, 1 annual reconsideration of maketing authorisation and to 1 refferal procedure were checked.

3.3.2 European Commission

European Commission – Committee for Veterinary Medicinal Products and Standing Committee on Veterinary Medicinal Products

The activity of the Institute in relation to European Commission proceeded in two levels.

Firstly in relation to European Commission committees – Standing Committee on VMP and Committee for Veterinary Medicinal Products and secondly the activity in relation to EC legal regulations implementation in Czech Republic conditions.

In first case the Institue took part actively in the meeting of Committee for Veterinary Medicinal Products. On March 2007 the proposal of law regulation was discussed - Annex I of Directive No. 2001/82/EC amendment.

Then on July 2007 the questions relating to environmental risk assessment for generic preparations were discussed, the questions of so called „cascade“ utilisation in bees and finally also the proposal of new regulations for marketing authorisation variations in human and veterinary medicinal products.

Concerning the second sphere – implementation of EC law regulations in Czech Republic conditions, here the Institute participated in comparative tables preparation, by which the implementation of the directive No. 2001/82/EC and the directive No. 2004/28/EC is documented.

Notice to Applicants Working Group

In the year 2007 the deputy of the Institute took part in meeting of the NTA Working Group attached to EC, which held three times during the year in Brussels in Centre Borschette. Together the sphere of human and veterinary medicinal products were discussed. Agenda was especially centred on the chapter 3 amendment relating to referral procedures, further chapter 7 amendment (general requirements), on preparing of new regulation relating to marketing authorisation variations, on preparing of electronic application submisson, on problems relating to data stated on labellings and finally on amendment of new Annex I of veterinary directive. Participation in meetings was very important with respect to the fact that rules stated in approved guidelines for applicants are asserted in marketing authorisation procedures of VMP in Czech Republic and they are implemented into guidelines issued by the Institute.

3.3.3 Institutions ensuring the cooperation of member states

HMA Meeting – Heads of Medicinal Agencies (human and veterinary) of particular EC member states

During the year 2007 the director of the Institute Prof. A. Hera DVM PhD took part in 4 HMA meetings. The meetings are always realized in the member state performing the EC presidency. The meeting then proceeded twice in Federal Republic of Germany (Berlin and Dresden) and twice in Portugese (Lisboa and Funchal). This working body processes the translations for EC and also for EMEA. It prepares the conceptions of development in the sphere of human and veterinary medicinal products for whole EC.
In the passed year the attention was especially given to the veterinary pharmacovigilance spheree, further VMP availability, IT problems preparation – information accessibility regarding VMP from all member states. New task also for VMP is so called medicinal products counterfeiting including the ilegal manufacturing of copies and their unauthorised distribution.
All furher tasks – the solution of insufficient coverage of VMP in some indications, active cooperation with IFAH and further harmonisation of package leaflets for VMP – they were in detail elaborated and their solution will continue also in the year 2008 and later on.
Especially important will be the cooperation from the second half-year 2008, when as participants of the so called operative „trio“ together with France and Sweden we will prepare the agenda for the period of CR presidency in the first half-year 2009 and we will participate in the proceeding of subject meetings .

Coodination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv)

The Institute deputy as a nominated member took part in the regular meetings of CMDv which were held ten times in 2007. The main function of CMDv is the coordination of the mentioned procedures including the preparation of guidelines and standard operation procedures relating immediately to the MA procedures. The meetings held always once a month at EMEA in London. The participation in the meetings of this group was essential from the view of the Institute, because the mutual recognition procedure and decentralised procedure are recently the most frequently used VMP marketing authorisation procedures in the EU which require the close coordination of all concerned parts (reference member state, concerned member states, applicants and CMDv secretary which is ensured by EMEA) and CR actively participates in the procedures as concerned or reference member state.

In connection with the implementation of Directive No. 2004/28/EC amending the Directive No. 2001/82/EC except the proceeded procedures discussing the preparation process of updated and new standard operating procedures and public guidelines administering the individual operations associated with the marketing authorisation and mentioned MA procedures continued and were finished.
CMDv also cooperates with the IFAH-Europe and EGGVP and in this connection the meetings of CMDv and mentioned associations were held several times a year of which the Institute deputy took part in as well.

3.3.4 Other Institutions

EDQM

In 2007 J. Jeřábková DVM worked on within the activities secured by EDQM and as a member of the Expert Group of the European Pharmacopoeia Committee she actively participated in the activities of this committee. J. Jeřábková DVM considering her expertness ensures namely the agenda relating to imunological veterinary medicinal products.

On November 2007 another ISCVBM employee - J. Maxa PharmDr. PhD joined the Expert Group of the European Pharmacopoeia Committee, which considering his position in the Institute and professional background and experience ensures the activities relating to quality of medicinal products and pharmaceuticals

Wihtin the framework of European Pharmacopoeia J. Jeřábková DVM as a 15V Group member (Expert Group for Veterinary Vaccines and Immune Serums) took part in 3 workshops in 2007, whereon the following topics were solved in the course of new pharmacopoeial articles elaboration and revisions of current articles:

- suggestions and finalization of the article relating to vaccine against coccidiosis in poultry
- compillation of data relating to number of authorised vaccines regarding new article elaboration relating to live vaccine against *Bordetella bronchiseptica* in dogs
- the revision of the article relating to vaccine against vibriosis in salmonoid fish
- the work on the new pharmacopoeia article relating to live vaccine against *Salmonella enteritidis*
- the work on the new pharmacopoeia article relating to live vaccine against *Salmonella typhimurium*
- the work on the new pharmacopoeia article relating to live vaccine against pneumoviruses in poultry
- the revision of the article relating to animal origin substances for the preparation of veterinary vaccines

On May 2007 the Institute together with the State Institute for Drug Control took part in the annual session of Official Medicines Control Laboratories (OMCL), EDQM was the main organiser.

Pharmaceutical Inspection Convention/Scheme (PIC/S)

The Institute has been PIC/S member from the year 2005. The membership contribution is partly access to seminars and trainings for inspectors on required level and partly the increase of the international reputation of the Institute and approval of its inspection results also by the authorities outside the EU/EEA (Australia, New Zealand, Israel, Iran, Egypt and others) and thus the simplification of czech industry access to these markets. In terms of PIC/S membership the Institute participates in the preparation of guideline within the PIC/S and in the harmonisation of inspectional procedures worldwide. Inconsiderable contribution is the possibility of participation in highly professional seminars and of many contacts of GMP inspectors obtaining. In 2007 the head of Inspection Section , J. Holý MSc took part in two PIC/S committees (Switzerland – Geneva, Singapore) and in one seminar in Singapore.

The assessment of application for PIC/S membership made by french medicines agency was assigned to the Institute in 2007. The assignment of the application assessment is the approval of ISCVBM full membership in this association and acknowledgement of its competences.

3.4 The Institute activity relating to the regulated subjects

In 2007 the seminary for MAHs was held by the Institute during 20. – 21. 9. 2007. The lectures were related to the situation in the sphere of medicine regulation in EU, information related to EMEA Working Groups activities, information related to new EMEA/CVMP guideline on anthelmintic preparations, environmental risk assessment of VMP, topics relating to validation of applications for marketing authorisation - MRP/DCP were presented. The second part of the seminary was related to problems with applications for type I variations, the assessment of residue studies and withdrawal periods, European Pharmacopoeia information and new guidelines relating to marketing authorisation of imunological VMP, pharmacovigilance.
Regarding the force of new Medicine Act the seminars arranged by the Inspection Section were postponed to the year 2008.

During the 2007 the ISCVBM experts lectured in course cycles arranged for QP (persons qualified in the medicinal products manufacturing and distribution in compliance with Medicine Act requirements).

Pursuant to Medicine Act possibilities and needs the Institute issued 5 guidelines during the year 2007, from that 2 generally true guidelines – UST series, 1 guideline on the sphere of marketing authorisation – REG series, 1 valid guideline on approval of veterinary products – REG/VP series and 1 guideline on the sphere of inspection – VMP manufacturers – INS/VYR series.

The review of ISCVBM guidelines issued in the year 2007:

UST – 02/2007	The procedure of Official Control Agency Batch Release (OCABR) of defined imunological VMP in the Czech Republic – Annex No. 1 amendment
UST – 01/2007	The procedure of Official Control Agency Batch Release (OCABR) of defined imunological VMP in the Czech Republic

REG – 01/2007	Guideline on the determination of criteria for removal of some VMP intended for animals from which the products for human consumption are gained, from the POM requirement

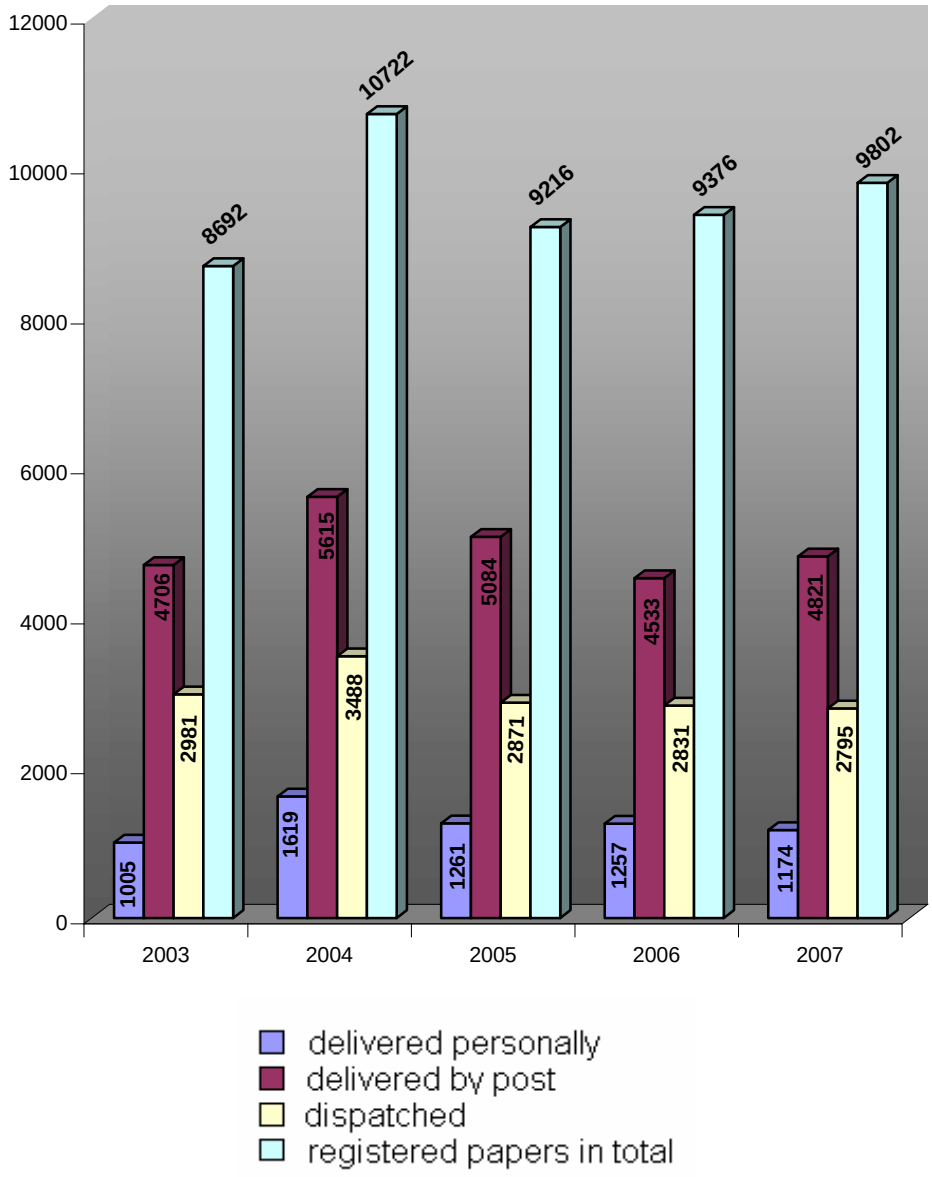
REG/VP – 01/2007	Requirements on application for VP approval, renewal of approval and variation of approval

INS/VYR – 01/2007	How to fill in the recipe for medicated feedingstuff and contact addressess for its sending to competent Regional Veterinary Administration

4 Agenda of the ISCVBM

The total of 9802 papers were registered in the ISCVBM registry and forwarding office in the year 2007, from these 4821 were delivered by post, 1174 delivered personally, 2795 papers were dispatched. The total annual growth of registered papers was increased in comparison with the year 2006, the growth was 426 papers, it is 4,35%.

Picture 4/1 The number of registered papers in the ISCVBM registry and forwarding office in years 2003 - 2007



5. Activity of the Marketing Authorisation Section, Approval, VTD Register and Clinical Evaluation

5.1 Marketing Authorisation of VMP

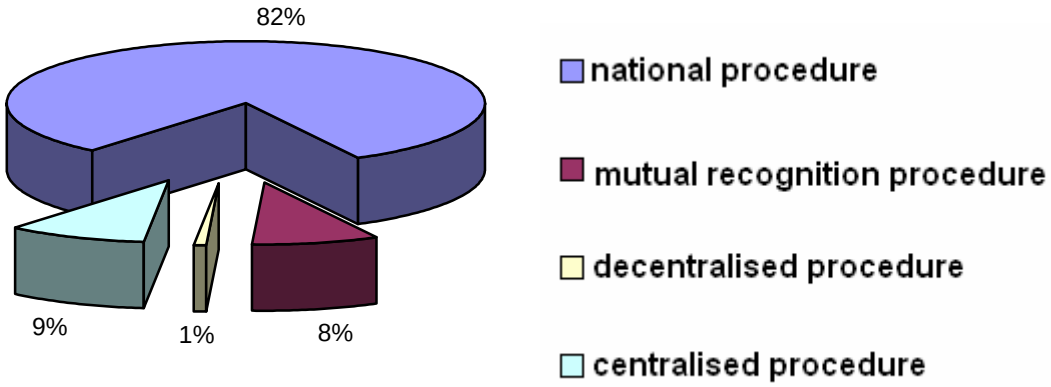
5.1.1 Incorporation of the CR to European Marketing Authorisation Procedures

In the course of VMP marketing authorisation the european marketing authorisation procedures were applied in the year 2007 in compliance with the regulations of the consolidated Directive No. 2001/82/EC (from 1. 11. 2005 amended by the Directive No. 2004/28/ES) – national procedure, mutual recognition procedure and decentralised procedure. Also VMP authorised by centralised procedure were marketed in CR in compliance with the regulation No. 726/2004.

le 5/1: Number of authorised VMP according to procedure type on the 31. 12. 2007

TYPE OF PROCEDURE	TOTAL
NATIONAL PROCEDURE	987
MUTUAL RECOGNITION PROCEDURE/ DECENTRALISED PROCEDURE	113/12
CENTRALISED PROCEDURE	126
TOTAL NUMBER OF AUTHORISED VMP IN CR	**1288**

Picture 5/1: Percentual representation of marketing authorisation procedures by total of VMP



In accordance with the valid legislative groundwork except the national procedure two other VMP marketing authorisation procedures were applied in the Czech Republic in 2007 – mutual recognition procedure and decentralised procedure.

In terms of decentralised procedure the number of applications was significantly higher in 2007, it was twofold in comparison with the last year. The number of MRP applications remained on the same level in comparison with the last year. The number of applications for MA renewal and the number of applications for MA variations were threefold. The administrative procedure of the repeat use was getting into the secrecy on the contrary.

The Czech Republic has taken part in mentioned procedures in the position of concerned member state and reference member state. In 2007 CR was executing the position of RMS for the first time in the case of new DCP marketing authorisation, in the case of repeat use of the MRP and in all types of marketing authorisation variations.

Table 5/2: Summary of total number of submitted applications and cases when MA was granted - decentralised procedure and mutual recognition procedure in the year 2007

MUTUAL RECOGNITION PROCEDURE	VMP TYPE pharm./ imunol.	NUMBER					
		SUBMITTED APPLICATIONS CR/CMS	MA GRANTED CR/CMS	SUBMITTED APPLICATIONS CR/RMS	MA GRANTED CR/RMS	REFUSED APPL. CR/CMS	REFUSED APPL. CR/RMS
FIRST USE	P	14	10	0	0	0	0
	I	14	6	0	0	0	0
REPEAT USE	P	4	7	0	0	0	0
	I	2	4	1	1	0	0
VARIATION OF MA TYPE IA	P	44	10	0	0	0	0
	I	8	12	2	1	0	0
VARIATION OF MA TYPE IB	P	30	15	0	0	0	0
	I	12	11	2	1	0	0
VARIATION OF MA TYPE II	P	10	11	0	0	0	0
	I	21	9	1	1	0	0
RENEWAL OF MA	P	7	8	0	0	0	0
	I	4	2	0	0	0	0
ADMINISTRATIVE REPEAT USE PROCEDURE	P	0	0	0	0	0	0
	I	0	0	0	0	0	0
DECENTRALISED PROCEDURE	P	44	9	1	0	0	0
	I	4	3	0	0	0	0

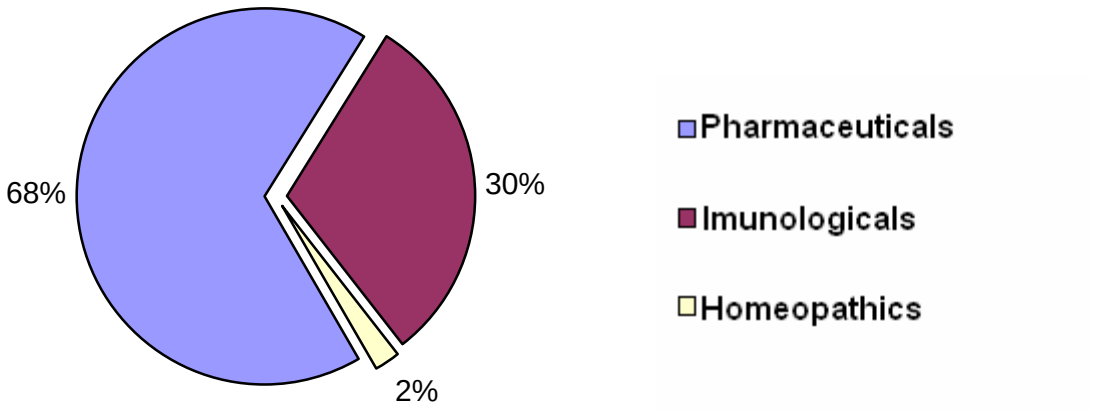
5.1.2 The situation of authorised VMP, agenda of submitted applications, results from the marketing authorisation proceedings

In total 1288 VMP were authorised on the 31. 12. 2007, from that 866 were pharmaceuticals, 392 imunologicals and 30 homeopathics. There were 7% of OTC preparations and it is 79 pharmaceuticals and 15 homeopathics.

Table 5/3: Total number of authorised VMP and the way of their release on the 31. 12. 2007

Type of VMP	Total	Total (percentage)	From that OTC	Total (percentage)
Pharmaceuticals	**866**	**68**	**79**	**9**
Imunologicals	**392**	**30**	**0**	**0**
Homeopathics	**30**	**2**	**15**	**50**
Total	**1288**	**100**	**94**	**7**

Picture 5/2: Percentual representation of authorised VMP types



Total of 899 applications were accepted by the Administrative Affairs Department in 2007, which is 14% more than in the year 2006. Especially the applications for MA variations outweighted. In total 67 applications for the new marketing authorisation were submitted, which is 28% more than in the year 2006. There were no significant changes in applications for MA renewal and MA transfer. In appeals against MA decisions it was firstly dealt with appeals against MA decisions related to dissproval of MA variations, when after obtaining of the decision the marketing authorisation holder together with the appeal completed the MA dossier and therefore the appeal could be allowed. Marketing authorisation holders started to assert the mechanism of application withdrawal in accordance with the administrative law. The number of renedered decisions and decrees closing the proceeding was approximately 10% more than in the year 2006

Table 5/4: The number of submitted applications and the number of MA granted in 2007 in comparison with the year 2006

Sort	Year	Submitted Applications	MA Granted
Application for the new MA	2007	87	58
	2006	60	46
Application for MA renewal	2007	201	133
	2006	198	92
Application for MA variation	2007	543	462
	2006	453	449
Application for MA transfer	2007	13	10
	2006	13	13
Application for MA revocation	2007	12	11
	2006	25	25
Application for administrative proceeding discontinuance	2007	21	21
	2006	11	11
Appeals against MA decision	2007	2	8
	2006	12	6
Administrative corrections in the MA decisions	2007	20	20
	2006	15	15
Summary	**2007**	**899**	**723**
	2006	788	657

The following table 5/5 shows the results of marketing authorisation procedures and as evident the absolute majority of the proceedings had the possitive result. Some of the proceedings stayed at the Institute for a longer time were discontinued because the applicant did not completed the required documentation. The revocated proceedings were related to type I variations above all.

Tab. 5/5: Results from marketing authorisation procedures in VMP numbers in 2007

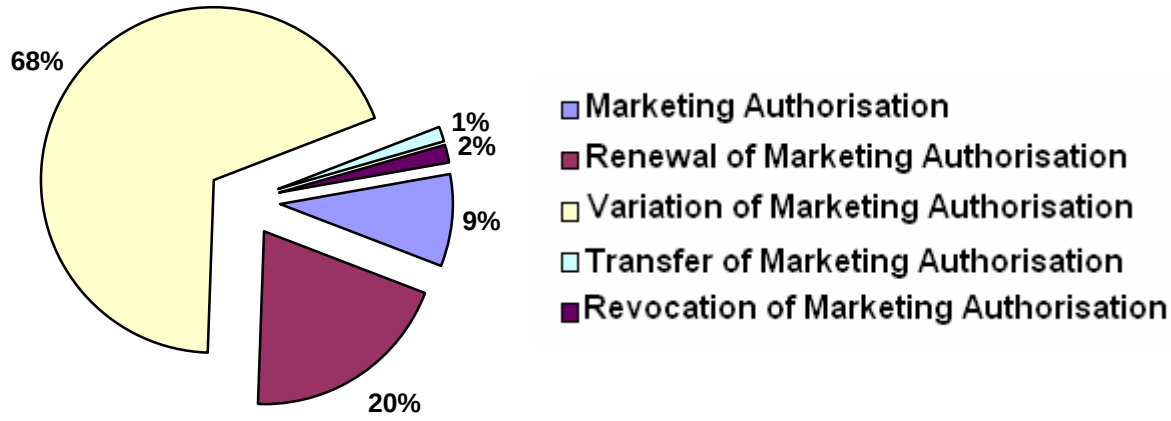
Result / Type of VMP	Approved	Approved in total	Discontinued	Refused	Executed in total
MARKETING AUTHORISATION					
Pharmaceuticals	**43**	**57**	**1**	-	**58**
Imunologicals	**14**		-	-	
RENEWAL					
Pharmaceuticals	**66**	**123**	**11**	-	**133**
Imunologicals	**57**		-	-	
VARIATION					
Pharmaceuticals	**294**	**431**	**12**	**17**	**462**
Imunologicals	**137**		**2**	-	
TRANSFER					
Pharmaceuticals	**10**	**10**	-	-	**10**
Imunologicals	-		-	-	
REVOCATION					
Pharmaceuticals	**10**	**11**	-	-	**11**
Imunologicals	**1**		-	-	

The VMP can be discarded from the register of authorised VMP which can be marketed in the Czech Republic from several reasons. Characterization of the reasons and the numbers of VMP which were discarded from the register of authorised VMP in 2007 is stated in the following table 5/6.

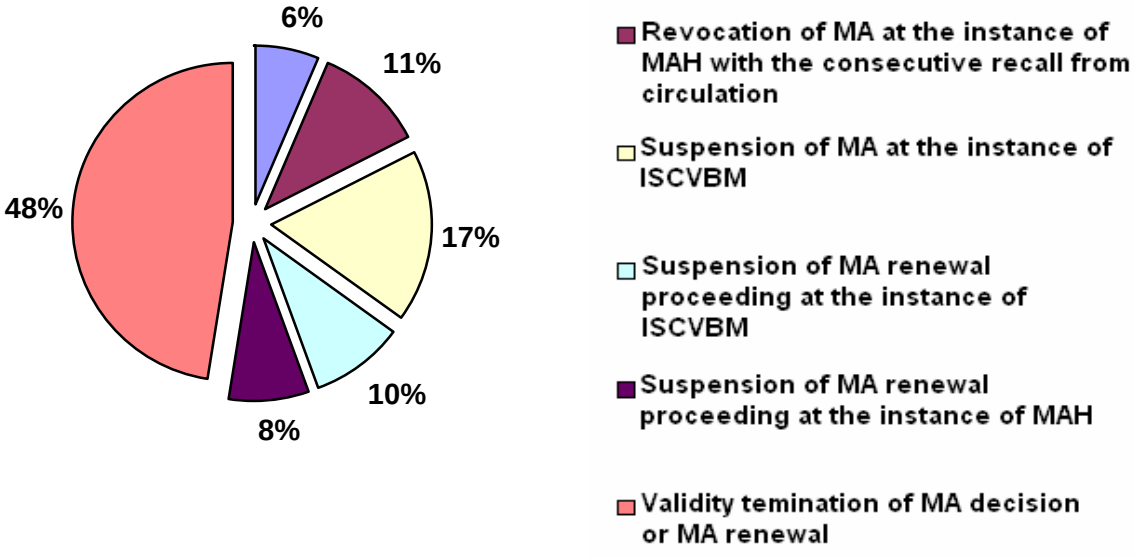
Table 5/6: Revocation of MA, Suspension of MA, Discontinuation of the MA Proceeding and Validity Temination of MA Decision or MA Renewal

Reason	Type of preparation	Number of VMP	In Total	In Total
Revocation of MA at the instance of MAH	Pharmaceuticals	**3**	**4**	**63**
	Imunologicals	**1**		
Revocation of MA at the instance of MAH with the consecutive recall from circulation	Pharmaceuticals	**7**	**7**	
	Imunologicals	**0**		
Suspension of MA at the instance of ISCVBM	Pharmaceuticals	**5**	**11**	
	Imunologicals	**6**		
Suspension of MA renewal proceeding at the instance of ISCVBM	Pharmaceuticals	**6**	**6**	
	Imunologicals	**-**		
Suspension of MA renewal proceeding at the instance of MAH	Pharmaceuticals	**5**	**5**	
	Imunologicals	**-**		
Validity temination of MA decision or MA renewal	Pharmaceuticals	**15**	**30**	
	Imunologicals	**15**		

Picture 5/3: Percentual Results of MA Proceedings Outputs in 2007



Obr. 5/4: The reasons for discard of VMP from the register of authorised VMP (percents)



5.2 Antibiotic policy

In the special meetings of Subcommittee for Antibiotic Policy of the CMS JEP where the ISCVBM has its delegates as well, besides the human medicines problems the use of antimicrobial veterinary medicinal products in veterinary medicine were discussed as well during the year 2007 – consumption of VMP, „prudent use“ recommendation for chosen antimicrobial VMP. In 2007 the preparation of national antimicrobial policy continued in meetings aimed at the formation of national antibiotic policy programme in both human and veterinary sphere, from now on the problem remains in the complex solution of legal rules for the activity of antibiotic centres, national monitoring of the antibiotic resistance. European antibiotic policy is administred by Scientific Advisory Group on Antimicrobials (SAGAM) which has a mandate form the CVMP for preparation of guideline on the use of selected antibiotics and on the assessment of antimicrobials in terms of centralised procedure.

5.3 Clinical evaluation of medicinal products

Total of 5 applications for approval of clinical evaluation of the product were submitted to the Department of clinical evaluation of VMP in the year 2007, namely from two submitters. After the fulfilment of suggestions or supplement requirements to submitted data the clinical evaluation was approved in all 5 products.

In connection with the approval of clinical evaluation of VMP the total of 36 control assignments were carried out including the appropriate writing records evaluating the compliance with the valid legislation. The control assignments were above all targeted on the field phase of the clinical evaluation, it is the complying with the principles of good clinical practice by the adherence of the approved protocols and accuracy and completennes of the filling of the record forms relating to product administration data, clinical conditions of animals and other actions associated with the laboratory examination. Some of the control assignments were performed also by the submitter, namely with a view to supplementation or specification of the submitted protocols and record forms and the results of laboratory examination provided by the submitter. No deficiencies were found in carrying out of the control assignments which could have the negative influence on the clinical evaluation process or that could lead to its suspension.

In one preparation the clinical evaluation was finished by the submission of appropriate clinical assessment report in 2007, field phase of the clinical evaluation was finished in 8 products, the clinical evaluation of 2 products will continue in 2008. In two products the clinical evaluation was revoked by request of the applicant.

In 46 products the fiel check in terms of running marketing authorisation proceeding, monitoring of the side effects of VMP administration and market surveillance were carried out. No findings requiring subsequent precautions were found out.
In total 40 applications for the opinion relating to the unauthorised VMP - approval of exception for importation or using in the CR, were submitted to State Veterinary Administration in 2007 (27 pharmaceuticals, 13 imunologicals). In many cases there were repeated applications for the products with the positive opinion from previous years. The negative opinion was taken in two cases, in which the stated arguments were not found satisfactory. Under the given conditions the exception to manufacturing and distribution of Xylased 500 inj. (Bioveta a.s.) for the use in form of narcotising projectiles was renewed.

In terms of tasks associated with the market surveillance the correspondence with the approved texts (outer package, package leaflet, labelling) was checked in 97 products. From that in 8 cases there were major discrepancies, in 32 cases discrepancies with no effect on the safety and efficacy of the product.
Two consulatations took place in 2007 relating to essential legislative data and requirements on clinical evaluation of VMP.

5.4 Veterinary products, veterinary technical devices and biocides

The review of the activity of the Department of approval of veterinary products (VP), the register of veterinary technical devices (VTD) and biocides in the year 2007 (actual situation on the date 31.12.2007)				
Sort of activities	**Transferred from the year 2006**	**Submitted in the year 2007**	**Finished**	**In proceeding**
Approval of VP	43	103	100	46
Variations of approved VP	3	28	31	0
Renewal of approved VP	24	56	60	20
Discontinuation of VP approval proceeding				
Revocation of approved VP				
Total	70	187	191	66
Evaluation if it is VP, article 65, paragraph 1, letter i)		6	6	
Number of requirements on completion of application for approval, renewal and variation				
Discontinuation of the proceeding/ transfer of approved VP/revocation of the approved VP/	Revocated			
	On application			
	transferred → biocides			
	transferred → VTD			
	transferred → VMP			
	transferred → feedingstuff/feed additive			
Register of VTD		9	9	
Standpoints to biocides		137	137	
Standpoints to active ingredients	2	5	7	
Solving of adverse reactions of VP		1		1
Solving of adverse reactions of VTD				
Solving of adverse reactions of biocides				
Appeals against the decision				
Department of approval of VP and VTD (number of operations in total)	**72**	**345**	**350**	**67**

Training of Marketing Authorisation Section Employees

The employees of the section analogous to previous years took part in training programmes within the scope of their professional positions in 2007.

In-house trainings relating to new informational of system registrar office and special trainings relating to VMP safe use and bioequivalence were in progress.

The employees further participated in following special seminars and conferences: DDD Seminar, Attenuation programme of Salmonella spp. presence in the environment – Větrný Jeníkov, VETFAIR Hradec Králové and Seminar of Czech Association of Avian Medicine centered on poultry problems, VETFAIR Hradec Králové – Urogenital tract diseases in pigs, Animal protection and welfare 2007 – VFU Brno, Genetically modified organisms – ČZU Praha, XXXVII Lenfeld and Hocl Days – VFU Brno, international seminar – Respiratory diseases in cattle – Horní Cerekev, international seminar – PCV in pigs – VRI Brno, training of EU agenda administration experts.

In terms of CR preparation for EU presidency an employee of the section took part in e-learning and other courses including the language ones.
From the courses and trainings held abroad the employees of the section took part in following seminars: EDQM – New Purviews of Medicinal Product Quality, OIE international conference – towards the rabies elimination in Eurasia – Paris, training course held by EDQM in London themed: European Pharmacopoeia - 6th Impression, Training Course on Environmental Risk Assessment (EMEA), training of assessors – antimicrobial preparations, pharmacokinetics.

Linguistic trainings of employees were proceeded again in 2007 including courses aimed at the preparation for FCE and CAE certificates obtaining.

6. Activity of the Inspection Section

6.1. GMP Division

6.1.1. Department for GMP of medicinal products (MP), autogenous vaccines (AV) and active ingredients (AI)

1) The review of the activity:

Main projects and visions fulfilment:

- ***fulfilment of the system inspection plan at the compliance of the interval provided by GMP and GDP Decree (responsible Mr. Holý)***
  ☺ all planned inspections were performed
- ***further improving of qualification and proficiency of GMP inspectors***
  ☺ trainings were performed in required range
- ***integration of the new inspector into the section activities (Dr. Radošová)***
  ☺ Dr. Radošová was fully integrated into the section activities
- ***participation in French Veterinary Authority evaluation within the scope of PIC/S and EMEA (JAP) (responsible Mr. Holý)***
  ☺ the evaluation started in 2007 with the evaluation elaboration of submitted documents, it will continue in place with the audit and report elaboration in 2008
- ***finalization of SOP documentation revision and quality reference manual of the Inspection Section (responsible Mr. Holý)***
  ☹ the revision of quality reference manual and SOP was postponed to 2008 regarding new Medicinal Act
- ***SOP on control inspections elaboration (responsible Mr. Holý and Mr. Kožíšek)***
  ☹ SOP elaboration was postponed to 2008 regarding new Medicinal Act
- ***continuation of cooperation with Inspection Sections of SIDC and Slovakian ISCVBM (responsible Mr. Holý)***
  ☺ joint inspections with SIDC, meetings with Slovakian ISCVBM and other agencies took place
- ***cooperation within EU – Slovakia, Lithuania (responsible Mr. Holý)***
  ☺ the visit of Lithuanian authority took place, Lithuanian inspectors took part in ISCVBM inspections and trainings
- ***preparation and realization of special seminars in connection with new Medicine Act (responsible Mr. Holý)***
  ☹ the execution of seminars was postponed to 2008 regarding new Medicinal Act
- ***the participation in the Official Control Authority Batch Release programme (responsible Mrs. Radošová)***
  ☺ the conditions for OCABR were made in cooperation with the Laboratory Control Section

Number of submitted applications in the GMP sphere of MP and AI: 13

Application for granting manufacturing authorisation for VMP – 0
Application for variation to a manufacturing authorisation for VMP
– 4 (variation affiliated with the ispection)
– 4 (variation without the inspection necessity)
Application for granting a licence for control laboratories – 0

Application for granting GMP certificate – 3
Application for variation to an AI manufacturer certificate – 0
Application for granting GMP certificate of VP – 1
Application for revocation of the authorisation – 1

Number of issued decisions: – 18
Manufacturing authorisation – 0
Manufacturing authorisation (variation of the decision)
– 12 (4 decisions issued pursuant to applications submitted in 2006)
Granting a licence for CL – 0
GMP Certificate pursuant to application – 3
GMP Certificate after inspection – 24 (according to obligation provided by the Directive No. 2004/28/EC)
AI Manufacturer Certificate (or variation) – 1 (pursuant to application submitted in 2006)
VP Manufacturer Certificate – 1
Revocation of the licence – 1

Review of performed systemic inspections and comparison with the plan in 2007

Company according to CoR (Company Register)	Plan	Carried out in	Remark
BIOVETA, a. s., Opava	January	11.1.2007	
CHEMOPHARMA, a. s.	January	23.10.2007	
NORDIC Pharma s.r.o.	January	25.1.2007	
DYNTEC spol. s r. o. Terezín	February	17.-19.10.2007	
CONTIPRO C, a.s.	February	27.-28.3.2007	+SIDC
PURUS-MEDA, s.r.o.	February	23.1.2007	
UNIVIT s. r. o.	March	22.-23.2007	
MEDICAMENTA Vysoké Mýto, a.s.	March	17.-18.5.2007	
SPOFA a.s.	March	-	With regard to manufacturing suspension postponed to 2008
Vétoquinol s.r.o.	April	28.3.2007	
CONTIPRO C, a.s.	April	1.8.2007	Subsequent inspection
Favea, spol. s r.o.	April	24.5.2007	
HERBACOS-BOFARMA, s.r.o.	May	21.6.2007	
VÝZKUMNÝ ÚSTAV VČELAŘSKÝ s. r. o.	May	9.5.2007	
Interpharma Praha a.s.	May	21.8.2007	
KOMVET spol s r.o.	June	-	Expected application for the approval of variation was not submitted
BIOVETA, a. s.	June	31.10.-1.11.2007 11.-12.12.2007	
Analytické laboratoře Plzeň, a.s.	June	8.8.2007	

Company according to CoR (Company Register)	Plan	Carried out in	Remark
ANALAB PRAHA s.r.o.	June	29.6.2007	
QUALICHEM, spol. s r. o.	July	8.8.2007	New Holder Stachema Kolín
BIOFAKTORY PRAHA spol. s r.o.	July	18.9.2007 24.10.2007	
BIOPHARM, Výzkumný ústav biofarmacie a veterinárních léčiv a.s.	August	13.-14.9.2007	
Tekro, s.r.o.	September	26.3.2007	
Spofa a.s.	October	-	Regarding suspense of AI manufacturing postponed to 2008
M+H VET s.r.o.	October	23.10.2007	
Zentiva, a.s.	November	5.-6.12.2007	
Veterinární zásobování spol. s r.o.	November	30.10.2007	
Státní veterinární ústav Jihlava	November	25.10.2007	
CAYMAN Pharma spol. s r.o.	December	7.-8.2.2007	+ SIDC

Further an inspection was carried out only in connection with the application for approval of variation in manufacturing (1 manufacturing site), one control inspection was carried out in MP manufacturer.
Within the frame of inspection of AI treatment 12 controls were carried out in 12 subjects.

Number of inspections carried out in the sphere of GMP and AI treatment: 31 (GMP) + 12 (AI treatment)

Initiatial Systemic Inspection + variations – 0
Periodical Systemic Inspections – 24
Subsequent Inspections – 2
Control Inspection – 1
Manufacturers of AI – 3
Manufacturers of MP – 1
Controls of AI treatment – 12
GLP – 0
Foreign inspections – 0

Number of processed protocols: 30 (GMP) + 12 (AI treatment)
1 inspection protocol from 2007 will be processed at the beginning of 2008 (Bioveta).

Summary of inspection activities
The number of scheduled inpections was 37, the number of inspection days was 60, in the sphere of AI treatment 25 inspections were scheduled.
Actually 31 inspections were processed, number of inspection days was 43, in the sphere of AI treatment 12 controls were scheduled. The total number of inpection days was 55in the year 2006. In 2006 the number of inspection days was 35 (in 2005 – 46, 2004 – 38). The difference compared to plan is caused firstly by the suspended applications which were not inspected and by the fact that inspections in third countries were not carried out (1 inspection was scheduled – 6 days) and by the transfer of inspections in the Spofa company on the year

2008 by the reason of manufacture suspension. Small number of inspections in the sphere of active ingredient treatment was caused by the workload of employees in other fields.

Training

The employees of Inspeciton Section – subdivision of GMP for MP, AV and AI took part in the training within the range 56 days (Holý, Müllerová, Radošová, Kožíšek) including the training of new GMP and GDP inspector (Dr. Radošová).
From the foreign trainings two inspectors took part TAIEX training in Visegrad, aimed at actual themes in the sphere of GMP (5 days), an inspector of SI took part in PIC/S seminar and following workshop (4 days), one inspector took part in the EMEA training of auditors (2 days), two inspectors took part in EMEA workshop themed „Quality Risk Management“ (1 day).

2) The Assessment of Quality Indicators:

The quality indicators appointed for the activities of this department were evaluated, all pivotal parameters were fulfilled, no periods as provided by the law were exceeded.

3) Assurance of quality, internal audits

The revisions of regulation documentation and the quality reference manual were planned with regard to approval of new Medicine Act not until the last day of the year, the revisions were postponed to the beginning of 2008.
The internal audit in the department for GMP of MP, AV and AI brought forward from 2006 was scheduled aimed at the established procedures, Quality Assurance System, internal audit was postponed again from time reasons on the year 2008, within the assurance of quality the annual activity evaluation was carried out including the variation and divergences.

4) The review of activity in terms of Rapid Alert System (RAS) in 2007

In 2007 the total number of received information regarding defects in quality of VMP in terms of RAS was 130. This number includes information concerning all cases of quality defects from external authorities (from that most comprises of information concerning quality defects in human medicinal products) and component organizational subdivisions of the Institute.
Total of 58 quality defect reports were received in the sphere of VMP.

reports from external authorities	concerning human medicinal products	72
	concerning veterinary medicinal products	5
internal reports from organizational subdivisions of the Institute	Laboratory Control Section - quality	19
	Marketing Authorisation Section – labelling	24
	Inspection Section	9
reports received from the MAH		1

Quality defects of VMP received by the subdivision of Laboratory Control Section concerned mainly:

unsatisfactory pH – 4
unsatisfactory density – 3
content of the active ingredient out of specification – 4
unsatisfactory appearance - 4
endotoxine level – 1
efficacy – 4

assay of excipients - 1

Quality defects in VMP received by the subdivision of Laboratory Control Section and by the Inspection Section were related to differences in labelling (immediate package, outer package, package leaflet). The most common shorcomings were the differences in withdrawal periods, storage temperatures of the products, different content of data on foreign labellings.

One report concerning unsuitable results of continuous product stability monitoring was received from the MAH, concerning 3 batches.

In two cases the information concerning quality defect was sent to external authorities within the scope of RAS. In both cases there was an unsatisfactory qualitative and quantitative composition of the product.

Pursuant to RAS background papers there were 8 administrative proceedings opened in 2007 with the MAH of the VMP for the Medicine Act No. 79/1997 Coll. violation, as amended by the subsequent regulations.

5) The summary of variances:

No significant variances from the set procedures for the main activities of the section were found out in 2007. But in the sphere of quality assurance the internal audit plan and plan of regulation documentation were not kept.

6) Precautions:

The performance of internal audits and finalization of regulation documentation are the key tasks for the first half-year 2008.
Since there were no significant variances from the set procedures found out during the 2007, no corrective action were taken in the sphere of performed inspections.

6.1.2. Activity of Department for GMP of medicated feedingstuffs

The fulfilment of main tasks in 2007:

- fulfilment of inspection plans stated in part A – executed
- further trainings and education of inspectors – executed
- setting the conditions for farm manufacturers of medicated feedinstuffs (1st quarter of the year 2007) – executed, the use of conditions in practice relates to new Medicinal Act
- SOP revisions in the sphere of medicated feedingstuffs manufacturing in connection with new Medicinal Act – postponed to the year 2008
- cooperation with Regional Veterinary Administration – seminar concerning mass medication problems, the use of VMP and medicated feedingstuff manufacturing (1st quarter 2008) – executed
- joint activity within EU – joint inspection with Slovakian ISCVBM - manufacturer of medicated feedingstuff in Slovakia or Czech Republic (2nd to 3rd quarter 2007) – postponed to year 2008 considering working load of Slovakian ISKVBM

- joint activities with Lithuanian authority – executed
- Central Institute for Supervising and Testing in Agriculture (CISTA) – periodic meeting of ISCVBM deputies with CISTA deputies (generally once to twice a year), including farm manufacturers solving (basic industry) – executed
- ISCVBM seminary centred on problems related to Medicinal Act and manufacturing of medicated feedingstuffs (1st to 3rd quarter 2008) – not executed, considering the adoption of Medicinal Act given in December 2007, postponed to 2008
- aiming at the quality of medicated feedingstuffs in the form of sampling (1st to 2nd quarter 2007) - executed

Number of submitted applications in the sphere of Good Manufacturing Practice of medicated feedingstuffs:

Type of application	Manufacturing authorisation	Variation to a manufacturing authorisation with inspection	Variation to a manufacturing authorisation without inspection	Application for revocation of manufacturing authorisation	Total
Number	0	7	13	2	22

Adherence of administrative terms for reply to applications:
Administrative limits for reply to applications were adhered (maximal limit is 30 days).

Number of issued decisions:

Type of decision	Manufacturing authorisation - new	Variation to a manufacturing authorisation with inspection	Variation to a manufacturing authorisation without inspection	Revocation of manufacturing authorisation	Total
Number	3	11	15	2	31

Adherence of terms for decision issuing:
The stated administrative proceedings were executed in appoited time limit maximum 90 days without inclusion of the suspension caused by the applicants. As far as the total time for suspension of administrative proceeding more than 90 days was tolerated, it was in the cases, when the applicants carried out the changes in technological equipment and simultaneously the transfer authorisations done by CISTA were proceeded and after their finishing and further technology engineering necessary for the granting a manufacturing authorisation for manufacture of medicated feedingstuffs, the proceeding continued in the ISCVBM, in one case (variation to a manufacturing authorisation for manufacture of medicated feedingstuffs in storage) the time limit was exceeded by reason of reconstruction delay of stock premises for manufacturing on the part of applicant.

Number of unfinished applications postponed to 2008:

Type of application	Variation to a manufacturing authorisation with inspection	From that inspected in 2007	Variation to a manufacturing authorisation - administrative	New manufacturers applications - unfinished	Unfinished applications - total
Number	3	2	0	0	3

Rationale: unfinished applications are suspended and waiting for the shortages relieve on the part of manufacturer. On this account the applications will be attended in the year 2008.

Number of inspections carried out in the year 2007

Type inspekce	Initial systemic	Systemic variation	Periodical systemic	Subsequent	Control	Total		
						Inspections	Inspection days	person/day
Number	6 (From that 3 times initial systemic inspection of existing manufacturer´s new plant)	5	31	2	7	51	54	112

Adherence of the inspection procedure:

The inspection procedures guidance described in appropriate SOP were adhered. The letter with announcement relating to inspection was sent to the manufacturer before the inspection. Inspections wer carried out according to the set schedule, the inspection protocol was elaborated from each inspection following the records made into control sheet and then it was sent to the manufacturer.

Time schedule of periodical systemic inspections for the year 2007 was fulfilled excepting two periodical systemic inspections from the December 2007, which could not be carried out due to lack of time (reason: the necessity of inspection performance in applicants for variation to a manufacturing authorisation for veterinary medicinal products and increased number of control inspections), hence they were included in inspection schedule in January 2008. The number of subsequent and control inspections compared to schedule was exceeded.

Sampling in manufacturers of medicated feedingstuffs

During the inspections the sampling of granulated medicated feedingsfuffs with the active ingredient CTC was proceeded in second half-year 2007 – in total 13 samples were taken.

Withing the frame of market surveillance program all requested samples of medicated premixes in manufacturers of medicated feedingstuffs were taken (see records from Market Surveillance).

Summary

During the year 2007 no significant deviations from set procedures were found out, no corrective actions were accepted. It is necessary to finalise the regulation documentation for the sphere of medicated feedingstuffs and to carry out an audit centred on this sphere. These tasks have been persisting already since 2006.

6.2. GDP Division – GDP Inspection and Market Surveillance

6.2.1. Department for GDP

Main projects and visions set down on 2007:

- fulfilment of system inspection plan in course of interval adherence provided by the GDP Decree - executed
- improving of qualification and proficiency of GDP inspectors - executed
- within the frame of systemic inspections in distributors – control implementation of MP supplies from foreign suppliers in connection with their possible parallel importation – executed in large distribution companies, will be performed henceforth in 2008
- control of MP labelling and the control of MP compliance with its valid MA dossier (packaging, package leaflet) – executed, will be performed hencefoth in 2008
- cooperation with Inspection Section of SIDC – six joint inspections were carried out
- preparation and performance of special seminars in connection with new Medicinal Act – not executed, new act came in force on 31. 12. 2007
- comprehensive revision of SOP in the sphere of GDP – not executed, new act came in force on 31. 12. 2007
- sampling in terms of market surveillance - executed

On 31. 12. 2007 there were total 75 distributors, which have authorisation for distribution, these distributors dispose of 109 supplies.

The reviwe of the activity:

Number of submitted applications: total 27

Type of application	Distributing authorisation	Variation to a distributing authorisation with inspection	Variation to a distributing authorisation without inspection	Extension to distributing authorisation for MF and AI	Suspension of distributing authorisation	Revocation of distributing authorisation
Number	3	7	10	1	1	5

Number of issued decisions: total 26

Type of decision	Distributing authorisation	Variation to a distributing authorisation with inspection	Variation to a distributing authorisation without inspection	Extension to distributing authorisation for MF and AI	Suspension of distributing authorisation	Revocation of distributing authorisation
Number	3	6	10	1	1	5

All administrative proceedings were finished within the prescribed time 90 days without inclusion of suspension caused by applicant.

Number of unfinished applications postponed to the year 2008: total 1

Variation to a distributing authorisation with inspection	Variation to a distributing authorisation without inspection	Applications of new distributors - unfinished	Extension to distributing authorisation for MF and AI	Revocation of distributing authorisation
1	0	0	0	0

Number of inspections carried out: total 54

The total of 57 inspections within the range 55 days were carried out by the GDP Department of Inspection Section in 2007. The review of inspection types is presented in the following table.

Type of inspection	Initial systemic	Periodical systemic	Variation with inspection	Control inspection	Inspection centred on MA dossier	Subsequent inspections
Number	3	22	8	15	4	5

The total of 50 protocols were processed in 2007. The average processing time of protocol was 10 working days. Some inspections were sorted out by joint protocol.

Cooperation and further activities
Total of 6 joint inspections with SIDC were carried out.
The waste production report of ISCVBM was delivered to Brno Municipal Council.
The sample of Aivlosin prm. 20 kg was taken and dispatched within the frame of EDQM testing.
Every employee of Inspection Section – GDP Department takes part in seminars and trainings every year within the range 6 days approximately. The real number of trainings and seminars was 22 days in 2007.

Summary
The total number of primary work activity performed outside the Institute was 142 person/days in the year 2007 in the sphere of inspection and authorisation of MP distribution. No crucial discrepancies were found out, all time limits provided by Medicinal Act or in regulation documentation during the year 2007.
Greater attention was given to sphere of parallel importation, the attention will be given to this sphere henceforth in 2008, and from now on the correct labelling of MP marketed in CR will be checked.

6.3 Division for market control and market surveillance

Inspection activity
Inspections carried out in 2007 were aimed at:

1. manufacturing, importation, distribution and using of VMP in pharmaceutical form powder

2. comparison of VMP sale statement in pharmaceutical form powder in distributors with actual pharmacy distribution and sale to veterinary surgeons.
3. marketing and using of chloramphenicol by veterinary surgeons, pharmacies and breeders
4. dispensing of prescription only veterinary medicinal products
5. failure of original VMP packaging while dispensing in pharmacies
6. shortcomings found out in VMP usage statement of distributors
7. marketing of authorised VMP

Part of inspection activity was also sampling of original VMP packaging within the frame of market surveillance and solving of complaints and petitions sent to ISCVBM.

Sampling within the scope of Market Surveillance 2007
The number of samples taken within the scope of market surveillance: plan - 162 samples, 102 samples were taken, 60 samples were not marketed in CR (taking of 83 samples was resolved by individual inspection).

The activity review of Deparment of market control and market surveillance in comparison with plan

Type of inspection	Plan	Executed - Louny	Executed - Brno	TOTAL
Distributor	6	2	13	15
Pharmacy	104	4	98	102
Veterinary surgeon	41	57	6	63
Veterinary technician	-	1	-	1
Trade network	40	3	48	51
Distributor of VMP	-	-	1	1
Manufacturer of medicated feedingstuffs	5	5	7	12
Manufacturer of VMP	-	-	2	2
Breeders	10	1	9	10
Total	**206**	**73**	**184**	**257**

Pursuant to suggestions from inspections the total of 17 administrative proceedings were initiated.

Non inspection activity

The new register of VMP for manufacturers, distributors and manufacturers of medicated feedinstuffs was prepared which is made for VMP usage statement.
The protocol on usage of antimicrobial substances in CR was elaborated.
The usage of active ingredients according to administration route, pharmaceutical form, target animals and according to director suggestions.
The statement regarding usage of narcotic and psychotropic substances in CR during the year 2006 was elaborated according to statements of detached Regional Veterinary Administrations for Institute for addictive substances which is attached to Ministry of Health.
The revision of ATC codes in authorised medicinal products was carried out during the year 2007.

Training:

17 – 18.10. 2007 Assertive behaviour – Lenka Koutecká DVM, Dalibor Dorn, Zita Kurfürstová, Ivana Kučerová

Participation in seminars:
20.9.2007 – ISCVBM for MAHs – Zita Kurfürstová, Ivana Kučerová.

Evaluation

The schedule of inspection count was exceeded namely in veterinary surgeons (22 more) and trade network (11 more), further in manufacturers of medicated feedingstuffs (7 more), in distributors (9 more). Two inspections less was carried out in pharmacies. These changes resulted from the VMP usage statements during the year, from the monitoring results and from the survey of active ingredients importation and distribution.
Together with Regional Veterinary Administration for South Bohemia region the joint control in breeder was carried out aimed at VMP usage in heifer and calf rearing. The administrative proceeding with the breeder was initiated. Greater attention will be also given to usage of VMP by veterinary surgeons in breeders henceforth (year 2008).
Controls of marketing and usage of chloramphenicol, metronidazole and nitrofurantoine were carried out. It was found out that these active ingredients were used only in aquarist fish breeding. These controls will continue in the year 2008 as well.

7. Activity of the Laboratory Control Section

In 2007 the audit of Laboratory Control Section workplaces associated with laboratory reaccreditation was carried out by the Czech Institute for Accreditation personnel. This audit examined the adherence of accreditation criteria resulting from standard CSN EN/ISO 17025 and assessed the professional level of the laboratory related to activity both in the field of monitoring of extraneous substances residues (drug residues) in the food chain and in the field of VMP quality control.

At this supervision the application for new methods accreditation was submitted

- rabies virus titre assay by microtitration method in fox rabies vaccine (live)
- stanazolol assay by LC MS/MS method in biological substances

Both methods were examined and approved by the Czech Institute for Accreditation personnel.

On the basis of audit outcome the Czech Institute for Accreditation issued to Laboratory Control Section an Accreditation Certificate with effect until 31th October 2012.

In the metrology sphere the metrological security system of measuring tools was maintained and evolved in the Institute. Metrological order and measuring tools index and accessory equipment were updated continuously. On the basis of legalities (Metrology Act) the defined measuring tool examination was carried out by Czech Metrology Institute employee, periodic maintenance checks and calibrations of relevant operational measuring tools and maintence checks of accessory equipment were carried out as well according to individual measuring tool user requirements.

7.1 Official laboratory for VMP control and laboratory for VP conrol

Also this year the professional workplaces personnel of Official laboratory for VMP control have participated in number of national and international aptitude tests for executing existing trials.

Especially the offer of tests organised by EDQM was accepted namely for the sphere of physico-chemical trials.

- Quality in microbiology scheme (QMS), Qualifood s.r.o., CDC Atlanta, Determination of mould and yeast count
- Bacteriological diagnostics, EHK SZÚ – AP CEM, Microorganisms identification and susceptibility specification to selected antibiotics
- PTS 085 Microbiological assay of antibiotics, EDQM; Determination of gentamicin amount in 2 samples
- PTS 086 Assay by UV-spectrophotometry &loss drying, EDQM; assay of cyanocobalamine and loss on drying
- PTS 089 Semi-micro determination of water, EDQM
- PTS 090 Dissolution test, EDQM

From now on the collaboration with EDQM is going further in the sphere of controlling VMP authorised by centralised procedure – the analytical chemistry department was charged with fulfilment of physico-chemical tests in imunological VMP Eurican Herpes 205 inj. in 2007.

The main activity of this department was focused on the sphere of quality control in VMP marketed in CR – this project was initiated in 2005 already.

Official laboratory for VMP control personnel closely collaborated with Inspection section personnel on the preparation of annual plans and surveillance evaluation. Inspection section ensures for the laboratory department qualified sampling from distribution network and executes the following steps in the event that the laboratory finds out the results aside from approved product specification.

The Market Surveillance Program 2007 was focused in control of VMP containing substances from the cephalosporins group, quinolones and tetracyclines respectively in all marketed pharmaceutical forms of authorised VMPs. Total of 113 preparations was included into the Market Surveillance plan of VMP – pharmaceuticals, 73 products were recovered and delivered to analysis.

In the sphere of imunological VMP quality control the surveillance was focused on targeted control of live vaccines on mycoplasma presence, then content of bacterial endotoxins in vaccines containing gram-negative bacteria and quality control of live and inactivated erysipelas vaccine (herein conformably to nature of the product either the efficiency tests were provided or count determination of the viable germs including vaccine purity and bacterial strain typing.) and fox rabies vaccine (live) – virus titre determination.

The total of 50 preparations were icluded into sampling schedule (mycoplasma test 19, live erysipelas vaccine 3, inactivated swine erysipelas vaccine inactivated 16, inactivated rabies vaccine 2, bacterial endotoxins 10); 31 specimen were sampled and analysed (mycoplasma 7, live erysipelas vaccine 3, inactivated swine erysipelas vaccine 12, inactivated rabies vaccine 2, bacterial endotoxins 7).

Summary of sample analyses sent for laboratory test in 2007:

The total of **306 samples** were analysed during January – December 2007 (see summary – graph 7.1 and table 7/1), which represented **789 analyses** fulfilment, from that:

Microbiological Methods Department	168
Analytical Chemistry Department	572
PCR and Imunochemistry Methods Department	28
Biological Methods Department	5
Laboratory for Desinfectant Effects Detection	16

Graph 7.1 Number of provided analyses in the quality control sphere – according to analysis type (2007)

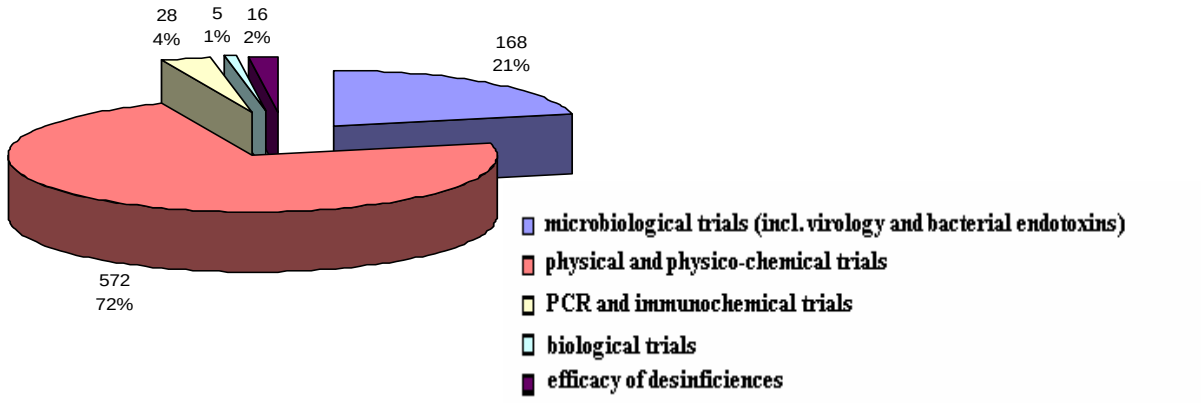


Table 7/1 Summary of analysed samples according to applicant and sample nature (2007)

Applicant	Sample	Quarter 2007				Total
		I	II	III	IV	
Marketing Authorisation	VMP pharmaceuticals	-	-	-	1	1
	VMP imunologicals	-	-	-	-	-
Approval	VP (desinficiences)	1	11	2	-	14
Inspection	VMP pharmaceuticals	17	33	30	24	104
	VMP imunologicals	7	26	11	6	50
	Medicated feedingstuffs	2	8	-	7	17
Pharmacovigilance	VMP pharmaceuticals	-	2	-	-	2
	VMP imunologicals	1	1	-	-	2
External Applicants	Human vaccines	28	29	-	-	57
	Others	11	17	11	20	59
Total	**Samples** /analyses/	**67** /157/	**127**/288/	**54** /168/	**58** /176/	**306** /789/

Table 7/2 Numbers of compliant and non compliant samples in 2007

Samples	Compliant	Non Compliant	Nature of quality imperfection
VMP Market Surveillance Pharmaceuticals	93	11	6× active ingredient content 3× density 2× pH 1× average tablet mass 1× degradation product content 1× appearance
VMP Market Surveillance Imunologicals	43	7	6× efficacy 1× bacterial endotoxins content
Control of medicated feedingstuffs	17	-	not evaluated
Marketing Authorisation	1	0	-
Approved VP	14	0	-
Pharmacovigilance	3	1	1× appearance
External Applicants	114	2	2× particle size
Total	**285[93,13%]**	**21 [6,87%]**	

Table 7/3 Developmental summary of analysed samples number and executed analyses quantity during 2003 – 2007

Samples / Year	2003	2004	2005	2006	2007
Number of analysed samples	395	234	238	300	306
Executed analyses quantity	450	440	580	739	789

7.2. Laboratory control - residues

7.2.1. Monitoring

The essential acitvity of the „Department for monitoring of extraneous substances residues“ is to carry out the monitoring according the Decree No 291/2003 Coll. concerning prohibition of administration of some substances to animals whose products are designated for human consumption, and monitoring of banned substances presence, residues and extraneous substances in animals and their products, due to the substances the animal products could be deleterious for human health. In June 2005 this Decree was amended by the Decree No 232/2005 Coll., furher in July 2006 by the Decree No 357/2006 Coll.

According to Decree No 291/2003 Coll., as amended by the subsequent acts the control of following substances is appertained to ISCVBM Laboratory: Group A substances – substances with anabolic effect and banned substances (in detail stated in Annex I of above mentioned Decree).
Sample survey summary for 2007 is stated in Annex 2 „Table 1 – appendix Monitoring 2007“.

The numbers of samples with unsatisfactory result from ELISA and RIA screening methods were passed on for conformation by GC-MS and LC MS/MS and were as follows:
nortestosterone – 22, RALs – 22, chloramphenicol – 27, methyltestosterone – 12, trebnolone – 2, clenbuterole – 10, ethinylestradiol – 1, gestagens – 1, nitrofurans – 1, dimetridazole – 2, metronidazole – 1.

Unsatisfactory samples in 2007

- chloramphenicol
  - prot. No. 648 urine – cattle live, locality - Radiměř, land register No. 73785, inspectorate Svitavy – Pardubice region
  - prot. No. 698 urine – cow live, locality Rusek, land register No. 74367, inspectorate Hradec Králové – Hradec Králove region
  - prot. No. 1065 muscle – pig, locality - Těšnovice, land register No. 76679, inspectorate Kroměříž – Zlín region (sampling point inspectorate Karviná - Moravian-Silesian region)
  - prot. No. 1260 muscle – pig, locality – Lužec nad Cidlinou, land register No. 68927, inspectorate Hradec Králové – Hradec Králové region
  - prot. No. 2179 muscle – chicken on farm, locality – Vysoké Veselí, land register No. 78835, inspectorate Jičín – Hradec Králové region
  - prot. No. 2518 muscle – pig, locality - Nepasovice, land register No. 70337, inspectorate Hradec Králové – Hradec Králové region (sampling point inspectorate Jičín – Hradec Králové region)
  - prot. No. 2706 muscle – pig, locality - Miskovice, land register No. 69599, inspectorate Kutná Hora – Central Bohemia region
  - prot. No. 2799 muscle – pig, locality – Kralovice u Rakovníka, land register No. 67264, inspectorate Plzeň - sever – Plzeň region (sampling point inspectorate Písek - South Bohemia region)
  - prot. No. 2868 muscle – chicken slaughtered, locality – Luže, land register No. 68925, inspectorate Chrudim – Pardubice region (sampling point inspectorate Ústí nad Orlicí - Pardubice region)

- 19 - nortestosterone
  prot. No. 1911 urine – pig slaughtered, lokality - Vlasatice, land region No. 78330, inpectorate Břeclav – South Moravia region (sampling point inspectorate Vyškov - South Moravia region)

In case of unsatisfactory results the method was proceeded according to Decree No. 291/2003 Coll. and „Sampling procedure and subsequent surveys in the event of excessive/unsatisfactory determinations of biological active substances used in animals and unpermitted treatments in terms of Monitoring plan of banned substances and VMP residues" – „Monitoring plan of banned substances, residues and contaminants in foodchains in 2007".

7.2.2. Special examinations

A) External Application

a) Invoicing – applications for examinations sent from manufacturers, owners etc.
Chloramphenicol – 25 (prot. No. 1, 1165, 1166, 1735 – 1743, 2882 – 2891, 2925, 2926, 2927)
Nitrofurans - 1 (prot. No. 2324)
Metronidazole – 1 (prot. No. 2928)

Special (circular) tests attendance in 2007:

Accredited HPLC testing laboratory

1) AOZ, AMOZ, AHD, SEM in crabs
organised by FAPAS,York,UK

2) Nitroimidazols in dried eggs
organised by BVL, Berlin, Germany

Accredited GC-MS testing laboratory

3) Chloramphenicol in dried milk
organised by BVL, Berlin, Germany

4) Chloramphenicol in honey and eggs
organised by AFSSA, Fougeres, France

5) Gestagens in fat
organised by RIVM, Bilthoven, Netherlands

Accredited ELISA testing laboratory

6) Chloramphenicol in dried milk
organised by BVL, Berlin, Germany

7) Chloramphenicol in honey and eggs
organised by AFSSA, Fougeres, France

Extra Actions:

- The ISCVBM application was granted and TAIEX approved the training project (EXP23917) - „Monitoring and Official Control of Veterinary Drug Residues“, proceeded in the term 26 – 30. 3. 2007. The programme included multiresidual method of anabolic hormones in urine, beta-agonists analysis and stanazole residues in urine and assessment of banned substances residues determination system on ISCVBM. These problems were presented as a report on workshop in Saskatoon – „The EC Education program: A Fast Lane to Effective Control in Veterinary Drug Residues in Foods“ – by Dr. Frgalová.

- The personnel was concerned in special workshops (business, metrological, statistical methods seminars etc.) according to its positions and qualification.

- Periodical annual workshop programmes of leaders EU CRL (BVG, RIVM) laboratories were reported on meetings of regional coordinators for national monitoring of extraneous substances, leaders of National Veterinary Institutes and ISCVBM Chemistry Departments.

- By deputy of DG SANCO the meeting of EU CRL-AFSSA Fougeres workers (Roudaut Brigitte, Hurtaud-Pessel Dominique) took place in 12 – 14. 11. 2007 with a view to activity of National Reference Laboratory.

- Mutual visit of Agency for Health and Nourishment workers in Wien and ISCVBM workers took place. The Agency practises the identical activities as ISCVBM in the sphere of monitoring.

8. Pharmacovigilance

In 2007 the Section of Pharmacovigilance was concerned with the following tasks:

- assessment of adverse effects reporting delivered to marketing authorisation holder, to veterinary surgeon and breeder and eventually taking measures related to this reporting
- Periodic Safety Update Reports assessing
- preparing adverse effects printouts upon manufacturers´ application.

V roce 2087 bylo Ústavu pro státní kontrolu veterinárních biopreparátů a léčiv hlášeno 18 podezření na výskyt nežádoucích účinků veterinárních léčivých přípravků a veterinárních přípravků v České republice.

Preparation	Popis nežádoucího účinku	Investigation results
Distemper and parvovirosis vaccine - live	Sudden death of puppy after vaccination	Suspect anaphylactic reaction, the result of postmortal examination was not available
Canine parvovirosis, distemper, infectious hepatitis, parainfluenza and leptospirosis vaccine	Injection site swelling, subsequently on the other body parts, apathy	Anaphylaxis after vaccination
Canine parvovirosis, distemper, infectious hepatitis, para-influenza and leptospirosis vaccine administered along with inactivated rabies vaccine	Vomiting, head swelling – circa 1 hour after vaccination	Anaphylaxis after vaccination
Canine parvovirosis, distemper, infectious hepatitis, parainfluenza, leptospirosis and rabies vaccine	trembling, apathy, anorexia, reluctance to movement	Anaphylaxis after vaccination
Porcine progressive atrophic rhinitis vaccine and Coli-infections vaccine	Abortion in sows	Simultaneous administration of 2 vaccines, high titre of antibodies against PRRS in vaccinated animals.
Vaccine against coccidiosis in poultry	Coccidiosis occurence after product administration	Coccidiosis caused by product administration probably. Circumstances and factors are being examined.
IBR vaccine - live	Antibodies in non vaccinated animals – suspect transfer of vaccine strain	Repeated blood taking from examinated animals – examination was made by Veterinary Research Institute Brno. According to results of the investigation there were probably persisting colostral antibodies
Vomiting inhibiting preparation	Dead circa 1 hour after administration	The preparation was used Off-Label.
Antibiotic solution for injection for dogs and cats	Trembling, vocalisation, heart arrest.	Possible relation with product administration, more simultaneously administered products
Intramammary antibiotic preparation for cows to go dry	Adverse effect was found in 8 cows from 20 treated 4th – 5th day after treatment – at the time of reporting 1 treated animal died	Acute parenchymatous mastitis – Klebsiella pneumoniae
Intramammary antibiotic preparation for cows to go dry	Adverse effect was found in 6 cows 3 – 10 days after administration – 4 treated animals	Acute parenchymatous mastitis – causative agent not isolated

	died, 2 recovered after treatment	
NSAID for dogs	Vomiting, haematochesis	Adverse effects stated in approved SPC
Antianemic solution for injection	Injection site abscesses spreading on the other parts of the body	The preparation was used off-label – repeat use
Antiparasitic preparation for dogs (spot-on)	Clinical symptoms appeared after administration of the product – frothing from oral cavity, vomiting, opistotonus, next day the patient was hospitalized and supportive treatment was given. Despite of the treatment, the patient died.	The result of patho-anatomical investigation – hydrocephalus, strong degenerative alterations in liver (susp. PS shunt)
Deworming preparation for dogs	Poor efficiency	
Deworming preparation for cats	Vomiting and apathy	
Ectoparasitic preparation	Treated animal died	Unexplained conditions regarding health state of treated animal

9. Legal department

During 2007 there were in total 34 administrative proceedings were initiated for breaching of the Medicine Act No. 79/1997 Coll. as amended by the subsequent acts or for breaching of the Veterinary Act No. 166/1999 Coll. as amended by the subsequent acts, based on the groundworks from the Section of Inspection and other competent Institute experts (in 2006 there were started and proceed in total 49 administrative proceedings, in 2005 – 48, in 2004 – 29). In 2007 there were 30 administrative proceedings finished (from that 2 started in 2006). The high of inflicted fines was 283,500 CZK, which are the revenues of the state budget. The highest fine was 90,000 CZK, the lowest 1,000 CZK.
Two administrative proceedings were accomodated due to reasoned disclaimer and this proceedings were stopped.
Refunding of proceeding expences in total high of 1,000 CZK was inflicted, the total charges were reimbursed amounting to 30,000 CZK.

10. Department of informatics, ISCVBM Bulletin, information providing, supervision of advertising

Information technology

During 2007 the common activities of maintaining and innovation both servers and workstations took place. The licences of MS Office, archival software WinRAR were purchased, then software and hardware equipment for operating of electronic document record system in registration procedures were bought which is in connection with registrar office.
Continuous renovation of computer equipment used on Institute network was done. The videoconferencing device was purchased and in consequence the videoconference room was built up.
For the year 2008 the adjustment of existing wireless connection to VUT Brno network to connection via optical fibre cable is being prepared.
Furher backround papers for connection to Cross Compliance System are being prepared and developing of connection to EudraPharm System database with EC competency is being finalized.

ISCVBM Bulletin

During 2007ISCVBM via its Bulletin was regularly informing the public about issued decisions on marketing authorisations of medicinal products, their renewals, variations, transfers, termination and deletion, about issued decisions of approved veterinary products, their renewal, variations, validity termination and deletion and about register of VTD. ISCVBM guidelines, important information for holders of marketing authorisation decisions, updated lists of VMPs and VP manufacturers, distributors of VMPs, MF manufacturers, medicinal substances manufacturers, list of over the counter VMPs and reviews of validity of marketing authorisation decisions for VMP were published in the ISCVBM Bulletin last year. The ISCVBM Bulletin was issued six time a year, every two months in the amount of 150 printed copies.

A public information about VMPs, their approved SPC and PL were regularly provided to compiler of the Automatted Information System of Medicinal Products (AISMP). These information including the essential information on VP, VTD and biocides were also provided for publication to the editors of the journal Veterinářství.

Information of the ISCVBM activities are also provided by ISCVBM web sites (www.uskvbl.cz).

Total of 34 personal consultations was carried out during the year 2007 relating to VMP marketing authorisation; from this amount there was 9 paid applications for consultation. In the field of approved veterinary products, VTP and biocides the total of 80 personal consultations was carried out. In the field of GMP 25 consultations took place, in the field of medicated feed GMP 5 and concerning GDP 9 personal consultations relating to licence permit application and variations in licence permit applications.

Information providing according to Act No. 106/1999 Coll.

Report on the activities of the Institute for State Control of Veterinary Biologicals and Medicaments in the sphere of information providing submitted in accordance with paragraph 18 of the Act No. 106/1999 Coll., relating to the free information access, as amended by the subsequent acts

In a year 2007

Article 1 a)
During the year 2007 there were 4384 information applications made to ISCVBM in total in accordance with Free Information Access Act

Article 1 b)
All applications for information providing were granted according to aforementioned Act, no appeal was brought.

Article 1 c)
In the matter of information providing according to aforementioned Act no legal proceedings were conducted with ISCVBM, no court judgment was delivered.

Article 1 d)
In the matter of information providing according to aforementioned Act no administrative proceeding were conducted regarding sanctions for its breaching.

Article 1 e)

The sphere of provided information	Number
Marketing authorisation of VMP	2648
Approval of VP, biocides and VTP	1250
Package Leaflet of VLP – the application revoked	-
Legal	74
VMP, VP, biocides lists	30
Pharmacovigilance	28
VMP manufacturing	190
MF manufacturing	100
Distribution	64
Total	**4384**

ISCVBM Library

The the operating of registrar premises and ISCVBM library is provided by Registration Section of ISCVBM.
The ISCVBM library manages the book stock and journal fund via the database. Total of 2690 books is registered on the 31. 12.2007 (acquisition of the library fund were total 49 books compared to year 2006, from that 25 were Czech and 24 foreign). Total of 33 journals were subscribed on the 31. 12.2007. From this amount 17 were czech journals and 16 foreign. (Acquisiton was 1 czech journal and 2 foreign journals compared to year 2006, from this amount 1 journal is electronic).

Total number of registration documentation items recorded in the database was 24.034 on the 31.12.2007 (annual acquisition 4.436 items).

Supervision in the sphere of VMP advertising

In 2007 the ISCVBM obtained 3 notifications regarding unethical advertising manners. Cases submitted for examination were related to two cases of advertising for prescription only VMP intended for general public, in one case advertising of VMP which was authorised neither in the Czech Republic nor in EC member states and to which the exception for importation was granted by State Veterinary Administration. In 2007 there was no administrative proceeding conducted and there were no penalties for Advertising Regulation Act violation.

11. Economical and operating sphere

Economical indexes of state budget final settlement in 2007

The total amount of financial resources assigned to ISCVBM in 2007 was 63,411,000 CZK, from that investment resources were 8,500,000 CZK, uninvestment resources 54,911,000 CZK, from these 22,381,000 CZK fell on salaries.

Investment resources in the total approved amount of 8,500,000 CZK were utilized for realization of conclusions resulting from energetic audit of the organisation – heat insulation of the building, part B and C, amounting to 3,536,000 CZK, furher initialization of covering with a roof, part B and C, amounting to 3,551,000 CZK. Units and machinery, vehicles and reconstructions were provided in total amount of 2,891,000 CZK. Reserve fund (RF) resources from 2006 were used amounting to 44,000 CZK. The amount of 3,270,000 CZK was transfered to RF 2007. In 2008 this sum will be used on finalization of attic for puposes of registration section in part B and C of main building.

Uninvestment resources were utilized amounting to 54,911,000 CZK, from these the highest part are payroll costs and lawful contributions to health and social insurance of employees in total of 22,381,000 CZK. This year the RF resources were used on current expences amounting to 5,500,000 CZK. Uninvestment resources utilization for the other purposes were accomplished according to needs of the Institute during this year. The resources on current expences amounting to 5,500,000 CZK were transfered into RF 2007 and will be used on finalization of repairing sanitary plumbing delivery in part B and C of the building. It is the realization of energetic audit conclusions.

In the year 2007 the resources from costs refund were withdrawn in total amount of 14,237,000 CZK. On 27 February 2006 the Service Pricelist – cost payment of marketing authorization applications, which are drawn by the Institute on the basis of article No. 65 of Medicine Act No. 79/1997 Coll., was published in the Ministry of Finance Bulletin. These financial resources are not part of state budget and were drawn in compliance with the act No. 218/2000 Coll. as amended, in compliance with internal regulations for drawing S-018/1000 and pursuant to Regulations for using the extra budget sources from Ministry of Agriculture, from 7 November 2006, Ref. No. 34386/2006-13012.

The regularity of resources drawing from the state budget is evident from the table No. 1, interannual fluctuations occured only in resources drawing for investment when the largest part of these costs are the resources used on building investments, and hence it is necessary to consider seasonal character of these operations.

The withdrawing of payroll costs was steady and corresponds to approved budget. In the Institute there were 87,24 recounted employees working in the year 2007.

In 2007 the Institute managed property by total of 136,966,000 CZK, from that 119,091,000 CZK was the corporeal property and incorporeal property, 17,875,000 CZK was the small corporeal property. Furher 6,354,000 CZK is small corporeal property and corporeal property in operational evidence.

On foreign working journeys the costs amounting to 1,508,000 CZK were drawn. These working journeys were undertaken by special employees from the Institute namely from the reason of participation on the EMEA meetings, scientific workshops and trainings.

The amount of commitments to suppliers was 2,373,780 CZK on the 31 December 2006 and the amount of claims was 537,530 CZK.

The Institute is the permanent member of following international organisations:

PIC/S
BfARM

The member fees in these organisations are fully covered by the Ministry of Agriculture.

The Institute actively engaged in the preparation of CR presidency of the Council, two experts were nominated to the special committees.

The Institute participates in the realization of the research and development project in cooperation with Veterinary Research Institute and in the food safety project in cooperation with the University of Veterinary and Pharmaceutical Sciences Brno.

The Institute deputies takes part regularly in the EMEA meetings, but all costs of activities accompanying are covered or refunded from the EC (EMEA) resources.

Basic index review of summary budget fulfilment – see Annex No. 3

12. Employees

12.1 Basic personal data

Table 12/1: Classification of employees according to age and sex – situation on the 31. 12. 2007

Age	Men- budget	Men - extra budget	Women- budget	Women – extra budget	Total	%
up to 20 years	0	0	0	0	0	0
21-30 years	3	1	1	1	6	6,4
31-40 years	5	0	25	0	30	31,9
41-50 years	5	0	20	0	25	26,6
51-60 years	1	0	20	0	21	22,3
61 years and more	4	0	8	0	12	12,8
Total	**18**	**1**	**74**	**1**	**94**	100
%	19,1	1,1	78,7	1,1	100	

Table 12/2: Classification of employees according to education and sex - situation on the 31. 12. 2007

Education	Men - budget	Men – extra budget	Women- budget	Women- – extra budget	Total	%
Elementary	0	0	5	0	5	5,3
Craft	0	0	1	0	1	1,1
High School	2	0	4	0	6	6,4
High School with Graduation	0	0	0	0	0	0
Vocational Training with Graduation	4	0	34	0	38	40,4
Advanced Vocational Training	0	0	0	0	0	0
University Degree	12	1	30	1	44	46,8
Total	**18**	**1**	**74**	**1**	**94**	100
%	19,1	1,1	78,7	1,1	100	

Table 12/3: Total data of average salaries on the 31. 12. 2007

	Total
Average gross monthly salary	20,751 CZK

Table 12/4: Total data concerning the beginning and ending of employment in 2007

	Total amount	From that extra budget	From that government regulation No. 436/2007
Coming	8	2	0
Outgoing	9	0	2

Table 12/5: Length of employment - situation on the 31. 12. 2007

Length	**Number of employees – budget**	**Number of employees - extra budget**	**%**
up to 5 years	28	2	31,9
5 - 10 years	23	0	24,5
10 - 15 years	21	0	22,3
15 - 20 years	10	0	10,6
over 20 years	10	0	10,6
Total	**92**	**2**	**100**

12.2 Training of employees

The cooperation in training of ISCVBM empoyees with the Institute of Agronomic and Food Information was going further in 2007. E.g. Entrance Training Course in appointees, 5 employees have successfully passed Information Science Training Course. During the year ISCVBM empoyees participate in seminars and various training programmes as necessary both in our country and abroad.

13. Work safety, fire prevention

The fire prevention inspections centred on electric appliances, patency of emergency exits, fire extinguishing equipment, condition of stand-by lighting and control of fire doors were carried out during the year 2007.
The periodical revision of fire main and fire extinguishers was carried out by TESPO company in May.
During the year the construction work, water distribution system reconstruction and waste disposal system took place in main building. Early in 2007 the fabrication of saddle roof on the main building was initiated.
All new employees were teached in fire prevention and protection. No fires were recorded during 2007.

14. Conclusions and perspectives by the year 2008

For the year 2008 it appears as a main aim to realize quality, efficacy and safety standards for veterinary medicinal products in compliance with newly passed Act No. 378/ 2007 Coll. and elaboration of implementing decrees for this purpose.
It will be necessary realize entire scientific activity with reduced number of employees also regarding new duties arising from Act No. 378/ 2007 Coll. (inspection, pharmacovigilance including electronic case reporting, antibiotic policy, monitoring of extraneous substances residues and so on).
Hereafter, there will be highly important preparation for presidency of CR in first half of 2009, the Institute will provide some activities in the sphere of veterinary pharmaceuticals.
Within the frame of collaboration with Ministry of Agriculture and State Veterinary Administration of CR the commitments for Cross compliance and for shared control activities will be attained.

Explanation of appplied abbreviations

Abbreviation		Explanation
Czech	**English**	
AISLP	AISMP	Automatic Information System of Medicinal Products
ATB	ATB	Antimicrobials
ATC	ATC	Anatomic Therapeutical Classification
ATM	ATS	Antimicrobial Substance
AV	AV	Autogenic Vaccine
AZL	ATL	Accredited testing laboratory
BOZ	HSP	Health safety and protection
CAVDRI		Collaboration Agreement between Veterinary Drug Regulatory Institutions
CVMP	CVMP	Comittee for Veterinary Medicinal Products
ČIA	CIA	Czech Institute for Accreditation
ČL	PhB	Pharmacopoeia Bohemica
ČLK	CPC	Czech Pharmacopoeia Committee
ČLS JEP	CMS JEP	Czech Medical Society of J. E. Purkyne
ČMI	CMI	Czech Metrology Institute
DIMDI	GIMDI	Deutsches Institut für Medizinische Dokumentation und Information
EDQM	EDQM	European Directorate for the Quality of Medicines
EEA	EEA	European Economy Area
EHK	EQA	External quality Assessment
EHS	EEC	European Economic Community
EK	EC	European Committee
EL	EuPh	European Pharmacopoeia
ELK	EuPhC	European Pharmacopoeia Committee
EMEA	EMEA	European Medicinal Agency
ES	EC	European Community
EU	EU	European Union
FGV	PVG	Pharmacovigilance
GC	GC	Gas Chromatography
GC-MS	GC-MS	Gas Chromatography – Mass Spectrometry
SVP	GMP	Good manufacturing practice
HEVRA	HEVRA	Heads of European Veterinary Regulatiory Authorities
HPLC	HPLC	High performance Liquid Chromatography
HVLP	MPMP	Mass Produced Medicinal Product
IPVPN	IPVPN	Internet Protocol Virtual Private Net
LL	ML	Medicinal substance
KL	CL	Control Laboratory
MěVS	MVA	Municipal Veterinary Administration
MK	MF	Medicated Feed
MRA	MRA	Mutual REcognition Agreement
MF	ME	Ministry of Finance
MZ	MH	Ministry of Health
MZE	MA	Ministry of Agriculture
NCCLS	NCCLS	National Committee for Clinical Laboratory Standards

PECA	PECA	Protocol on European Conformity Assessment Agreement
PERF	PERF	Pan-European Regulatory Forum
PIC/S	PIC/S	Pharmaceutical Inspection Co-operation Scheme
PN	CS	Company Standard
PO	FP	Fire Protection
RHP	HFE	Hand Fire Extinguisher
SAGAM	SAGAM	Scientific Advisory Group on Antimicrobials
SDP	GDP	Good Distribution Practice
SKP	GCP	Good Clinical Practice
SLK	SLC	Section of Laboratory Control
SOP	SOP	Standard Operating Procedure
SÚKL	SIDC	State Institute for Drug Control
SVS ČR	SVA CR	State Veterinary Administration of the Czech Republic
SZÚ	SHI	State Health Institute
TAIEX	TAIEX	Technical Assistance Information Exchange Office
ÚKZÚZ	CITAI	Central Inspection and Testing Agricultural Institute
ÚSKVBL	ISCVBM	Institute for State Control of Veterinary Biologicals and Medicaments
VAS	VAC	Veterinary Antibiotic Centres
VEDDRA	VEDDRA	Veterinary Dictionary for Drug Regulatory Activities
VICH	VICH	Veterinary International Conference on Harmonisation
VLP	VMP	Veterinary Medicinal Product
VPN	VPN	Virtual Private Network
VTP	VTD	Veterinary Technical Device

Annex No. 1
Table A Organizational structure of the Institute for State Control of Veterinary Biologicals and Medicaments valid from 1st December 2007 till 1st February 2008

Directorate			
Director			
	Secretariate		
	Legal Department		
	Office for Publicity, Information and Market Supervision		
	Quality Manager		
	Office for International Harmonisation		
	Personnel Office		
	Economics Department		
		Department of Registrar Office and Dispatching Office	
		Department of Accountant and Material and Technical Support	
		Department for Work and Wages	
		Department for Administration and Register Office	
		IT Department	
		Technical-operational Department	
			Maintenance Office
			Cleaning Office
	Laboratory Control Section		
		Quality Manager	
		Secretariat	

Continuing on further page

	Division of Laboratory for Monitoring of Veterinary Drug Residues	
		Office for Acceptance and Records of Monitoring Samples
		HPLC Department
		GC Department
		Department of Screening Methods
	Division of Official Control Laboratory for Medicinal Products	
		Department of Analytical Chemistry
		Department of Microbiological Methods
		Workplace for decontamination, washing and sterilisation of laboratory glassware and preparation of nutrient media
		Laboratory for bacterial endotoxines *Laboratory for virology*
		Department of PCR and Imunological Methods
		Department for „in vivo“Biological Methods and Experimental Plants for „in vivo“ Experiments
	Division of Conrol Laboratory for Veterinary Products	
Inspection Section		
	Quality Manager	
	Secretariat	

Continuing on further page

		Division for GMP of Medicinal Products, Medicated Feedingstuffs, Autogenous Vaccines and Veterinary Products	
			Department for GMP of Medicinal Products, Active Ingredients and Autogenous Vaccines
			Department for GMP of Medicated Feedinstuffs
		Division for GDP	
			Department for GDP Inspection
		Division for Market Control, Dispensing and Usage of Medicinal Products	
			Department for Monitoring of Medicinal Product Usage
			Department for Control of Dispensing and Usage of Medicinal Products and Veterinary Products
		Department for Pharmacovigilance	
		Field Office Louny	
	Section of Marketing Authorisation, Approval and Register of VTD		
		Quality Manager and Coordinator of Matters concerning EC Marketing Authorisations and CVMP **Division for Administrative Affairs – MA Procedures and Approval** **Division for Marketing Authorisation of Pharmaceuticals**	
			Department for the Quality Assessment of VMP

Continuing on further page

		Department for the Safety Assessment of VMP
		Department for the Safety Assessment of VMP Residues
		Department for Efficacy Assessment of VMP
	Division for Marketing Autorisation of Imunologicals	
		Department for the Assessment of Bacterial Vaccines and Hyperimmune Sera
		Department for the Assessment of Poultry and Rabbit Viral Vaccines
		Department for the Assessment of Viral Vaccines for Other Target Species
	Department for Approval of Veterinary Products and the Register of Veterinary Technical Devices	
	Department for Clinical Evaluation	
	Department for Pharmacopoeia	

Annex No. 2

Table No. 1 – Monitoring 2007

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality
A (1)	STILBENS	Cattle live	urine	28	28
		Cattle slaughtered	urine	35	35
		Cow live	urine	28	28
		Cow slaughtered	urine	33	33
		Calf live	urine	4	4
		Calf slaughtered	urine	2	2
		Sheep live	urine	1	1
		Sheep slaughtered	urine	1	1
		Goat live	urine	1	1
		Pig live	urine	5	5
		Pig slaughtered	urine	90	90
		Horse live	urine	1	1
		Chicken slaughtered	muscle	23	23
		Chicken on farm	muscle	4	4
		Turkey slaughtered	muscle	3	3
		Turkey on farm	muscle	1	1
		Waterfowl slaughtered	muscle	3	3
		Waterfowl on farm	muscle	1	1
		Layer slaughtered	muscle	1	1
		Layer on farm	muscle	2	2
		Quail	muscle	0	0
		Fish	muscle	30	30
		Rabbit	muscle	2	2
		Farm game	muscle	3	3
		Total		**302**	**302**
A (2)	THYREOSTATICS	Cattle live	urine	13	13
		Cattle slaughtered	urine	13	13
		Cow live	urine	34	34
		Cow slaughtered	urine	24	24
		Calf live	urine	2	2
		Calf slaughtered	urine	1	1
		Sheep live	urine	1	1
		Sheep slaughtered	urine	1	2
		Goat live	urine	1	0
		Pig live	urine	5	5
		Pig slaughtered	urine	50	50
		Horse live	urine	1	1
		Chicken slaughtered	muscle	21	21
		Chicken on farm	muscle	3	3
		Turkey slaughtered	muscle	3	3
		Turkey on farm	muscle	2	2
		Waterfowl slaughtered	muscle	3	3

		Waterfowl on farm	muscle	**0**	0
		Layer slaughtered	muscle	**3**	3
		Layer on farm	muscle	**3**	3
		Quail	muscle	**0**	0
		Rabbit	muscle	**1**	1
		Farm game	muscle	**3**	3
		Total		**188**	**188**

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality
A (3)	TREBNOLONE	**Cattle live**	urine	**6**	6
		Cattle slaughtered	urine	**5**	5
		Cow live	urine	**6**	6
		Cow slaughtered	urine	**5**	5
		Calf live	urine	**2**	2
		Calf slaughtered	urine	**1**	1
		Goat live	urine	**1**	1
		Pig live	urine	**4**	4
		Pig slaughtered	urine	**39**	39
		Horse live	urine	**1**	1
		Chicken slaughtered	muscle	**18**	18
		Chicken on farm	muscle	**5**	5
		Turkey slaughtered	muscle	**2**	2
		Turkey on farm	muscle	**1**	1
		Waterfowl slaughtered	muscle	**2**	2
		Waterfowl on farm	muscle	**1**	1
		Layer slaughtered	muscle	**1**	1
		Layer on farm	muscle	**1**	1
		Quail	muscle	**0**	0
		Rabbit	muscle	**1**	1
		Farm game	muscle	**2**	2
		Total		**104**	**104**
A (3)	ETHINYLESTRADIOL	**Cattle live**	urine	**6**	6
		Cattle slaughtered	urine	**5**	5
		Cow live	urine	**6**	6
		Cow slaughtered	urine	**4**	4
		Calf live	urine	**1**	1
		Calf slaughtered	urine	**1**	1
		Sheep live	urine	**1**	1
		Pig live	urine	**2**	2
		Pig slaughtered	urine	**39**	39

		Horse live	urine	**0**	0
		Fish	muscle	**15**	15
		Total		**80**	**80**
A (3)	**NORTESTOSTERONE**	**Cattle live**	urine	**6**	6
		Cattle slaughtered	urine	**6**	6
		Cow live	urine	**6**	6
		Cow slaughtered	urine	**5**	5
		Calf live	urine	**2**	2
		Calf slaughtered	urine	**2**	2
		Sheep live	urine	**0**	0
		Sheep slaughtered	urine	**0**	0
		Goat slaughtered	urine	**0**	0
		Pig live	urine	**5**	5
		Pig slaughtered	urine	**42**	42
		Horse live	urine	**1**	1
		Total		**75**	**75**

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality
A (3)	**METHYLTESTOSTERONE**	**Cattle live**	urine	**6**	6
		Cattle slaughtered	urine	**5**	5
		Cow live	urine	**4**	4
		Cow slaughtered	urine	**5**	5
		Calf live	urine	**2**	2
		Calf slaughtered	urine	**1**	1
		Goat slaughtered	urine	**1**	1
		Pig live	urine	**2**	2
		Pig slaughtered	urine	**39**	39
		Horse live	urine	**0**	0
		Chicken slaughtered	muscle	**4**	4
		Chicken on farm	muscle	**2**	2
		Turkey slaughtered	muscle	**1**	1
		Turkey on farm	muscle	**0**	0
		Waterfowl slaughtered	muscle	**1**	1
		Waterfowl on farm	muscle	**0**	0
		Layer slaughtered	muscle	**1**	1
		Layer on farm	muscle	**0**	0
		Quail	muscle	**0**	0
		Rabbit	muscle	**0**	0

		Farm game	muscle	**1**	1
		Fish	muscle	**15**	15
		Total		**90**	**90**
A (3)	**GESTAGENS**	**Cattle**	fat	**18**	18
		Cow	fat	**8**	8
		Calf	fat	**2**	2
		Sheep	fat	**1**	2
		Goat	fat	**1**	0
		Pig	fat	**50**	50
		Total		**80**	**80**
A (3)	**ESTRADIOL**	*Heifer live*	serum	***8***	*8*
		Bullock live	serum	***7***	*6*
		Cattle live	serum	**15**	**14**
		Heifer slaughtered	serum	***6***	*7*
		Bullock slaughtered	serum	***5***	*6*
		Cattle slaughtered	serum	**11**	**13**
		Total		**26**	**27**
A (3)	**TESTOSTERONE**	*Heifer live*	serum	***7***	*7*
		Bullock live	serum	***7***	*7*
		Cattle live	serum	**14**	**14**
		Heifer slaughtered	serum	***5***	*5*
		Bullock slaughtered	serum	***6***	*6*
		Cattle slaughtered	serum	**11**	**11**
		Total		**25**	**25**
A (3)	**CORTICOSTEROIDS (DEXAMETHAZONE, TRIAMCINOLONE)**	**Cattle live**	urine	**5**	5
		Cattle slaughtered	urine	**5**	5
		Cow live	urine	**5**	5
		Cow slaughtered	urine	**4**	4
		Calf live	urine	**1**	1
		Calf slaughtered	urine	**0**	0
		Sheep slaughtered	urine	**1**	1
		Pig live	urine	**1**	1
		Pig slaughtered	urine	**10**	10
		Horse live	urine	**0**	0
		Total		**32**	**32**

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality
A (3)	**BOLDENONE**	**Cattle live**	urine	**5**	5
		Cattle slaughtered	urine	**4**	4
		Cow live	urine	**0**	0
		Cow slaughtered	urine	**2**	2
		Calf live	urine	**1**	1
		Calf slaughtered	urine	**0**	0
		Sheep slaughtered	urine	**0**	0
		Pig live	urine	**1**	1

		Pig slaughtered	urine	4	4
		Horse live	urine	0	0
		Total		17	17
A (3)	STANOZOLE	Cattle live	urine	2	2
		Cattle slaughtered	urine	0	0
		Cow live	urine	1	1
		Cow slaughtered	urine	0	0
		Calf live	urine	0	0
		Calf slaughtered	urine	0	0
		Sheep slaughtered	urine	0	0
		Pig live	urine	0	0
		Pig slaughtered	urine	7	7
		Horse live	urine	0	0
		Total		10	10
A (4)	RALs	Cattle live	urine	24	24
		Cattle slaughtered	urine	23	23
		Cow live	urine	18	18
		Cow slaughtered	urine	20	20
		Calf live	urine	3	3
		Calf slaughtered	urine	2	2
		Sheep live	urine	1	1
		Sheep slaughtered	urine	1	1
		Goat slaughtered	urine	1	1
		Pig live	urine	5	5
		Pig slaughtered	urine	80	80
		Horse live	urine	1	1
		Chicken slaughtered	muscle	22	22
		Chicken on farm	muscle	7	7
		Turkey slaughtered	muscle	3	3
		Turkey on farm	muscle	1	1
		Waterfowl slaughtered	muscle	3	3
		Waterfowl on farm	muscle	1	1
		Layer slaughtered	muscle	2	1
		Layer on farm	muscle	1	1
		Quail	muscle	0	0
		Rabbit	muscle	1	1
		Farm game	muscle	3	3
		Total		223	222

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality

A (5)	BEAGO	**Cattle live**	urine	**30**	30
		Cattle slaughtered	liver	**24**	24
		Cow live	urine	**26**	26
		Cow slaughtered	liver	**23**	23
		Calf live	urine	**4**	4
		Calf slaughtered	liver	**3**	3
		Sheep live	urine	**1**	1
		Sheep slaughtered	liver	**1**	1
		Goat live	urine	**1**	1
		Pig live	urine	**5**	5
		Pig slaughtered	liver	**80**	80
		Horse slaughtered	liver	**1**	1
		Chicken slaughtered	liver	**21**	21
		Chicken on farm	liver	**7**	7
		Turkey slaughtered	liver	**4**	4
		Turkey on farm	liver	**1**	1
		Waterfowl slaughtered	liver	**3**	3
		Waterfowl on farm	liver	**1**	1
		Layer slaughtered	liver	**2**	2
		Layer on farm	liver	**1**	1
		Rabbit	liver	**1**	1
		Farm game	liver	**7**	7
		Feedingstuff for cattle	feedingstuff	**10**	10
		Feed water for cattle	water	**10**	10
		Total		**267**	**267**
A (6)	CHLORAMPHENICOLE	**Cattle live**	urine	**50**	50
		Cattle slaughtered	muscle	**30**	30
		Cow live	urine	**55**	54
		Cow slaughtered	muscle	**32**	32
		Calf live	urine	**5**	5
		Calf slaughtered	muscle	**6**	6
		Sheep slaughtered	muscle	**1**	2
		Goat slaughtered	muscle	**1**	0
		Pig live	urine	**30**	30
		Pig slaughtered	muscle	**190**	190
		Horse slaughtered	muscle	**1**	1
		Chicken slaughtered	muscle	**143**	143
		Chicken on farm	muscle	**32**	32
		Turkey slaughtered	muscle	**10**	10
		Turkey on farm	muscle	**3**	3
		Waterfowl slaughtered	muscle	**14**	14
		Waterfowl on farm	muscle	**3**	3
		Layer slaughtered	muscle	**8**	10
		Layer on farm	muscle	**10**	9
		Quail	muscle	**0**	0
		Fish	muscle	**20**	20

		Rabbit	muscle	**6**	6
		Farm game	muscle	**3**	3
		Cow milk	milk	**85**	85
		Goat milk	milk	**4**	4
		Sheep milk	milk	**2**	2
		Hen egg	eggs	**46**	46
		Quail egg	eggs	**2**	2
		Poultry feedingstuff	eggs	**10**	10
		Feed water for poultry	water	**10**	10
		Component-fish farina	feedstuff	**5**	5
		Honey domestic	honey	**10**	10
		Total		**827**	**827**

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality
A (6)	**NITROIMIDAZOLS** (DIMEZ METRO RONID)	**Cattle**	muscle	**5**	5
		Cow	muscle	**8**	8
		Calf	muscle	**2**	2
		Sheep	muscle	**1**	1
		Goat	muscle	**0**	0
		Pig	muscle	**25**	25
		Chicken slaughtered	muscle	**20**	20
		Chicken on farm	muscle	**8**	8
		Turkey slaugthered	muscle	**4**	4
		Turkey on farm	muscle	**1**	1
		Waterfowl slaughtered	muscle	**4**	4
		Waterfowl on farm	muscle	**1**	1
		Layer slaughtered	muscle	**3**	3
		Layer on farm	muscle	**4**	4
		Hen egg	eggs	**6**	6
		Rabbit	muscle	**4**	4
		Fish	muscle	**5**	5
		Farm game	muscle	**2**	2
		Poultry feedingstuff	feedstuff	**30**	30
		Total		**133**	**133**
A (6)	**CHLORPROMAZINE**	**Cattle**	kidney	**3**	3
		Cow	kidney	**2**	2
		Calf	kidney	**1**	1
		Sheep	kidney	**1**	1
		Goat	kidney	**1**	1
		Pig	kidney	**20**	20
		Total		**28**	**28**
A (6)		**Cattle**	muscle	**10**	10
		Cow	muscle	**10**	10
		Calf	muscle	**5**	5
		Sheep	muscle	**1**	2
		Goat	muscle	**1**	0

		Pig	muscle	**25**	25
		Chicken slaughtered	muscle	**30**	30
	NITROFURANS	**Chicken on farm**	muscle	**12**	12
		Turkey slaugthered	muscle	**13**	13
	(AOZ	**Turkey on farm**	muscle	**1**	1
	AHD	**Waterfowl slaughtered**	muscle	**8**	8
	AMOZ	**Waterfowl on farm**	muscle	**1**	1
	SEM)	**Layer slaughtered**	muscle	**3**	3
		Layer on farm	muscle	**4**	4
		Fish	muscle	**5**	5
		Rabbit	muscle	**4**	4
		Farm game	muscle	**2**	2
		Hen egg	eggs	**16**	16
		Quail egg	eggs	**1**	1
		Cow milk	milk	**10**	10
		Goat milk	milk	**1**	1
		Sheep milk	milk	**1**	1
		Honey domestic	honey	**10**	10
		Total		**174**	**174**

Group	Analysed substance	Animal	Matrix	Plan 2007	Reality
A (6)	**PROPIONYLPROMAZINE**	**Cattle**	kidney	**19**	19
		Cow	kidney	**16**	16
		Calf	kidney	**5**	5
		Sheep	kidney	**3**	3
		Goat	kidney	**1**	1
		Pig	kidney	**80**	80
		Horse	kidney	**1**	1
		Total		**125**	**125**
A (6)	**CARAZOLOL**	**Cattle**	kidney	**19**	19
		Cow	kidney	**16**	16
		Calf	kidney	**5**	5
		Sheep	kidney	**3**	3
		Goat	kidney	**1**	1
		Pig	kidney	**80**	80
		Horse	kidney	**1**	1
		Total		**125**	**125**
T O T A L				**2931**	**2931**

Annex No. 3 **Table No. 1**

Basic index review of summary budget fulfilment
in 2007

ORGANIZATIONAL STATE UNITS

Organization (OSU):

Budget Functional Enlistment (article)									
	Thousands CZK			***%***	***Thousands CZK***	***%***	***Thousands CZK***	***%***	***CZK***
Obligatory Indexes	**Approved Budget 2007**	**Amended Budget on the 31.12.2007**	**Actuality on the 31.3.2007**	**UR Drawing 2007**	**Actuality on the 30.6.2007**	**UR Drawing 2007**	**Actuality on the 30.9.2007**	**UR Drawing 2007**	**Actuality on 30.9.2007 in to incl. Using of E budget resour without the tra to RF**
a	**1**	**2**	**3**	**4 (sl.3/sl.2)**	**5**	**6 (sl.5/sl.2)**	**7**	**8 (sl.7/sl.2)**	**9**
Income Budget									
Incomes OSU in total	**350**	350	178	50,86	250	71,43	398	113,71	
(incl. additional, occasional and other incomes)									
Outgoing Budget									
1. Common Outgoings OSU in total	**54 597**	54 911	10 944	19,93	26 196	47,71	41 519	75,61	6
in that: salaries of employees and other payments for work fulfilment	**22 337**	22 381	4 677	20,90	10 609	47,40	17 614	78,70	2

(subgroup item 501,2)									
from that: State Administration (budget branch 106)	**22 337**	22 396	4 677	20,88	10 609	47,37	17 614	78,65	2
salaries of employees (item 5011)	**22 118**	22 162	4 580	20,67	10 406	46,95	17 268	77,92	2
Mandatory insurance paid by employer*	**7 818**	7 833	1 635	20,87	3 701	47,25	6 153	78,55	
(subgroup item 503)									
Fund of Cultural and Social Needs (item 534)	**442**	443	126	28,44	244	55,08	381	86,00	
Objective and Other Common Outgoings	**24 000**	24 254	4 506	18,58	11 642	48,00	17 371	71,62	2
from that: common outgoings KIVS_ISPROFIN PP 229011									
common outgoings PRES (§ 1091)		337			24	7,12	38	11,28	
2. Capital outgoings OSU in total	**8 500**	8 500	3 221	37,89	3 928	46,21	7 899	92,93	1
(drawing from budget outgoing account 916-)									
in that:									
System defined outgoings – ISPROFIN P 229010	**8 500**	8 500	3 221	37,89	3 928	46,21	7 899	92,93	1
from that: Shared EC and CR projects (Phare, TF):									
in that (separately):									
Capital outgoings PRES (§ 1091)									
Outgoings summary (1 and 2)	**63 097**	63 411	14 165	22,34	30 124	47,51	49 418	77,93	7

***) health and social insurance of employees**