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  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of November 2005**
- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 2005**
    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 Czech Pharmacopoeia becoming official standards**
  - **Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic**
- **Information**
  - **Information for healthcare providers – potential risks of self-investigation of adverse incidents of medical devices**
    This information is intended as a recommendation for healthcare providers, to respect certain principles when conducting internal investigation of adverse incidents of medical devices.
  - **Information on current legislation in the area of medical devices - amendment**
  - **Information on starches as excipients in medicinal products from the coeliac disease point of view**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of November 2005**
    The information on evaluated notifications in the month of November 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of November 2005**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in November 2005 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of November 2005**
  - **List of medicinal products whose marketing authorisation will expire in February 2006**

The validity of marketing authorizations of the listed products will expire during February 2006 and the products will be marked 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, 2005.

- **Information on authorised medicinal products and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from October 20, 2005 to November 16, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from November 1, 2005 to November, 30, 2005
  - List of specific therapeutic programmes approved in the period from November 1, 2005 to November 30, 2005

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  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of October 2005**
- **SÚKL quidelines**
  - **Information on revocation of a SUKL guideline REG-71**
  - **List of guidelines valid as of December 1, 2005**
- **Information**
  - **Information on the implementation of new European pharmaceutical legislation**
    Questions concerning the transition period till the new European pharmaceutical legislation is transposed in the national legislation were discussed with interested parties. Minutes from these meetings as well as Questions and Answers document are published on the SUKL website.
  - **Information of the State Institute for Drug Control on vaccination against influenza**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of October 2005**
    The information on evaluated notifications in the month of October 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of October 2005**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**

A list of new documents issued by the EMEA in October 2005 is published. Documents are available in SUKL library.

- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the third quarter of 2005**
- **Overview of data on basic activities of the Inspection Branch in the third quarter of 2005**
- **Overview of data on activities of the Medical Devices Branch in the third quarter of 2005**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of October 2005**
- **List of medicinal products whose marketing authorisation will expire in January 2006**
  The validity of marketing authorizations of the listed products will expire during January 2006 and the products will be marked 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 October 31, 2005.

- **Information on authorised medicinal products and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from September 22, 2005 to October 19, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from October 1, 2005 to October, 31, 2005
  - List of specific therapeutic programmes approved in the period from August 1, 2005 to October 31, 2005

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  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of September 2005**
- **SÚKL quidelines**
  - **Information on revocation of a SUKL guideline**
  - **List of guidelines valid as of November 1, 2005**
  - **DIS-14-Humanitarian aid shipments containing medicinal products**
    Legal requirements for providing medicinal products as humanitarian aid are described. The rules are based on Act no. 79/1997 Coll., on Pharmaceuticals.
- **Information**
  - **Information on current legislation in the area of medical devices**
    After accession of the Czech Republic to the European Union the

legislation in the area of medical devices changed. This information is intended in particular for providers of health care, manufactures and distributors.

- **Outline of notifications on the use of non-authorised medicinal products in the month of September 2005**
  The information on evaluated notifications in the month of September 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
- **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of September 2005**
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in September 2005 is published. Documents are available in SUKL library.
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of September 2005**
- **List of new pharmacies and detached departments for dispensing pharmaceuticals and medical devices approved by SUKL in the third quarter of 2005**
- **List of medicinal products whose marketing authorisation will expire in December 2005**
  The validity of marketing authorizations of the listed products will expire during December 2005 and the products will be marked 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 September 30, 2005.

- **Information on authorised medicinal products and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from August 11, 2005 to September 21, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from September 1, 2005 to September, 30, 2005
  - List of specific therapeutic programmes approved by MoH CR - Correction

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- **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of August 2005**

- **SÚKL quidelines**
  - **List of guidelines valid as of October 1, 2005**
  - **UST-32-Reporting and evidence 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. Authorised products without being marked with the EAN code or those marked with a code different from that in SUKL records shall be considered defective and appropriate action will be taken.

- **Information on drug consumption**
  - **Team of authors: Drug consumption in the Czech Republic in the 2nd quarter of the year 2005**
    Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.

- **Information**
  - **Information on seminars held by SUKL in the 2nd half of 2005 – II. part**
    The programme of seminars and the application form are included.
  - **Outline of notifications on the use of non-authorised medicinal products in the month of August 2005**
    The information on evaluated notifications in the month of August 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of August 2005**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in August 2005 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of August 2005**
  - **List of medicinal products whose marketing authorisation will expire in November 2005**
    The validity of marketing authorizations of the listed products will expire during November 2005 and the products will be marked 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 August 31, 2005.

- **Information on authorised medicinal products and approved specific therapeutic programmes**
    - Authorised medicinal products and variations to marketing authorisations approved in the period from July 14, 2005 to August 10, 2005
    - Medicinal products authorised under the EU centralised procedure in the period from August 1, 2005 to August, 31, 2005

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- **Front page news**
    - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of July 2005**
- **SÚKL quidelines**
    - **List of guidelines valid as of September 1, 2005**
    - **UST-31-Principles for identification of human medicinal products in the CR**
      The guidance specifies and explains use of the medicinal products identification codes in the Czech Republic.
    - **REG-82-Guidance on the national procedure for authorisation of generic medicinal products**
      The guidance describes steps of national authorisation procedure for generics. It is intended to provide the applicant with overview of timelines and individual steps within the authorisation procedure concerning his application.
    - **REG-83-Requirements on stability studies in registration dossier**
      The guideline, which is based on the translation of Note for Guidance CPMP/QWP/122/02, STABILITY TESTING OF EXISTING ACTIVE SUBTANCES AND RELATED FINISHED PRODUCTS and CPMP/QWP/609/96, DECLARATION OF STORAGE CONDITIONS FOR MEDICINAL PRODUCTS IN THE PARTICULARS, gives information on data to be submitted with the application and recommendations on texts to be provided in package leaflet and labelling, if appropriate. The guideline replaces REG-49 and is valid as of September 1, 2005.
- **Information**
    - **Information for marketing authorisation holders on adjustment of MA numbers of some medicinal products**
    - **Instruction for successful delivery of e-mail messages to SUKL**
      Due to potential problems with Internet communication, which are out of SUKL's control, in rare cases your e-mail message may not be delivered to the intended addressees in SUKL.
    - **List of hygienic service centres approved to carry out testing of purified water for pharmacies**
    - **Outline of notifications on the use of non-authorised medicinal products in the month of July 2005**

The information on evaluated notifications in the month of July 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.

- **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of July 2005**
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in June 2005 is published. Documents are available in SUKL library.
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the second quarter of 2005**
- **Overview of data on basic activities of the Inspection Branch in the second quarter of 2005**
- **Overview of data on activities of the Medical Devices Branch in the second quarter of 2005**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of July 2005**
- **List of medicinal products whose marketing authorisation will expire in October 2005**
  The validity of marketing authorizations of the listed products will expire during October 2005 and the products will be marked 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 July 31, 2005.

- **Information on authorised medicinal products and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from June 16, 2005 to July 13, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from July 1, 2005 to July, 31, 2005
  - List of specific therapeutic programmes approved during the period of June 1, 2005 to July 31, 2005

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of June 2005**

- **Announcement concerning medicinal products**

- **SÚKL quidelines**
  - **List of guidelines valid as of August 1, 2005**
  - **VYR-34-Heat sterilisation processes**
    The guideline provides the interpretation of GMP and Pharmacopoeias requirements for the heat sterilisation processes. It replaces the guideline VYR-12 and compared to that guideline it is extended by metrological aspects in relation to qualification and validation of sterilisers. The guideline is complementary to the guideline VYR-33 describing the other sterilization processes..

- **Pharmacopoeia activities**
  - **Information on publishing of texts of the Czech Pharmacopoeia 2002 – Addendum 2005 becoming official standards**

- **Information**
  - **Information on seminars held by SUKL in the 2nd half of 2005 – I. part**
    The programme of seminars and the application form are included.
  - **The common form of the Opinion of the Ethics Committee on Clinical Trial on Human Medicinal Products recommended for all Ethics Committees (Czech-English version)**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of June 2005**
    The information on evaluated notifications in the month of June 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of June 2005**
  - **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 separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the second quarter of 2005**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of June 2005**
  - **List of medicinal products whose marketing authorisation will expire in September 2005**
    The validity of marketing authorizations of the listed products will expire during September 2005 and the products will be marked 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 June 30, 2005.

- **Information on authorised medicinal products and approved specific therapeutic programmes**

- Authorised medicinal products and variations to marketing authorisations approved in the period from May 19, 2005 to June 15, 2005
- Medicinal products authorised under the EU centralised procedure in the period from June 1, 2005 to June, 30, 2005

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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 2005**
- **SÚKL quidelines**
  - **List of guidelines valid as of July 1, 2005**
  - **PHV-5-Plan for transfer of pharmacovigilance obligations** The guideline sets out a template for plan for transfer of pharmacovigilance obligations related to the transfer of marketing authorization. It describes in detail the way of transfer planning from the old to the new marketing authorization holder in order to ensure continuity of pharmacovigilance process.
- **Information on drug consumption**
  - **Team of authors: Drug "consumption" in the Czech Republic in the 1st quarter of the year 2005** Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.
- **Pharmacy activities**
  - **Control of pharmacies in the year 2004** Out of the total number of 3 657 samples taken from pharmacies 13 % of samples were found to be non-compliant and 7,2 % of samples were found "non-compliant with adjustment". The number of non-compliant samples from pharmacies continues to be relatively high, but since 2003 the quality of medicinal products and purified water prepared in pharmacies has slightly improved.
- **Information**
  - **Information for persons interested in the topic "regulations related to Advanced Therapy Medicinal Products"**
  - **Outline of notifications on the use of non-authorised medicinal products in the month of May 2005** The information on evaluated notifications in the month of May 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of May 2005**

- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in May 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 2005**
- **List of medicinal products whose marketing authorisation will expire in August 2005**
  The validity of marketing authorizations of the listed products will expire during August 2005 and the products will be marked 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 May 31, 2005.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period from April 21, 2005 to May 18, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from May 1, 2005 to May, 31, 2005
  - List of specific therapeutic programmes approved during the period of May 1, 2005 to May 31, 2005

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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 2005**
- **SÚKL quidelines**
  - **List of guidelines valid as of June 1, 2005**
  - **REG-81-Authorisation of medicinal gases**
    The guideline provides information on conditions under which medicinal gases should be authorised as medicinal products including references to relevant pharmaceutical legislation and guidelines.
  - **DIS-13-Reporting of deliveries of distributed medicinal products**
    The provision defines more exactly the way of reporting deliveries of medicinal products from wholesalers or manufacturers to health care facilities or vendors of selected medicinal products and the structure of the report.
- **Information**

- **Physicians and information on drugs – the survey made in the year 2004**
  Selected physicians were asked about sources of information on medicinal products which they use. Some questions were asked with the aim to evaluate the impact of advertising activities of pharmaceutical industry on physicians and their information on prescribed drugs.
- **Information on training of users of EudraVigilance system**
- **Outline of notifications on the use of non-registered medicinal products in the month of April 2005**
  The information on evaluated notifications in the month of April 2005, 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 Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in April 2005 is published. Documents are available in SUKL library.
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the first quarter of 2005**
- **Overview of data on basic activities of the Inspection Branch in the first quarter of 2005**
- **Overview of data on activities of the Medical Devices Branch in the first quarter of 2005**
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of April 2005**
- **List of medicinal products whose marketing authorisation will expire in July 2005**
  The validity of marketing authorizations of the listed products will expire during July 2005 and the products will be marked 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 April 30, 2005.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of March 24, 2005 to April 20, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from April 1, 2005 to April, 30, 2005
  - List of specific therapeutic programmes approved during the period of April 1, 2005 to April 30, 2005

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of March 2005**
  - **Information on reported adverse incidents of medical devices**
- **SÚKL quidelines**
  - **List of guidelines valid as of May 1, 2005**
  - **SLP-6-National GLP Programme - Components of Procedures for GLP Monitoring**
    Joint document covering both pharmaceuticals (the GLP Monitoring Authority in the Czech Republic for pharmaceuticals is SUKL) and chemicals (this area is monitored by the National Inspection Authority NIO).
- **Information**
  - **Experiences from supervision over advertising of medicinal products in 2004**
    Numbers of investigated cases of reports on breaches of legal regulations were published together with solutions set up. Information on survey among physicians describing advertising activities of pharmaceutical firms is included.
  - **Outline of notifications on the use of non-registered medicinal products in the month of March 2005**
    The information on evaluated notifications in the month of March 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of March 2005**
  - **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in March 2005 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the first quarter of 2005**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of March 2005**
  - **List of medicinal products whose marketing authorisation will expire in June 2005**
    The validity of marketing authorizations of the listed products will expire during June 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 March 31, 2005.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of February 24, 2005 to March 23, 2005
  - Medicinal products authorised under the EU centralised procedure in the period from January 27, 2005 to March, 31, 2005
  - List of specific therapeutic programmes approved during the period of March 1, 2005 to March 31, 2005

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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 2005**
- **SÚKL quidelines**
  - **List of guidelines valid as of April 1, 2005**
  - **PHV-4-Electronic Reporting of Adverse Drug Reactions**
- **Information on drug consumption**
  - **Team of authors: Drug "consumption" in the Czech Republic in the year 2004**
    This article is focused on drug "consumption" in the Czech Republic in the year 2004 and on the comparison against previous years. Figures are given in the number of packages, Czech crowns and Defined Daily Doses. Consumption of several ATC groups with highest level of consumption is discussed.
- **Information**
  - **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. Authorised products released for circulation after 1 st January 2005 without being marked with the EAN code or those marked with a code different from that in SUKL records shall be considered defective and appropriate action will be taken.
  - **Outline of notifications on the use of non-registered medicinal products in the month of February 2005**
    The information on evaluated notifications in the month of February 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.

- **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of February 2005**
- **Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
- **Information on documents issued by the European Medicines Agency (EMEA)**
  A list of new documents issued by the EMEA in February 2005 is published. Documents are available in SUKL library.
- **Data on applications submitted to SUKL**
  Data on numbers of various types of applications submitted monthly to SUKL.
- **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of February 2005**
- **List of medicinal products whose marketing authorisation will expire in May 2005**
  The validity of marketing authorizations of the listed products will expire during May 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 February 28, 2005.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of January 27, 2005 to February 23, 2005
  - List of specific therapeutic programmes approved during the period of January 27, 2005 to February 28, 2005

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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 January 2005**
- **SÚKL quidelines**
  - **List of guidelines valid as of March 1, 2005**
  - **KLH-21-Reporting of suspected unexpected serious adverse reactions of medicinal products for human use in clinical trials**
    The guidance KLH-21 is based on the the relevant national and European legislation and other related guidance documents. It describes reporting responsibilies of the sponsor towards the State Institute for Drug Control, ethics committees and investigators.
  - **PHV-3-Non-Interventional Post-Authorisation Safety Studies with Prescription-Only Medicinal Products for Human Use**
    This guideline sets out terms and conditions for conducting of non-

interventional post-authorization safety studies with prescription-only medicinal products for human use that are partly or fully sponsored by pharmaceutical industry or by organizations or persons supported by pharmaceutical industry. The guideline also establishes the public register of these studies and is coming into force on 1st March 2005.

- **Information**
  - **Information on seminars held by SUKL in the 1st half of 2005 – 2 nd part**
    The programme of seminars and the application form are included.
  - **Outline of notifications on the use of non-registered medicinal products in the month of January 2005**
    The information on evaluated notifications in the month of January 2005, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.
  - **List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of January 2005**
  - **Information on documents issued by the European Medicines Agency (EMEA)**
    A list of new documents issued by the EMEA in December 2004 and January 2005 is published. Documents are available in SUKL library.
  - **Data on applications submitted to SUKL**
    Data on numbers of various types of applications submitted monthly to SUKL.
  - **Quarterly evaluation of pharmacies activity**
    Results of the inspection activities of SUKL in pharmacies during the fourth quarter of 2004 are published.
  - **Overview of data on basic activities of the Inspection Branch in the fourth 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 fourth quarter of 2004**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of January 2005**
  - **List of medicinal products whose marketing authorisation will expire in April 2005**
    The validity of marketing authorizations of the listed products will expire during April 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 January 31, 2005.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of December 30, 2004 to January 26, 2005

- Medicinal products authorised under the EU centralised procedure in the period from December 30, 2004 to January 26, 2005
- List of specific therapeutic programmes approved during the period of December 30, 2004 to January 26, 2005

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- **Front page news**
  - **Measures taken in case of quality defects or adverse reactions to medicinal products in the month of December 2004**
- **SÚKL quidelines**
  - **List of guidelines valid as of February 1, 2005**
  - **REG-80-Inclusion of a medicinal product already authorised in the CR into Mutual Recognition Procedure**
    The guideline provides information on conditions under which a medicinal product already authorised in the CR can be included into Mutual Recognition Procedure and its marketing authorisation number can be maintained.
  - **VYR-33-Ethylene oxide sterilization, sterilization by irradiation and estimation of the population of micro-organisms**
    The aim of this guideline is to provide manufacturers with GMP standards in the area of sterilization processes. The guideline amends document VYR-12 and sets basic principles of ethylene oxide sterilization, sterilization by irradiation and estimation of the population of micro-organisms on material.
- **Information**
  - **Outline of notifications on the use of non-registered medicinal products in the month of December 2004**
    The information on evaluated notifications in the month of December 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 December 2004**
  - **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 separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2004**
  - **List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of December 2004**

- **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 March 2005**
  The validity of marketing authorizations of the listed products will expire during March 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 December 31, 2004.

- **Information on registered drugs and and approved specific therapeutic programmes**
  - Authorised medicinal products and variations to marketing authorisations approved in the period of November 19, 2004 to December 29, 2004
  - Medicinal products authorised under the EU centralised procedure in the period from November 19, 2004 to December 29, 2004
  - List of specific therapeutic programmes approved during the period of November 19, 2004 to December 29, 2004