SUKL Bulletin 12/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of November 2003**
  - **Measures taken in case of adverse incidents of medical devices**
- **SÚKL quidelines**
  - **List of guidelines valid as of January 1, 2004**
  - **REG-71-Phasing-in of the centrally authorised medicinal products in the market of the Czech Republic**
    The guidance gives legal background for phasing-in of medicinal products authorised by the centralised procedure in the EU in the Czech market and phasing-out of the same products authorised nationally before accession as well as the procedures and their timing which should be followed in practice.
  - **VYR-30-Issuing of GMP Certificates for Medicinal Products**
    The guideline sets up the requirements and procedure for issuance of GMP certificates for medicinal products. SUKL issues GMP certificates for manufacture of medicinal products and certificates for the medicinal product according to the WHO scheme. The guideline includes an application form.
  - **VYR-31-Issuing of GMP Certificates for Active Pharmaceutical Ingredients**
    The guideline sets up the requirements and procedure for issuance of GMP certificates for Active Pharmaceutical Ingredients. SUKL issues GMP certificates for manufacture of Active Pharmaceutical Ingredients certifying that the manufacturer complies with GMP requirements for Active Pharmaceutical Ingredients in accordance with guidelines Q7A. The guideline includes an application form and questionnaire.
  - **VYR-32-Guidelines for Good Manufacturing Practice**
    The guidelines set up requirements for Good Manufacturing Practice in manufacture of medicinal products. The guidelines are translations of the EU GMP Guide issued in The Rules Governing Medicinal Products in the European Union, Volume 4, Good Manufacturing Practices.
  - **DIS-9-Guidelines for Good Distribution Practice**
    The guidelines set up requirements for Good Distribution Practice for wholesalers of medicinal products. The guidelines are developed on the basis of EU Guidelines on GDP of Medicinal Products for Human Use (94/C63/03).
  - **LEK-8-Commentary to the decree No. 255/2003 Coll.**
    The decree laying down details on preparation and supply of medicinal products and conditions of pharmacy operation is valid as of July 2003. The commentary has been prepared to help pharmacists in understanding of this decree.
- **Information on drug consumption**
  Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 2003

Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.

- **Information**
  - **Information for applicants for registration within centralised procedure specifying the documentation to be submitted to SUKL representatives in the CPMP**
    The centralised procedures currently being started in the EMEA will be finalised after accession with the full participation of new CPMP members from new Member States. To allow for smooth implementation in these pending procedures SUKL asks for the submission of Modules 1 and 2 preferably on CD ROMs in two copies. Contact details are provided.
  - **Outline of notifications on the use of non-registered medicinal products in the month of November 2003**
    The information on evaluated notifications in the month of November 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
    The list of new documents issued by the EMEA in October 2003 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 November 2003**
  - **List of medicinal products registration decision of which will expire in February 2004**
    Registration decision of the listed products will be no longer valid during February 2004 and it 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 November 30, 2003.
- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period of October 9, 2003 to November 5, 2003
  - List of specific therapeutic programmes approved during the period of October 23,2003 to November 30, 2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of October 2003**
- **SÚKL quidelines**
  - **List of guidelines valid as of December 1, 2003**
  - **Announcement for manufacturers and wholesalers of medicinal products on revocation of some SUKL guidelines**
    Guidelines VYR-3, VYR-5, VYR-8, VYR-18 and DIS-5 are revoked without replacement as of December 1, 2003 due to duplicities and non-compliance with the new legislation (Act No. 79/1997 Coll., on Pharmaceuticals, as amended and its implementing decrees as last amended).
  - **UST-24 - Waivers and refund of costs reimbursement for expert activities performed on request**
    Basic rules and procedure for waivers and refund of costs reimbursement for expert activities performed on request is provided.
  - **UST-25 - Consultation procedure with SUKL staff**
    Procedure for request and provision of consultations is provided.
  - **DIS-8 - Application for an authorisation/change to authorisation for distribution of medicinal products**
    New application forms for authorisation for distribution of medicinal products and for a change to that authorisation, including annexes as resulted from the amended legislation.
  - **VYR-27 - Application for an authorisation/change to authorisation for manufacture of medicinal products**
    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.
  - **VYR-28 - Application for an authorisation/change to authorisation for activities of control laboratory**
    New application forms for authorisation for activities of control laboratory and for a change to that authorisation, including annexes as resulted from the amended legislation.
  - **VYR-29 - Application for an authorisation/change to authorisation for manufacture of blood components and materials derived from blood and its components for further manufacture**
    New application forms for authorisation for manufacture of blood components and materials derived from blood and its components for further manufacture and for a change to that authorisation, including annexes as resulted from the amended legislation.
- **Information**
  - **Information on the authorisation procedure for import of medicinal products from third countries and related variations to marketing authorisations of medicinal products**
    Brief description of procedure for authorising the import of medicinal products from third countries and related variations to marketing authorisations of medicinal products including reference to relevant SÚKL guidelines and forms is provided. According to the amended

legislation these procedures have to be completed before the EU accession.

- **Information for registration decision holders, manufacturers, distributors, blood establishments and control laboratories on the system of collecting contact addresses which is being introduced by SUKL**
- **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**
- **Outline of notifications on the use of non-registered medicinal products in the month of October 2003**
  The information on evaluated notifications in the month of October 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
  The list of new documents issued by the EMEA in September 2003 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.
- **Quarterly evaluation of pharmacies activity**
  Results of the inspection activities of SUKL in pharmacies during the third quarter of 2003 are published.
- **Overview of data on basic activities of the Inspection Branch in the third quarter of 2003**
  Data on numbers of various types of inspection activities including times are published.
- **Outline of data on activities of the Medical Devices Branch in the third quarter of 2003**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of October 2003**
- **List of medicinal products registration decision of which will expire in January 2004**
  Registration decision of the listed products will be no longer valid during January 2004 and it 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 October 30, 2003.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period of September 11, 2003 to October 8, 2003
  - List of specific therapeutic programmes approved during the period of October 11,62003 to October 31, 2003

SUKL Bulletin 10/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of September 2003**
  - **Measures taken in case of adverse incidents of medical devices**
- **SÚKL quidelines**
  - **List of guidelines valid as of November 1, 2003**
  - **Announcement for applicants for registration of medicinal products on revocation of some SUKL guidelines**
    Guidelines REG-39, REG-43, REG-48 and REG-61 are revoked as of October 31, 2003 as a result of the Act No. 129/2003, amending the Act No. 79/97 Coll., on Pharmaceuticals, and the approaching accession of the CR to the EU.
  - **UST-23 - Providing of free samples of medicinal products for human use for promotional purposes**
    According to the amendment to Act on Advertising (No. 138/2002 Coll.) providing of free samples of medicinal products is considered to be advertising. SUKL as the authority responsible for monitoring of medicinal products advertising sets up more detailed rules for providing free samples of medicinal products in this guideline, which replaces UST-14 as of November 1, 2003.
- **Information**
  - **New sections on the SUKL website**
    The new sections are: “Advertising” and “Questions and answers”
  - **Announcement of the change of the SUKL e-mail addresses**
    See the SUKL website www.sukl.cz
  - **Outline of notifications on the use of non-registered medicinal products in the month of September 2003**
    The information on evaluated notifications in the month of September 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **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 2003**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of September 2003**
  - **List of medicinal products registration decision of which will expire in December 2003**
    Registration decision of the listed products will be no longer valid

during December 2003 and it 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 September 30, 2003.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period of July 31, 2003 to September 10, 2003
  - List of specific therapeutic programmes approved during the period of September 22, 2003 to September 30, 2003

SUKL Bulletin 9/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of August 2003**
- **SÚKL quidelines**
  - **List of guidelines valid as of October 1, 2003**
  - **UST-22 - Standard terms for pharmaceutical forms, routes of administration and containers – addendum**
    The new provision specifies how to use the previously published standard terms in case of differences between standard term and lay term.
  - **VYR-26 - Guidelines for good manufacturing practice for active pharmaceutical ingredients**
    The guideline is a translation of ICH guideline Q7A laying down the requirements for Good Manufacturing Practice in manufacture of active pharmaceutical ingredients. The introduction and list of contents are provided and the full text is available on the SUKL website.
- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 2nd quarter of the year 2003**
    Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.
- **Pharmacopoeia activities**
  - **Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic**
  - **Announcement of texts of the Czech Pharmacopoeia becoming official standards**
- **Information**

- **Information on seminars held by SUKL in the 2nd half of 2003 – Part II**
  The programme of seminars and the application form are included.
- **Information for ethics committees concerning amended Act No. 79/1997 Coll., on Pharmaceuticals**
  The issues concerning the establishment, activities and operation procedures of ethics committees are discussed in the form of questions and answers.
- **Outline of notifications on the use of non-registered medicinal products in the month of August 2003**
  The information on evaluated notifications in the month of August 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
  The list of new documents issued by the EMEA in May and June 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 2003**
- **List of medicinal products with expired validity of the registration decision**
  The listed products are indicated by "Z" in SUKL database as of August 31, 2003.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of June 26, 2003 to July 30, 2003
  - List of specific therapeutic programmes approved during the period of June 4, 2003 to August 18, 2003

SUKL Bulletin 8/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of July 2003**
- **SÚKL quidelines**
  - **List of guidelines valid as of September 1, 2003**
  - **REG-70 - Application for registration of the medicinal product**
    This application form replaces previous REG-44 as of September 1 st 2003. This new application form is derived from the form used in EU

countries and its Czech translation is provided. This form facilitates the phasing-in the EU procedures.

- **UST-21 - Notification of selected medicinal products to SUKL before being placed on the Czech market (Official batch release)**
  The procedure and documentation to be submitted in accordance with the guidelines for Official Control Authority Batch Release of blood medicinal products and vaccines in the EC/EEA are given.

- **Information**
  - **Information for registration decision holders concerning EAN bar codes**
    Due to the new legal requirement to specify EAN code on the labelling of a medicinal product, the procedure for informing SUKL of EAN codes for already registered products is given. These codes will be included in the database of registered medicinal products.
  - **Information on seminars held by SUKL in the 2nd half of 2003 – Part I**
  - **Outline of notifications on the use of non-registered medicinal products in the month of July 2003**
    The information on evaluated notifications in the month of July 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
    The list of new documents issued by the EMEA in May and June 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.
  - **Quarterly evaluation of pharmacies activity**
    Results of the inspection activities of SUKL in pharmacies during the second quarter of 2003 are published.
  - **Overview of data on basic activities of the Inspection Branch in the second quarter of 2003**
    Data on numbers of various types of inspection activities including times are published.
  - **Outline of data on activities of the Medical Devices Branch in the second quarter of 2003**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of July 2003**
  - **List of medicinal products with expired validity of the registration decision**
    The listed products are indicated by "Z" in SUKL database as of July 31, 2003.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of May 29, 2003 to June 25, 2003

SUKL Bulletin 7/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of June 2003**
  - **Measures taken in case of adverse incidents of medical devices**
- **SÚKL quidelines**
  - **List of guidelines valid as of August 1, 2003**
  - **UST-19 - Application for a decision whether a product should be classified as a pharmaceutical or a medicinal product subject to registration**
    According to the Act No. 79/1997 Coll., on pharmaceuticals, as amended, the State Institute for Drug Control is competent to decide whether a product should be classified as a pharmaceutical or a medicinal product subject to registration. The form providing guidance for such an application is given.
  - **UST-20 - Application for an opinion on the proposal for a specific therapeutic programme**
    The last amendment to the Act No. 79/1997 Coll., on pharmaceuticals, introduces a new feature in the Czech pharmaceutical legislation, i.e. specific therapeutic programmes and the State Institute for Drug Control issues its opinion on the proposal for a specific therapeutic programme. The form providing guidance for an application for an opinion on the proposal for a specific therapeutic programme is given.
  - **REG-69 - Application for transfer of the registration**
    The last amendment to the Act No. 79/1997 Coll., on pharmaceuticals, introduces a specific procedure for the transfer of registration to another holder. The form providing guidance for an application for the transfer of registration is given.
- **Information**
  - **Specific therapeutic programmes**
    According to the last amendment to the Act No. 79/1997 Coll., on pharmaceuticals, there is a possibility to use, distribute and supply for the treatment, prophylaxis or diagnosis of rare or serious diseases, or in other cases of emergency, a non-registered medicinal product within the scope of specific therapeutic programmes. Such programme can be carried out only on condition that an appropriate registered medicinal product is not available.
  - **Information for health care professionals concerning medicinal products with expired validity of the registration decision**
    SUKL analyses the cases, when the validity of registration decision has expired without renewal with regard to possible impact on therapeutic practice in the Czech Republic, and in case of potential difficulties SUKL provides information in this Bulletin. Conclusions from the first half of 2003 do not imply problems for therapeutic practice.

- **Information for registration decision holders on specification of EAN codes on labelling of medicinal products**
  The last amendment to the Act No. 79/1997 Coll., on pharmaceuticals, introduces a new obligation to specify the EAN code on the labelling of a medicinal product. This requirement will be applied to all the decisions issued after June 5, 2003, when the amendment entered into force. The procedure for implementation of this requirement regarding products on the market will be specified later on.
- **Notice to applicants for renewal of registration**
  The last amendment to the Act No. 79/1997 Coll., on pharmaceuticals, has reduced the timeline for submission of the applications for renewal from 6 to 3 months. As a consequence, the next list of products for which the application for renewal has not been submitted in due time prior to the expiry date, published monthly by SUKL in this Bulletin, will be available in the issue No. 10.
- **Information for health care facilities**
  The last amendment to the Act No. 79/1997 Coll., on pharmaceuticals, specifies the obligations and competences of health care facilities when dealing with medicinal products. More detailed conditions with regard to handling medicinal products will be laid down by a decree, which is now under preparation and will be published also on the SUKL website.
- **Information for pharmacies concerning a list of hygienic service centres approved to carry out testing for pharmacies**
- **List of new pharmacies and detached departments for dispensing pharmaceuticals and medical devices approved by SUKL in the second quarter of 2003**
- **Outline of notifications on the use of non-registered medicinal products in the month of June 2003**
  The information on evaluated notifications in the month of June 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
  The list of new documents issued by the EMEA in March 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 June 2003**
- **List of medicinal products with expired validity of the registration decision**
  The listed products are indicated by "Z" in SUKL database as of June 30, 2003.

- **Information on registered drugs and drugs with exemptions from registration**

- Recently registered medicinal products and variations to registrations approved during the period of May 1, 2003 to May 28, 2003
- List of exemptions from registration granted by the Ministry of Health during the period of May 24, 2003 to May 27, 2003

SUKL Bulletin 6/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of May 2003**
  - **Measures taken in case of adverse incidents of medical devices**
- **SÚKL quidelines**
  - **List of guidelines valid as of July 1, 2003**
  - **UST-18 -Administration fees and costs reimbursement for activities performed on request**
    Following the new legislation which came into force on June 5, 2003, the procedures for payment of administration fees and costs reimbursement for professional activities performed on request are stipulated and the cost of fees and reimbursement is specifed.
- **Pharmacy activities**
  - **Control of pharmacies in the year 2002**
    Out of the total number of 4 335 samples taken from pharmacies 15,9 % of samples were found to be non-compliant and 8,6 % of samples were found "non-compliant with adjustment". The number of non-compliant samples from pharmacies continues to be relatively high, but since 1997 the quality of medicinal products and purified water prepared in pharmacies has slightly improved.
- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 1st quarter of the year 2003**
    Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.
- **Information**
  - **Notice of the State Institute for Drug Control on the change of date of a seminar**
    The programme of seminars and the application form are included.
  - **Announcement for pharmacies and health care facilities preparing medicinal products**
  - **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-registered medicinal products in the month of May 2003**

The information on evaluated notifications in the month of May 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.

- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
  The list of new documents issued by the EMEA in March 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 May 2003**
- **List of medicinal products registration decision of which will expire in November 2003**
  Registration decision of the listed products will be no longer valid during November 2003 and it 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 May 31, 2003.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of April 3, 2003 to April 30, 2003
  - List of exemptions from registration granted by the Ministry of Health during the period of April 10, 2003 to May 23, 2003

SUKL Bulletin 5/2003

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of April 2003**
  - **Measures taken in case of adverse incidents of medical devices**
- **SÚKL provisions**
  - **Survey of provisions valid as of June 1, 2003**
  - **REG-68 - Additional data to pending applications for registration in the pre-accession period** As on accession to the EU it will not be possible to complete the national procedure of certain types of applications for registration pending at the day of accession, it is necessary to prepare a smooth transition to European procedures. Therefore a form has been prepared to collect information necessary for such preparation. This form has to be filled in for each pending application for registration (except applications for registration of a

homeopathic product) and submitted before May 31, 2003 to the SUKL.

- **SLP-5 - OECD Documents of Good Laboratory Practice This provision is an update of the provision SLP-2. Test facilities which are in compliance with the "OECD Principles of Good Laboratory Practice" should in conducting their studies follow the OECD Consensus Documents. These documents are available on the following web site: http://www.oecd.org/env/glp.**

- **Information**
  - **Information on seminars held by SUKL in the 1st half of 2003 – Part III**
    The programme of seminars and the application form are included.
  - **Information for operators on application of pharmacopoeial standards in connection to the Amendment to the Act on Pharmaceuticals (issued as the Act No. 129/2003 Coll.)**
  - **Annual report of the State Institute for Drug Control for the year 2002**
    The report is available in the Mail room for 50,-CZK.
  - **Outline of notifications on the use of non-registered medicinal products in the month of April 2003**
    The information on evaluated notifications in the month of April 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
    The list of new documents issued by the EMEA in February 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.
  - **Quarterly evaluation of pharmacies activity**
    Results of the inspection activities of SUKL in pharmacies during the first quarter of 2003 are published.
  - **Overview of data on basic activities of the Inspection Branch in the first quarter of 2003**
    Data on numbers of various types of inspection activities including times are published.
  - **Outline of data on activities of the Medical Devices Branch in the first quarter of 2003**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of April 2003**
  - **List of medicinal products registration decision of which will expire in October 2003**
    Registration decision of the listed products will be no longer valid during October 2003 and it 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 April 30, 2003.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of March 6, 2003 to April 2, 2003
  - List of exemptions from registration granted by the Ministry of Health during the period of March 28, 2003 to April 10, 2003

SUKL Bulletin 4/2003

- **Contents**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of March 2003
- **SÚKL provisions**
  - **UST-17-Standard terms for pharmaceutical forms, routes of administration and containers**
  - **Czech terms for pharmaceutical forms, routes of administration and containers published in the „List of Standard Terms 2002“ (EDQM) are listed. The provision includes also terms for non-professional users in lay language and abbreviations of dosage forms and of routes of administration and it replaces UST-4 as of May 1, 2003.**
- **Information**
  - **Outline of notifications on the use of non-registered medicinal products in the month of March 2003**
    The information on evaluated notifications in the month of March 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the EuropeanAgency for the Evaluation of Medicinal Products (EMEA)**
    The list of new documents issued by the EMEA in January 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 first quarter of 2003**
  - List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of March 2003

- **List of medicinal productsregistration decision of which will expire in September 2003**
  Registration decision of the listed products will be no longer valid during September 2003 and it 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, 2003.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of February 19, 2003 to March 5, 2003
  - List of exemptions from registration granted by the Ministry of Health during the period of March 3, 2003 to March 21, 2003

SUKL Bulletin 3/2003

- **Contents**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of February 2003
- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the year 2002**
    This article is focused on drug “consumption” in the Czech Republic in the year 2002 and on the comparison with previous years. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses. Consumption of several ATC groups with highest level of consumption is discussed.
- **Information**
  - **Information on new lists for „update exercise“**
    Since February the following lists have been made available on the SUKL website: the List of medicinal products considered by their registration holders as products based on self-standing documentation with either own experimental data or literature data and the List of SUKL monographs (model SPCs) including texts of monographs.
  - Information for applicants for marketing authorization, approval of manufacture or distribution of medicinal products concerning fees payment method
  - **Information on seminars held by SUKL in the 1sthalf of 2003 – Part II**
    The programme of seminars and the application form are included.
  - **Outline of notifications on the use ofnon-registered medicinal products in the month of February 2003**
    The information on evaluated notifications in the month of February

2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
    - Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
    - **Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)**
      The list of new documents issued by the EMEA in December 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 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 February 2003
    - **List of medicinal productsregistration decision of which will expire in August 2003**
      Registration decision of the listed products will be no longer valid during August 2003 and it 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, 2003.
- **Information on registered drugs and drugs with exemptions from registration**
    - Recently registered medicinal products and variations to registrations approved during the period of January 22, 2003 to February 5, 2003
    - List of exemptions from registration granted by the Ministry of Health during the period of January 24, 2003 to February 10, 2003

SUKL Bulletin 2/2003

- **Contents**
- **Front page news**
    - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of January 2003
    - The Black Triangle - a New Pharmacovigilance Activity of the SUKL
    - Measures taken in case of adverse incidents of medical devices
- **Pharmacy activities**
    - Survey on the extent of preparation of medicinal products in Czech pharmacies
      The survey was conducted by e-mail messages sent to 928 pharmacies, answers were received from 283 pharmacies.
- **Information**
    - Information on seminars held by SUKL in the 1st half of 2003

- Outline of notifications on the use of non-registered medicinal products in the month of January 2003
  The information on evaluated notifications in the month of January 2003, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
- Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
  The list of new documents issued by the EMEA in November 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.
- Quarterly evaluation of pharmacies activity
  Results of the inspection activities of SUKL in pharmacies during the fourth quarter of 2002 are published.
- Overview of data on basic activities of the Inspection Branch in the fourth quarter of 2002 Data on numbers of various types of inspection activities including times are published.
- Outline of data on activities of the Medical Devices Branch in the fourth quarter of 2002
- List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of January 2003
- List of medicinal products registration decision of which will expire in July 2003
  Registration decision of the listed products will be no longer valid during July 2003 and it 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, 2003.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of December 18, 2002 to January 8, 2003
  - List of exemptions from registration granted by the Ministry of Health during the period of December 16, 2002 to January 10, 2003

SUKL Bulletin 1/2003

- **Contents**
- **PF 2003**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of December 2002
  - Measures taken in case of adverse incidents of medical devices

- **SÚKL provisions**
  - Survey of provisions valid as of February 1, 2003
  - VYR-25-Good manufacturing practice in blood establishments
- **Pharmacopoeia activities**
  - Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic
- **Information**
  - Notice for hospital pharmacies concerning the change of their legal status
  - Outline of notifications on the use of non-registered medicinal products in the month of December 2002
  - Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
  - Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
  - Data on applications submitted to SUKL
  - List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of December 2002
  - List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2002
  - List of medicinal products registration decision of which will expire in June 2003
  - List of medicinal products with expired validity of the registration decision
- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of November 20, 2002 to December 4, 2002
  - List of exemptions from registration granted by the Ministry of Health during the period of December 2, 2002 to December 9, 2002