SUKL Bulletin 12/2004

- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of November 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of January 1, 2005**
  - **Dis-11-Guidelines on Good Distribution Practice of Medicinal Products for human use**
    The guidelines set up requirements for Good Distribution Practice for wholesalers of medicinal products. The guidelines are translations of the EU Guidelines on GDP of Medicinal Products for Human Use (94/C63/03).
  - **Dis-12-Guidelines on Distribution of Active Substances and Excipients to persons authorised to prepare Medicinal Products**
    Requirements to be met by companies distributing pharmaceutical active substances and excipients to persons authorised to prepare medicinal products are given.
- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 2004**
    Comparison with the situation in the previous period is given. Figures are expressed in numbers of packages, Czech crowns and Defined Daily Doses.
- **Pharmacopoeia activities**
  - **Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic**
- **Information**
  - **Information for Marketing Authorisation Holders concerning ATC codes of centralised medicinal products and radiopharmaceuticals**
  - **Outline of notifications on the use of non-registered medicinal products in the month of November 2004**
    The information on evaluated notifications in the month of November 2004, 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 2004**
- **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 2004 is published. Documents are available in SUKL library. In addition, a reference to documents adopted by the MRFG is published.
- **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 2004**
- **List of medicinal products whose marketing authorisation will expire in February 2005**
  The validity of marketing authorizations of the listed products will expire during February 2005 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 indicated by "Z" in SUKL database as of November 30, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from October 21, 2004 to November 18, 2004
  - Medicinal products recently registered by EU centralised procedure in the period from October 21, 2004 to November 18, 2004
  - List of specific therapeutic programmes approved in the period from October 21, 2004 to November 18, 2004

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of October 2004**
- **Information**
  - **Information for Marketing Authorisation Holders on reporting of EAN codes**
    Since January 1, 2004, there is a legal requirement for all medicinal products to be labelled with EAN codes. The MA holders should fulfil this duty and inform SUKL about EAN codes of their medicinal products by December 31, 2004.

- **Information on seminars held by SUKL in the 1st half of 2005**
  he programme of seminars and the application form are included.
- **Outline of notifications on the use of non-registered medicinal products in the month of October 2004**
  The information on evaluated notifications in the month of October 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of October 2004**
- **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 2004 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 2004 are published.
- **Overview of data on basic activities of the Inspection Branch in the third quarter of 2004**
  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 2004**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of October 2004**
- **Change in the list of test facilities included in the national GLP programme in the field of medicinal products**
- **List of medicinal products whose marketing authorisation will expire in January 2005**
  The validity of marketing authorizations of the listed products will expire during January 2005 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 October 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from Semtember 23, 2004 to October 20, 2004
  - Medicinal products recently registered by EU centralised procedure during the period from September 23, 2004 to October 20, 2004
  - List of specific therapeutic programmes approved in the period from September 23, 2004 to October 20, 2004

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of September 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of November 1, 2004**
  - **REG-79-Active Substance Master File**
    The guideline is based on CPMP/QWP/227/02 (EMEA/CVMP/134/02) „Guideline on Active Substance Master File Procedure“, valid in the EU Member Sates since 31.8.2004. Procedure for submission of Active Substance Master File within MAA procedure or variation procedure, as well as the contents of Active Substance Master File, templates of Letter of Access and Covering Letter are provided.
  - **ZP-21-Inspection of the conduct of clinical evaluation of medical devices at health care providers**
    This guideline
    - describes the system and requirements for inspections of clinical evaluations, incl. clinical trials, which can be performed at health care providers,
    - provides information which can be used to develop clinical evaluation, incl. clinical trial documentation,
    - is addressed to all professional staff responsible for conducting clinical evaluation, incl. clinical trials (sponsors, investigators, ethics committees, etc.),
    - provides references to other sources (e.g. European directives and standards, Czech laws and Acts).
- **Laboratory control**
  - **Outcomes of projects completed by the SUKL Laboratory Control Branch**
    The laboratory control branch performed, based on the specific projects, controls on medicinal products taken from the Czech market by inspectors. Outcomes of the following projects are included in this report: Products authorised in the years 1998-2000 (two projects verifying methods and quality of newly authorised products), Control of selected products I and II (survey of quality), Products of manufacturers from the EU acceding countries, Products of manufacturers from the third countries (verifying the quality of products imported from these countries), Vitamin products (quality of large volume OTC products), Products of selected manufacturers (selection was made on the basis of frequent complaints concerning manufactured products) and Products containing essential oil drugs or

extracts prepared from them (examination of suitability of GC methods).

- **Information**
  - **Information about readiness of health care providers to fulfil legal requirements laid down in paragraph 52 of the Act No. 123/2000 Coll., on Medical Devices, as resulted from monitoring conducted by SUKL**
    The information describes action and activities preformed by SÚKL in relation to requirements of paragraph 52. The current state of play is described in graphical format and in figures.
  - **Information about the possibility of training for future users of EudraVigilance system**
  - **Outline of notifications on the use of non-registered medicinal products in the month of September 2004**
    The information on evaluated notifications in the month of September 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of September 2004**
  - **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 2004 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 third quarter of 2004**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of September 2004**
  - **List of medicinal products registration decision of which will expire in December 2004**
    The validity of marketing authorizations of the listed products will expire during December 2004 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 September 30, 2004.
- **Information on registered drugs and and approved specific therapeutic programmes**

- Recently registered medicinal products and variations to registrations approved during the period from August 26, 2004 to September 22, 2004
- Medicinal products recently registered by EU centralised procedure during the period from August 24, 2004 to September 22, 2004

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of August 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of October 1, 2004**
  - **UST-30-Basic principles for distinguishing between medicinal products for human use and other products, including detailed specification of medicinal products subject to marketing authorization**
    The guideline provides information on borderline products, including important definitions, instructions for applicants and requirements on documentation submitted with the application for a decision whether a product is classified as a pharmaceutical or a medicinal product subject to Marketing Authorization. The guideline has been revised and updated in order to comply with the new legislation for foodstuffs and food supplements.
  - **ZP-19-Inspections of medical devices operated by health care providers**
    This guideline
    - describes the system of inspections conducted in health care establishments (including inspection covering compliance with the requirements defined in Article 52 of the Act No. 123/2000 Coll., on Medical Devices), activities of SUKL related to the conduct of preventive inspections, maintenance and repair of medical devices, verification of measurement accuracy, technical condition and compliance with the intendedpurpose of use of such devices, keeping and maintenance of the records and documentation related to medical devices, instructions for their use,
    - is intended for professional staff responsible for supply, use, maintenance and servicing of medical devices in hospitals, clinics, etc.
  - **ZP-20-Medical Devices Vigilance system and Post Marketing Surveillance including monitoring and reporting of adverse incidents in the Czech Republic**
    This guideline
    - describes the system for notification, evaluation and investigation of adverse incidents, known as the Medical Devices Vigilance,

- is intended to facilitate the uniform application and implementation of the requirements laid down in the Act No. 123/2000 Coll.,
- covers the activities of SUKL, manufacturers (including their authorised representatives or distributors responsible for placing on the market), users and others concerned with the continuing safety of medical devices.

- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 2nd quarter of the year 2004**
    Comparison with the situation in the previous period is given. Figures are expressed in numbers of packages, Czech crowns and Defined Daily Doses.

- **Information**
  - **Information on seminars held by SUKL in the 2nd half of 2004**
    The programme of seminars and the application form are included.
  - **Clinical trials involving genetically modified organisms**
    Instructions for applicants concerning requirements of the Ministry of Environment.
  - **Information of the State Institute for Drug Control concerning medical devices**
  - **Information concerning programme equipment („software“) classified as medical device**
    The document provides guidance to regulatory bodies, manufacturers and healthcare providers on the application of provisions that apply to software within the scope of the Medical Device Directives and Czech Government Regulations.
  - **Information on the Certified Pharmacy**
  - **Outline of notifications on the use of non-registered medicinal products in the month of August 2004**
    The information on evaluated notifications in the month of August 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**
  - **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 July 2004 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 2004**
- **List of medicinal products registration decision of which will expire in November 2004**
  The validity of marketing authorizations of the listed products will expire during November 2004 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 August 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from July 29, 2004 to August 25, 2004
  - Medicinal products recently registered by EU centralised procedure during the period from July 24, 2004 to August 23, 2004
  - List of specific therapeutic programmes approved during the period from July 29, 2004 to August 25, 2004

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  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of July 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of September 1, 2004**
  - **LEK-9-Handling of medicinal products in healthcare facilities**
    Commentary on the decree No. 255/2003 Coll., laying down details on handling of medicinal products, especially conditions of storage, dilution of preparations etc. in hospitals. The commentary has been prepared to assist healthcare professionals in understanding and implementation of this decree.
- **Information**
  - **Outline of notifications on the use of non-registered medicinal products in the month of July 2004**
    The information on evaluated notifications in the month of July 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**

- **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 June 2004 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 2004 are published.
- **Overview of data on basic activities of the Inspection Branch in the second quarter of 2004**
  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 2004**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of July 2004**
- **List of medicinal products registration decision of which will expire in October 2004**
  Registration decision of the listed products will be no longer valid during October 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 July 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from July 1, 2004 to July 28, 2004
  - Medicinal products recently registered by EU centralised procedure during the period from June 17, 2004 to July 23, 2004

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- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of June 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of August 1, 2004**
  - **Announcement for applicants for registration of medicinal products on revocation of some SUKL guidelines**
    Guidelines REG-11 and REG-12 are revoked as the complete

requirements on labelling of medicinal products and patient leaflets are stipulated by Sections 24, 26c and 26d of the Act No. 79/1997 Coll., on Pharmaceuticals, as amended, Section 4 and Annex 4 of the Registration Decree No. 288/2004 Coll. and based on the provisions of the Act on Pharmaceuticals all guidelines of the European Commission and the EMEA apply.

- **UST-29-Administration fees and costs reimbursement for activities performed on request**
  The guideline updates UST-18. The main changes and amendments concern the price list and result from acccession to the EU and new SUKL activities.
- **REG-78-Application form for CZ outgoing Mutual Recognition Procedure**
  The application to be submitted after completion of national marketing authorisation procedure for the medicinal product in the case of requesting the initiation of MRP with the Czech Republic as a Reference Member State.
- **DIS-10-Notification of a change in information on the distributor performing distribution activities within the territory of the Czech Republic based upon distribution authorisation for medicinal products issued by another EU Member State**
  The obligation to notify SUKL of distribution activities in the CR in advance is based on the provision of Section 42 par. 4 of Act No. 79/1997 Coll., on Pharmaceuticals, as amended

- **Pharmacopoeia activities**
  - **Drafts of national monographs**
  - Drafts are presented for discussion on the SUKL website.

- **Information**
  - **Information on office hours of the mail room in August**
  - **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 June 2004**
    The information on evaluated notifications in the month of June 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**
  - **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 June 2004 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 2004**
- **List of medicinal products registration decision of which will expire in September 2004**
  Registration decision of the listed products will be no longer valid during September 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 June 30, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from June 1, 2004 to Jume 30, 2004
  - Medicinal products recently registered by EU centralised procedure during the period from April 29, 2004 to June 16, 2004
  - List of specific therapeutic programmes approved during the period of June 1, 2004 to June 30, 2004

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of May 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of July 1, 2004**
  - **REG-76 - Variations to a marketing authorisation**
    This guideline provides requirements on submission of the application for variation to a marketing authorisation, detailed guidance for filling-in the application form, explanation of consequential and parallel variations, the conditions to be fulfilled for each Type IA / Type IB variation, as well as documentation to be submitted with these notifications.
  - **REG-77 - Variation to a marketing authorisation of medicinal product - Application for approval of variation II / notification of variation IA/IB**
    Application form to be used in a national variation procedure. This form is based on the European variation application form with exclusion of data regarding variations for veterinary medicinal products and data specific for centralised procedure.
  - **UST-28 - Approval procedure for parallel import of a medicinal product**

The guideline summarizes conditions for parallel import of a medicinal product, including obligations of a parallel importer and provides detailed instructions for parallel import authorisation application and the description of approval procedure.

- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 1st quarter of the year 2004**
    Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.

- **Information**
  - **Medicinal products registered by EU centralised procedure – information on a new section in Vestnik SUKL and website**
  - **Outline of notifications on the use of non-registered medicinal products in the month of May 2004**
    The information on evaluated notifications in the month of May 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**
  - **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 April 2004 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 2004**
  - **List of medicinal products registration decision of which will expire in August 2004**
    Registration decision of the listed products will be no longer valid during August 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 May 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from April 29, 2004 to May 31, 2004
  - Medicinal products recently registered by EU centralised procedure during the period from April 14, 2004 to April 28, 2004
  - List of specific therapeutic programmes approved during the period of April 30, 2004 to May 31, 2004

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of April 2004**
- **SÚKL guidelines**
  - **List of guidelines valid as of June 1, 2004**
  - **UST-27 - Basic provisions of the Act on Advertising Regulation concerning the advertising of human medicinal products**
    The guideline includes conditions relating to advertising in communication media (especially printed and electronic advertisements), their explanation and examples expressing the attitude of SUKL. It is based on the provisions of the Act No. 40/1995 Coll., as amended.
  - **KLH-20 - Application for Approval/Notification of Clinical Trial**
    The guideline replaces KLH-7 and the clinical part of KLH-19 and is valid since May 1 st , 2004. This guideline updates KLH-7 in accordance with the new requirements for submission of documentation with the new European Application Form. It contains the information required by SÚKL (see table K- Check List of the information appended to the application form), Annex 1 provides detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial. Annex 2 specifies the requirements for summary of the protocol.
- **Pharmacopoeia activities**
  - **Announcement of text of the Czech Pharmacopoeia 2002, Supplement 2003 becoming official standards**
  - **Water for injection, Water-highly purified, Water-purified – translation of the European Pharmacopoeia**
    Information about some of the European Pharmacopoeia monographs and translations of their texts.
- **Information**
  - **Information concerning placing medicinal products on the Czech market after accession to the EU**
    Several questions and answers related to the EU accession are published.
  - **Outline of notifications on the use of non-registered medicinal products in the month of April 2004**
    The information on evaluated notifications in the month of April 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**

- **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 2004 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 2004 are published.
- **Overview of data on basic activities of the Inspection Branch in the first quarter of 2004**
  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 2004**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of April 2004**
- **List of medicinal products registration decision of which will expire in July 2004**
  Registration decision of the listed products will be no longer valid during July 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 April 30, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from April 1, 2004 to April 28, 2004
  - List of specific therapeutic programmes approved during the period of April 1, 2004 to April 28, 2004

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- **Contents**
- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of March 2004**
  - **Cisaprid Containing Medicinal Products - Revocation of Registration**
    Cisaprid withdrawal by the 1 st May 2004 is described. Access to paediatric formulation will be maintained as a named patient use. The

article includes detailed guideline for doctors and pharmacists how to obtain and prescribe the non-registered medicinal product.

- **Information on reported adverse incidents of medical devices**

- **SÚKL guidelines**
  - **List of guidelines valid as of May 1, 2004**
  - **REG-75-Categorisation of Medicinal Products as Selected Pharmaceuticals**
    This guideline replaces the provision REG-56 and describes the categories of "selected pharmaceuticals", provides instructions how to apply for this legal status in case of medicinal products that have already been registered and in case of new applications for registration, as well as the requested documentation and the principles for the evaluation of the product as "selected pharmaceutical".

- **Information**
  - **Information for applicants for registration of products classified in the list of pending applications as „non-perspective for completing by national procedure" who withdraw their applications**
    Information on the possibility to get partial refund. This information specifies already published announcemen in Věstník SÚKL No.3/2004.
  - **Changes in approach of SUKL to reply to queries of applicants/ holders of registration**
    Due to growing numbers of disturbing phone calls to staff dealing with registration, after discussion with associations of manufacturers a pilot phase of new communication practices in this area, based mainly on e-mail communication is prepared to be introduced.
  - **Annual report of the State Institute for Drug Control for the year 2003**
    The report will be available in the Mail room for 50,-CZK from June 1, 2004.
  - **Information on current regulation of foodstuffs for special nutrition and food supplements**
    The information describes the new legislation for foodstuffs for special nutrition and food supplements and its impact on current principles concerning the evaluation of such products. Several questions and answers related to this issue are included.
  - **Information for Registration Holders of dietary medicinal products (ATC code V06)**
    SUKL issues advice to those registration holders, who were granted in the past registration for dietary products and foodstuffs for special medical purposes. Upon the change of legislation, these products can be no longer classified as medicinal products. The registration holders concerned are advised to apply for revocation of registration of these products before May 2004, as sell out period may be permitted by SUKL in such situation.
  - **Outline of notifications on the use of non-registered medicinal products in the month of March 2004**
    The information on evaluated notifications in the month of March 2004,

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

- **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**
- **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 2004 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 2004**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of March 2004**
- **List of medicinal products registration decision of which will expire in June 2004**
  Registration decision of the listed products will be no longer valid during June 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 March 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period from February 19, 2004 to March 31, 2004
  - List of specific therapeutic programmes approved during the period of February 19, 2004 to March 31, 2004
  - Withdrawal of approval with the conduct of specific therapeutic programmes on the request of person who submitted the programme proposal

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of February 2004**
- **Information on drug consumption**
  - **Team of authors: Drug “consumption” in the Czech Republic in the year 2003**

This article is focused on drug “consumption” in the Czech Republic in the year 2003 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.

- **Pharmacy activities**
  - **Control of pharmacies in the year 2003**
    Out of the total number of 4 402 samples taken from pharmacies 13 % of samples were found to be non-compliant and 8,0 % of samples were found "non-compliant with adjustment". The number of non-compliant samples from pharmacies continues to be relatively high, but since 2002 the quality of medicinal products and purified water prepared in pharmacies has improved by about 2 %.

- **Information**
  - **Information for applicants for registration of products classified in the list of pending applications as „non-perspective“ for completing by national procedure after accession to the EU**
    Information on the possibility to get full or partial refund of the fee in case that the applicant withdraws the “non-perspective” application. The procedure is described in the SUKL guideline REG-24 and the form is annexed to this information. Yet another summary of pros and cons of the withdrawal is provided.
  - **Outline of notifications on the use of non-registered medicinal products in the month of February 2004**
    The information on evaluated notifications in the month of February 2004, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of registered medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved**
  - **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 January 2004 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 2004**
  - **List of test facilities included in the national GLP programme in the field of medicinal products**
  - **List of medicinal products registration decision of which will expire in May 2004**
    Registration decision of the listed products will be no longer valid during May 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 February 29, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period of January 22, 2004 to February 18, 2004
  - Withdrawal of approval with the conduct of specific therapeutic programmes on the request of person who submitted the programme proposal

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  - **List of guidelines valid as of March 1, 2004**
  - **Announcement on revocation of SUKL guideline UST-10**
    Guideline UST-10 is revoked without replacement as of March 1, 2004 due to non-compliance with the new legislation (Act No. 79/1997 Coll., on Pharmaceuticals, as amended).
  - **UST-26-Basic principles of differentiation of human pharmaceuticals from other products, including specification of medicinal products requiring registration**
    Updated guideline deals with borderline products, including important definitions, the instructions for applicants and requirements on documentation submitted with the application for a decision whether a product should be classified as a pharmaceutical or a medicinal product subject to registration. The guideline has been revised to comply with the new legislation.
  - **REG-74-Summary of Product Characteristics**
    Revised guideline on the structure and content of Summary of Products Characteristics is based on the provisions of the Act No. 79/1997 Coll., on pharmaceuticals, as amended, its implementing decrees, the guideline of the European Commission of December 1999 and on the documents prepared by the EMEA Quality Review Group.
- **Information**
  - **Information on seminars held by SUKL in the 1st half of 2004**
    The programme of seminars for the 1st half of 2004 and the registration form are included.
  - **Outline of notifications on the use of non-registered medicinal products in the month of January 2004**
    The information on evaluated notifications in the month of January

2004, 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 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 fourth quarter of 2003 are published.
- **Overview of data on basic activities of the Inspection Branch in the fourth 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 fourth quarter of 2003**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of January 2004**
- **List of test facilities included in the national GLP programme in the field of medicinal products**
- **List of medicinal products registration decision of which will expire in April 2004**
  Registration decision of the listed products will be no longer valid during April 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 January 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period of January 7, 2004 to January 21, 2004
  - List of specific therapeutic programmes approved during the period of December 22, 2003 to January 31, 2004

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  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of December 2003**
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- **List of guidelines valid as of February 1, 2004**
- **REG-72-Application for revocation of the registration of medicinal product**
  A new form should be used for applications for revocation of the registration of medicinal product since January 1, 2004.
- **REG-73-Application for renewal of the registration of medicinal product**
  The form, which replaces form REG-25 as well as the renewal guideline REG-32, should be used for applications for renewal of the registration of medicinal product since January 1, 2004.
- **PhV-1-Reporting of Adverse Drug Reactions to Proprietary Medicinal Products**
  The guideline opens a new series of SUKL pharmacovigilance guidelines coded as „PhV“. The first one deals with basic requirements for adverse drug reaction reporting for marketed medicinal products when used under normal conditions, including follow-up of these reports. It is intended mainly for marketing authorisation holders; nevertheless, it also sets up requirements for health care professionals, distributors, parallel importers and others involved in the health care system.
- **PhV-2-Preparation and Submission of Periodic Safety Update Reports**
  The guideline sets up a detailed model for PSUR based on the ICH guidelines. It describes the way of PSUR submission harmonisation according to the IBD and explains the preparation and rules for Summary Bridging Reports and Addendum Reports. It encompasses a terminology index and explanations of principles behind the rules.

- **Information**
  - **Information on requirements of § 52 of amendment of the Act No. 123/2000 Coll., on Medical Devices that were put into operation before the end of 1999**
    This article describes new requirements for medical devices that were put into operation before the end of 1999 and that don’t have permission for use in providing health care (§ 62 of the Act No.20/1966 Coll.,) or don’t have assessment of conformity according to the relevant Czech Government Acts. It also stipulates duties for health care providers concerning provision of maintenance, repairs and servicing for medical devices in Class I and IIa (§ 28). incl. records from such activities. This regulation has been in force since September 1, 2003. It further includes provision of technical quality of medical devices in Class IIb and III incl. report from such activities. This regulation will be in force from January 1, 2005 for medical devices that were put into operation before January 1, 1991 and from January 1, 2006 for medical devices that were put into operation between January 1, 1991 and December 31, 1999.
  - **Information for sponsors of clinical trials - revision of the SUKL guideline KLH-7**
    Minor change of the guideline KLH-7 consists in revised instruction for applicants regarding payment of costs reimbursement referring to the SUKL guideline UST-18.

- **Preliminary information on a forthcoming seminar**
  On March 18, 2004 from 2.00 pm the following seminar will be held: " Changes of the EU pharmaceutical legislation after the adoption of ´Review 2001´ and their impact and implementation in the CR" The seminar is intended mainly for those pharmaceutical representatives who are interested in a general outline and conceptual changes in legislation rather than in practical guidance. A complete list of seminars planned for the first half of 2004 will be available in the February issue of Vestnik SUKL.
- **Variations to registration published in the Vestnik 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 December 2003**
  The information on evaluated notifications in the month of December 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 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 new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2003**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of December 2003**
- **List of medicinal products registration decision of which will expire in March 2004**
  Registration decision of the listed products will be no longer valid during March 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 December 31, 2003.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Recently registered medicinal products and variations to registrations approved during the period of November 6, 2003 to December 17, 2003
  - List of specific therapeutic programmes approved during the period of November 26, 2003 to December 31, 2003