SUKL Bulletin 12/2006

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of November 2006**
  - **Important notice on withdrawal of a medical device**
- **SÚKL guidelines**
  - **List of guidelines valid as of January 1, 2007**
  - **UST-25 Version 1 - Consultation procedure with SUKL staff**
    Change in procedure of consultations (consultation upon request and scientific consultation upon request) is provided.
  - **UST-29 Version 1 - Administration fees and costs reimbursement for activities performed on request**
    Minor changes in the guideline UST-29 concern payment of administrations fees and costs reimbursement (in particular, payments in EUR will be accepted).
- **Information on drug consumption**
  - **Team of authors: Drug "consumption" in the Czech Republic in the 3rd quarter of the year 2006**
    Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.
- **Information**
  - **Information on seminars held by SUKL in the 1st half of 2007**
    The overview of seminars and the application form are included.
  - **Outline of notifications on the use of non-authorised medicinal products in the month of November 2006**
    The information on evaluated notifications in the month of November 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of November 2006**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in October 2006 is published. Documents are available in SUKL
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of November 2006**
  - **List of medicinal products whose marketing authorisation will expire in February 2007**
    The validity of marketing authorizations of the listed products will expire

during February 2007 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

- **List of medicinal products with expired marketing authorisation**
  The listed products are marked by "Z" in SUKL database as of November 30, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from October 26, 2006 to November 22, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from November 1, 2006 to November 30, 2006

SUKL Bulletin 11/2006

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of October 2006**
- **Information**
  - **Information on lists of pharmacies on the SUKL website**
  - **Change in the list of test facilities included in the national GLP programme in the field of medicinal products**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of October 2006**
    The information on evaluated notifications in the month of October 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of October 2006**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in September 2006 is published. Documents are available in SUKL
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the third quarter of 2006**
  - **Overview of data on basic activities of the Inspection Branch in the third quarter of 2006**
  - **Overview of data on activities of the Medical Devices Branch in the third quarter of 2006**

- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of October 2006**
- **List of medicinal products whose marketing authorisation will expire in January 2007**
  The validity of marketing authorizations of the listed products will expire during January 2007 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
- **List of medicinal products with expired marketing authorisation**
  The listed products are marked by "Z" in SUKL database as of October 31, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from September 21, 2006 to October 25, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from October 1, 2006 to October 31, 2006
  - List of specific therapeutic programmes approved during the period of October 1, 2006 to October 31, 2006

SUKL Bulletin 10/2006

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of September 2006**
- **SÚKL guidelines**
  - **List of guidelines valid as of November 1, 2006**
  - **DIS-13 Version 1 - Reporting of deliveries of distributed medicinal products**
    The revised provision defines more exactly the way of reporting deliveries of medicinal products from wholesalers or manufacturers to health care facilities or vendors of selected medicinal products and the structure of the report.
- **Information**
  - **Information on seminars held by SUKL in the 2nd half of 2006**
    The overview of seminars and the application form are included.
  - **Information for holders of authorisation for manufacture of medicinal products and for holders of authorisation for control laboratories**
  - **List of pharmacies offering 24-hour emergency service**
  - **List of dispensaries of medicinal products (pharmacies performing supply of medicinal products only)**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of September 2006**
    The information on evaluated notifications in the month of September

2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.

- **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of September 2006**
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **List of new pharmacies and detached departments for dispensing pharmaceuticals and medical devices approved by SUKL in the third quarter of 2006**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of September 2006**
- **List of medicinal products whose marketing authorisation will expire in December 2006**
  The validity of marketing authorizations of the listed products will expire during December 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
- **List of medicinal products with expired marketing authorisation**
  The listed products are marked by "Z" in SUKL database as of September 30, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from August 24, 2006 to September 20, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from September 1, 2006 to September 30, 2006
  - List of specific therapeutic programmes approved during the period of September 1, 2006 to September 30, 2006

SUKL Bulletin 9/2006

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of August 2006**
- **SÚKL guidelines**
  - **List of guidelines valid as of October 1, 2006**
  - **VYR-27 Version 1 - Application for an authorisation/change to authorisation for manufacture of medicinal products and guidance for provision of detailed information on manufacture**
    New application forms for authorisation for manufacture of medicinal products and for a change to that authorisation, including Site Master File format as resulted from the amended legislation.

- **Information on drug consumption**
  - **Team of authors: Drug "consumption" in the Czech Republic in the 2nd quarter of the year 2006**
    Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.
- **Information**
  - **Screening of number of non-usable medicinal products returned to pharmacies in the CR**
  - **Information for blood service centres on the storage temperature and shelf life of fresh frozen plasma**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of August 2006**
    The information on evaluated notifications in the month of August 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of August 2006**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in July 2006 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of August 2006**
  - **List of medicinal products whose marketing authorisation will expire in November 2006**
    The validity of marketing authorizations of the listed products will expire during November 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
  - **List of medicinal products with expired marketing authorisation**
    The listed products are marked by "Z" in SUKL database as of August 31, 2006.
- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from July 20, 2006 to August 23, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from August 1, 2006 to August 31, 2006
  - List of specific therapeutic programmes approved during the period of August 1, 2006 to August 31, 2006

SUKL Bulletin 8/2006

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of July 2006**
- **Pharmacopoeia activities**
  - **Announcement of texts of the Czech Pharmacopoeia being recognized as official standards**
  - **Announcement of texts of the European Pharmacopoeia being recognized as official standards in the Czech Republic**
- **Information**
  - **Information on forthcoming publications**
    List of pharmacies, manufacturers and wholesalers of medicinal products in the CR and List of OTC medicinal products and products with narcotic substances will be published.
  - **Outline of notifications on the use of non-authorised medicinal products in the month of July 2006**
    The information on evaluated notifications in the month of July 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of July 2006**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in May and June 2006 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the second quarter of 2006**
  - **Overview of data on basic activities of the Inspection Branch in the second quarter of 2006**
  - **Overview of data on activities of the Medical Devices Branch in the second quarter of 2006**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of July 2006**
  - **List of medicinal products whose marketing authorisation will expire in October 2006**
    The validity of marketing authorizations of the listed products will expire during October 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
  - **List of medicinal products with expired marketing authorisation**
    The listed products are marked by "Z" in SUKL database as of July 31, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
    - Authorised medicinal products and variations to marketing authorisations approved in the period from June 22, 2006 to July 19, 2006
    - Medicinal products authorised under the EU centralised procedure in the period from July 1, 2006 to July 31, 2006
    - List of specific therapeutic programmes approved during the period of July 1, 2006 to July 31, 2006

SUKL Bulletin 5/2006

- **Contents**
- **Front page news**
    - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of April 2006**
- **SÚKL guidelines**
    - **List of guidelines valid as of June 1, 2006**
    - **VYR-35-Procedure for licencing of manufacture of medicinal products and investigational medicinal products for the purpose of import from third countries**
      The guideline is intended for subjects who apply for manufacturing licence in order to import medicinal products and investigational medicinal products from third countries or for manufacturers who apply for variation to their manufacturing licence. The guideline sets up requirements to be met by applicants for a manufacturing licence who wish to import medicinal products and investigational medicinal products, the course of approval procedure and system of inspections at manufacturing licence holders by SÚKL.
- **Information**
    - **Physicians and information on drugs – the survey made in the year 2005**
      Selected physicians were asked about sources of information on medicinal products that are prepared or approved by SUKL. Some questions were asked with the aim to evaluate the impact of mentioned information on their daily practice. A drug bulletin Pharmacotherapeutical Information was the most widely used source of information prepared by SUKL for physicians.
    - **Up-to-date information for applicants submitting applications for approval of a clinical trial on products of the following nature: gene therapy medicinal products, somatic cell therapy medicinal products (including cells of xenogeneic origin) or medicinal products containing genetically modified organisms**
      Following our existing experience with reviews of applications for approval of clinical trials on the above mentioned investigational medicinal products and the compexity thereof, the applicants (e.g. sponsors, contact persons, CRO) are kindly requested to inform the

Institute of the intended submissions in advance (by e-mail: alice.nemcova@sukl.cz).

- **Outline of notifications on the use of non-authorised medicinal products in the month of April 2006**
  The information on evaluated notifications in the month of April 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of April 2006**
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in March 2006 is published. Documents are available in SUKL library.
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the first quarter of 2006**
- **Overview of data on basic activities of the Inspection Branch in the first quarter of 2006**
- **Overview of data on activities of the Medical Devices Branch in the first quarter of 2006**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of April 2006**
- **List of medicinal products whose marketing authorisation will expire in July 2006**
  The validity of marketing authorizations of the listed products will expire during July 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
- **List of medicinal products with expired marketing authorisation**
  The listed products are marked by "Z" in SUKL database as of April 30, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of March 23, 2006 to April 19, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from April 1, 2006 to April 30, 2006
  - List of specific therapeutic programmes approved during the period of April 1, 2006 to April 30, 2006

SUKL Bulletin 4/2006

- **Contents**

- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of March 2006**
- **Pharmacy activities**
  - **Control of pharmacies in the year 2005**
    Out of the total number of 2.849 samples taken from pharmacies 12 % of samples were found to be non-compliant. The number of non-compliant samples from pharmacies continues to be relatively high, but since 2004 the quality of medicinal products and purified water prepared in pharmacies has slightly improved.
- **Information**
  - **Information on controls made in healthcare facilities**
    Controls were focused on treatment with medicinal products and were conducted as initial ones.
  - **Information on seminars held by SUKL in the 1st half of 2006 – 1st part**
    The programme of seminars and the application form are included.
  - **Outline of notifications on the use of non-authorised medicinal products in the month of March 2006**
    The information on evaluated notifications in the month of March 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of March 2006**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in February 2006 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the first quarter of 2006**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of March 2006**
  - **List of medicinal products whose marketing authorisation will expire in June 2006**
    The validity of marketing authorizations of the listed products will expire during June 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
  - **List of medicinal products with expired validity of the registration decision**
    The listed products are indicated by "Z" in SUKL database as of March 31, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
    - Authorised medicinal products and variations to marketing authorisations approved in the period of February 23, 2006 to March 22, 2006
    - Medicinal products authorised under the EU centralised procedure in the period from March 1, 2006 to March 31, 2006
    - List of specific therapeutic programmes approved during the period of March 1, 2006 to March 31, 2006

SUKL Bulletin 3/2006

- **Contents**
- **Front page news**
    - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of February 2006**
- **Information on drug consumption**
    - **Team of authors: Drug "consumption" in the Czech Republic in the year 2005**
      This article is focused on drug "consumption" in the Czech Republic in the year 2005 and on the comparison against previous years. Figures are given in the number of packages, Czech crowns and Defined Daily Doses. Consumption of several ATC groups with highest level of consumption is discussed.
- **Information**
    - **Plan of seminars prepared by the State Institute for Drug Control in the 1st half of 2006**
    - **Information on conditions for running external courses intended to obtain education of qualified persons of manufacturers of medicinal products**
      The information is intended for manufacturers of medicinal products seeking SÚKL´s or ÚSKVBL´s approval with qualified persons who do not have a university degree in pharmacy. This information is meant also for organizers who run courses aimed at providing professional education for qualified persons.
    - **Outline of notifications on the use of non-authorised medicinal products in the month of January 2006**
      The information on evaluated notifications in the month of January 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
    - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of February 2006**
    - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
    - **Information on documents issued by the European Medicines Agency (EMEA)**
      A list of new documents issued by the EMEA in January 2006 is published. Documents are available in SUKL library.

- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of February 2006**
- **List of medicinal products whose marketing authorisation will expire in May 2006**
  The validity of marketing authorizations of the listed products will expire during May 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
- **List of medicinal products with expired validity of the registration decision**
  The listed products are indicated by "Z" in SUKL database as of February 28, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of January 19, 2006 to February 22, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from February 1, 2006 to February 28, 2006
  - List of specific therapeutic programmes approved during the period of February 1, 2006 to February 28, 2006

SUKL Bulletin 2/2006

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of January 2006**
  - **Measures taken in the case of adverse event to medical device**
- **SÚKL quidelines**
  - **List of guidelines valid as of March 1, 2006**
  - **VYR-32-Guidelines on Good Manufacturing Practice – revision 1**
    The EU Commission has published Revision of GMP Guidelines, Part I: new GMP Provisions for Product Quality Review (Chapter 1), On-going Stability Programme (Chapter 6), new Annex 19 Reference and Retention samples and the basic requirements for the manufacture of active substances used as starting materials as GMP Part II replacing the former GMP Annex 18. SÚKL is publishing the translation of changes only. Thefull version of GMP Guidelines is published on the SUKL website (www.sukl.cz).
- **Information**
  - **Information for applicants regarding applicability of the new Administrative Procedure Code**
    SUKL informs that with effect from 1 January 2006 its activities will be governed by the new Administrative Procedure Code (Act No.

500/2004 Coll., as amended). This act introduces certain new provisions in administrative procedures:

- Each participant may have simultaneously only one representative in one proceeding;
- Any person acting on behalf of the applicant must provide proof of his/her authorisation;
- SUKL may deliver to an electronic address, however, this delivery must be based on the request made by a participant in proceedings;
- SUKL accepts documents in the Czech, Slovak and English languages, documents in other languages have to be submitted with an authenticated translation.

- **Information for applicants regarding applicability of provisions of the Directive 2004/27/EC in the Czech Republic**
  As a consequence of delayed transposition of Directive 2004/27/EC amending Directive 2001/83/ES on the Community code relating to medicinal products for human use, SUKL provides brief information for applicants on how to act when submitting applications. SUKL accepts applications submitted in accordance with the requirements stipulated by Directive 2004/27/EC.
- **List of medicinal products prescribed on prescription with blue strip (containing narcotic and psychotropic substances)**
- **Outline of notifications on the use of non-authorised medicinal products in the month of January 2006**
  The information on evaluated notifications in the month of January 2006, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of January 2006**
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the fourth quarter of 2005**
- **Overview of data on basic activities of the Inspection Branch in the fourth quarter of 2005**
- **Overview of data on activities of the Medical Devices Branch in the fourth quarter of 2005**
- **List of test facilities included in the national GLP programme in the field of medicinal products**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of January 2006**
- **List of medicinal products whose marketing authorisation will expire in April 2006**
  The validity of marketing authorizations of the listed products will expire during April 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
- **List of medicinal products with expired validity of the registration decision**

The listed products are indicated by "Z" in SUKL database as of January 31, 2006.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of December 15, 2005 to January 18, 2006
  - Medicinal products authorised under the EU centralised procedure in the period from January 1, 2006 to January 31, 2006
  - List of specific therapeutic programmes approved during the period of January 1, 2006 to January 31, 2006

SUKL Bulletin 1/2006

- **Contents**
- **PF 2006**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of December 2005**
  - **Announcement concerning medical devices**
- **SÚKL quidelines**
  - **List of guidelines valid as of February 1, 2006**
  - **DIS-15-Monitoring and control of storage and transportation temperatures for pharmaceuticals**
    This guideline replaces DIS-7 and determines additional standards to complete basic requirements which are specified in SÚKL guideline DIS-11. Detailed procedures recommended for monitoring and control of storage and transportation temperatures of pharmaceuticals are described.
- **Information**
  - **Information for pharmacies regarding other than standard ways of obtaining non-authorised medicinal products** (e.g. from pharmacies in other EU Member states)
  - **Information for healthcare facilities concerning preparation of injectable cytostatics**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of December 2005**
    The information on evaluated notifications in the month of December 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of December 2005**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**

- **Information on documents issued by the European Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in December 2005 is published. Documents are available in SUKL library.
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **List of new pharmacies and detached departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2005**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of December 2005**
- **List of medicinal products whose marketing authorisation will expire in March 2006**
  The validity of marketing authorizations of the listed products will expire during March 2006 and the products will be indicated in SUKL database by "Z" and published in Věstník SÚKL.
- **List of medicinal products with expired validity of the registration decision**
  The listed products are indicated by "Z" in SUKL database as of December 31, 2005.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of November 17, 2005 to December 14, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from December 1, 2005 to December 31, 2005
  - List of specific therapeutic programmes approved during the period of December 1, 2005 to December 31, 2005