SUKL Bulletin 12/2002

- **Content**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of November 2002
  - Measures taken in case of adverse incidents of medical devices
  - Information on reported adverse incidents of medical devices
- **SÚKL provisions**
  - Survey of provisions valid as of January 1, 2003
  - REG-66 - Postponement justification and undertaking to submit a medicinal product documentation within "Update" procedure in case that the documentation cannot be submitted by due date as required by REG-64 and 65
  - REG-67 - Retrospective inclusion in the simplified system for products which passed through Centralised Procedure or Mutual Recognition Procedure in the EU
- **Information on drug consumption**
  - Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 2002
    Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.
- **Information**
  - Update of registration documentations - protection of patients or pointless burden for manufacturers
    Explanation of the substance of the project and reasons which lead to its initiation is provided. The fundamental aim is to evidence the safety and efficacy of all medicinal products on the Czech market, regardless whether they are domestic of foreign, cheap or expensive, original or generics.

  - Information on the progress of the first phase of "Update" project
    Approx. 75 % of registration holders replied to the questionnaire according to REG-64. Those who did not reply are hereby asked to do so. SUKL will initiate the administrative procedure with those registration holders who will not provide the answers.

  - Information for holders of registration decision for products registered following the centralised procedure in the EU
    The use of labelling as approved in the EU including EU holder and registration number, provided that Czech holder and registration number are specified in the blue box, has been enabled for medicinal products registered in the Czech Republic by simplified procedure following the centralised procedure.

  - Information for registration decision holders concerning termination of the possibility to use same names for medicinal products of different

registration holders manufactured under licence, which has been legally allowed till December 31, 2002.

- Outline of notifications on the use of non-registered medicinal products in the month of November 2002
  The information on evaluated notifications in the month of November 2002, 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 EMEA in September is published. Documents are available in SUKL library.

- Data on applications submitted to SUKL

- List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of November 2002

- List of medicinal products registration decision of which will expire in May 2003

- 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, 2002.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of October 23, 2002 to November 6, 2002
  - List of exemptions from registration granted by the Ministry of Health during the period of November 4, 2002 to November 14, 2002

SUKL Bulletin 11/2002

- **Content**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of October 2002
- **SÚKL provisions**
  - Survey of provisions valid as of December 1, 2002
  - UST-16-Sponsorship according to the Act on Advertising
    According to the amendment to the Act on Advertising (No. 138/2002 Coll.), which came into force on June 1, 2002, sponsorship of promotional meetings and scientific congresses attended by persons

qualified to prescribe or supply medicinal products is considered as advertising. SUKL as the authority responsible for monitoring of medicinal products advertising sets up more detailed rules for sponsorship in this guideline

- **Laboratory control**
  - Outcomes of projects finished by the Laboratory Control Branch
    The Laboratory Control Branch performed, based on the special projects, controls on medicinal products taken from the Czech market by inspectors. Outcomes of the following projects are included in this report: Newly registered products in the years 1997-1998, Products containing tetracycline derivatives (survey of purity), Potency of enzymes and enzymatic products (conversion of CSL 4 units into Ph.Eur. units), Project based on requests of the SUKL Inspection Branch (control of quality) and Products containing iron (survey of quality preparations with high consumption).
- **Information**
  - EU helps Czech Republic in implementation of Community Medicines Legislation and EU Medicines Regulatory System
    New twinning project worth CzK 32.7 million was launched on 8th November 2002 in the State Institute for Drug Control.

  - Notice to applicants and marketing authorisation holders
    SUKL cannot accept any documentation that is not in accordance with Czech law and international standards any more. Applicants and MA holders are kindly requested to follow standards in force.

  - The Black Triangle - a New Pharmacovigilance Activity of the SUKL
    Health care professionals and marketing authorisation holders are informed about essential activity principles. The Black Triangle focuses on drawing health care professionals´attention to selected problems with drugs in order to encourage spontaneous reporting of suspected adverse drug reactions. Active substances and their safety problems are selected according to defined criteria. Marketing authorisation holders are informed in advance about an intention to put their medicinal products to the Black Triangle.

  - Outline of notifications on the use of non-registered medicinal products in the month of October 2002
    The information on evaluated notifications in the month of October 2002, 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 manufacturers and distributors of pharmaceuticals in the CR approved in the month of October 2002

- Up-to-date list of control laboratories with GMP certificate of SUKL

- Quarterly evaluation of pharmacies' activity
  Results of the SUKL inspection activities of in pharmacies during the third quarter of 2002 are published.

- Outline of data on basic activities of the Inspection Branch in the third 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 third quarter of 2002

- List of medicinal products registration decision of which will expire in April 2003
  Registration decision of the listed products will be no longer valid during April 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 October 31, 2002.

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of September 25, 2002 to October 9, 2002
  - List of exemptions from registration granted by the Ministry of Health during the period of September 24, 2002 to October 22, 2002

SUKL Bulletin 10/2002

- **Content**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of September 2002
- **SÚKL provisions**
  - Survey of provisions valid as of November 1, 2002
  - UST-15-Procedure to be followed by health care professionals and vendors of selected pharmaceuticals in case of suspected quality defect of a medicinal product
- **Information**

- Information on seminars organized by SUKL in the 2nd half of 2002 - Part II
  The programme of seminar and the application form are attached.
- Information for registration decision holders who are concerned with the "update" project
  Announcement of publishing information and various aids concerning the project of amending dossiers of already registered medicinal products (e.g. lists of selected medicinal products, frequently asked questions) on the SUKL website Léčiva
- Announcement for applicants for registration
- Information for prospective buyers of the Czech Pharmaceutical Codex 1
- Administration fee waivers for certain procedures granted to manufacturers and distributors of medicinal products afflicted by recent floods
- Outline of notifications on the use of non-registered medicinal products in the month of September 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)
  The list of new documents issued by EMEA in July is published. Documents are available in SUKL library.
- Data on applications submitted to SUKL
- List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of September 2002
- List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the third quarter of 2002
- List of medicinal products registration decision of which will expire in March 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 August 28, 2002 to September 11, 2002
  - List of exemptions from registration granted by the Ministry of Health during the period of August 29, 2002 to September 16, 2002

SUKL Bulletin 09/2002

- **Content**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of August 2002
- **SÚKL provisions**

- Survey of provisions valid as of October 1, 2002
- REG-65-Detailed approach to dossier amendments for specified categories of medicinal products ("Update" - part 2)
- UST-14-Providing of free samples of human medicinal products for promotional purposes
- VYR-24-Oxygen concentrators for use with medical gas pipeline systems

- **Information on drug consumption**
  - Team of authors: Drug consumption in the Czech Republic in the 2nd quarter of the year 2002
- **Information**
  - Information on measures taken by the Branch of Clinical Trials and Pharmacovigilance in relation to lack of specialists in the field of clinical trial assessment
  - Announcement for wholesalers of active substances and excipients on requested quality of hydrogen peroxide - amendment
  - Outline of notifications on the use of non-registered medicinal products in the month of August 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 August 2002
  - List of medicinal products registration decision of which will expire in February 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 July 17, 2002 to August 7, 2002
  - List of exemptions from registration granted by the Ministry of Health during the period of August 7, 2002 to August 28, 2002

SUKL Bulletin 08/2002

- **Content**
- **Front page news**
  - Measures taken in case of quality defects or adverse reactions to medicinal products in the month of July 2002
- **SÚKL provisions**
  - Survey of provisions valid as of September 1, 2002

    - REG-64-Requirements for specification of a type of registration of medicinal products registered in the CR in connection with the expected accession to the EU ("Update" - part 1)
    - UST-13-Application of the Act No 477/2001 Coll., on packages in relation to pharmaceuticals
- **Information**
    - Information on seminars organized by SUKL in the 2nd half of 2002
    - Outline of notifications on the use of non-registered medicinal products in the month of July 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
    - Quarterly evaluation of pharmacies' activity
    - Outline of data on basic activities of the Inspection Branch in the second quarter of 2002
    - Outline of data on activities of the Medical Devices Branch in the second quarter of 2002
    - List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of July 2002
    - List of medicinal products registration decision of which will expire in January 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 June 16, 2002 to June 26, 2002
    - List of exemptions from registration granted by the Ministry of Health during the period of May 16, 2002 to July 26, 2002

SUKL Bulletin 07/2002

- **Content**
- **Front page news**
    - Measures taken in case of defects or adverse reactions to medicinal products in the month of June 2002
    - Measures taken in case of adverse incidents of medical devices
- **SÚKL provisions**
    - Survey of provisions valid as of August 1, 2002
    - PZT-18-Minimum documentation requirements at inspection of in vitro diagnostic medical devices (IVD)
- **Information**
    - Information about the Act on Advertising

- The approach of the State Institute for Drug Control for the classification of the product "artificial tears"
- Announcement for wholesalers of active substances and excipients on requested quality of hydrogen peroxide
- Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
- Overview of notifications on the use of non-registered medicinal products in the month of June 2002
- Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
- Data on applications submitted to SUKL
- List of new pharmacies and detached departments for dispensing pharmaceuticals and medical devices approved by SUKL in Q II of 2002
- List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the month of June 2002
- List of medicinal products registration decision of which will expire in December 2002
- 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 May 15, 2002 to May 29, 2002

SUKL Bulletin 06/2002

- **Content**
- **Always active Dr. Pavel Drábek celebrating his 70th birthday**
- **Front page news**
  - Measures taken in case of defects or adverse reactions of medicinal products in the month of May 2002
  - Measures taken in case of adverse incidents of medical devices
- **SÚKL provisions**
  - Survey of provisions valid as of July 1, 2002
  - REG-63-Requirements for evidence of GMP compliance in the registration dossier of medicinal product
- **Pharmacy activities**
  - Survey on information provided to patients in pharmacies together with supplied OTC medicinal products conducted by employees of regional departments of SUKL
  - Survey on compliance with conditions of supply of medicinal products on prescription only carried out in pharmacies
- **Information on drug consumption**
  - Team of authors: Drug “consumption in” the Czech Republic in the 1st quarter of the year 2002

- **Information**
  - Information for blood service centres on the storage temperature and shelf life of fresh frozen plasma
  - Information on forthcoming publications
  - Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
  - Overview of notifications on the use of non-registered medicinal products in the month of May 2002
  - Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
  - Data on applications submitted to SUKL
  - A new test facility included in national GLP programme in the field of medicinal products
  - List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the month of May 2002
  - List of medicinal products where the registration decision will be no longer valid in November 2002
  - List of medicinal products where the registration decision is no longer valid
- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of April 17, 2002 to April 30, 2002
  - List of exemptions from registration granted by Ministry of Health during the period of May 3, 2002 to May 16, 2002

SUKL Bulletin 05/2002

- **Content**
- **Front page news**
  - Measures taken in case of defects or adverse reactions of medicinal products in the month of April 2002
  - Measures taken in case of adverse incidents of medical devices
  - Information on reported adverse incidents of medical devices
- **SÚKL provisions**
  - Survey of provisions valid as of June 1, 2002
  - VYR-23-Implications of the Operational phase of the GMP annexes to the Protocol to the European agreement on Conformity assessment and Acceptance of industrial products (PECA) with European Union associated countries
  - PZT-17-Haemodialysers (haemofilters, haemodiafilters) - principles of their good clinical use, related hazards and procedures for near occurrence adverse incidents
- **Information**
  - Information for wholesalers of medicinal products
  - Announcement of duties resulting from the Act on packaging

- Information of the State Institute for Drug Control about rehabilitative pools
- Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
- Overview of notifications on the use of non-registered medicinal products in the month of April 2002
- Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
- Data on applications submitted to SUKL
- Quarterly evaluation of pharmacies activity
- Overview of data on basic activities of the Inspection Branch in the first quarter of 2002
- Overview of data on activities of the Medical Devices Branch in the first quarter of 2002
- List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the month of April 2002
- List of medicinal products where the registration decision will be no longer valid in October 2002
- List of medicinal products where the registration decision is no longer valid

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of March 20, 2002 to April 3, 2002
  - List of exemptions from registration granted by Ministry of Health during the period of March 29, 2002 to April 4, 2002

SUKL Bulletin 04/2002

- **Front page news**
  - Measures taken in case of defects or adverse reactions of medicinal products in the month of March 2002
  - Measures taken in case of adverse incidents of medical devices
  - Information on reported adverse incidents of medical devices
- **Pharmacy activities**
  - Control of pharmacies in the year 2001
- **Information**
  - Warning: TSE risk and medicinal products
  - Change in the date of seminar of the Clinical trials and pharmacovigilance branch
  - Information for pharmacies and wholesalers on supply of medicinal product ALUTARD SQ, inj sus
  - Information for pharmacies concerning analysis performed by centres of hygienic service
  - Information on Czech standards relating to medical devices published in the Bulletin of the COSMT

- Overview of notifications on the use of non-registered medicinal products in the month of March 2002
- Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
- 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 2002
- List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the month of March 2002
- List of medicinal products where the registration decision will be no longer valid in September 2002
- List of medicinal products where the registration decision is no longer valid

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the period of February 20, 2002 to March 6, 2002
  - List of exemptions from registration granted by Ministry of Health during the period of February 25, 2002 to March 15, 2002

SUKL Bulletin 03/2002

- **Content**
- **Front page news**
  - Measures taken in case of defects or adverse reactions of medicinal products in the month of February 2002
- **Information on drug consumption**
  - Team of authors: Drug consumption in the Czech Republic in the year 2001
- **Information**
  - Information on seminars prepared by SUKL in the 1st half of 2002
  - Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
  - Overview of notifications on the use of non-registered medicinal products in the month of February 2002
  - 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 wholesalers of pharmaceuticals in the CR approved in the month of February 2002
  - List of medicinal products where the registration decision will be no longer valid in August 2002
  - List of medicinal products where the registration decision is no longer valid

- **Information on registered drugs and drugs with exemptions from registration**
    - Recently registered medicinal products and variations to registrations approved during the period of January 23, 2002 to February 6, 2002
    - List of exemptions from registration granted by Ministry of Health during the period of January 25, 2002 to February 5, 2002

SUKL Bulletin 02/2002

- **Content**
- **Front page news**
    - Measures taken in case of defects or adverse reactions of medicinal products in the month of January 2002
    - Measures taken in case of adverse incidents of medical devices
    - Information on reported adverse incidents of medical devices
- **SÚKL provisions**
    - Survey of provisions valid as of March 1, 2002
    - REG-62- Parametric release
    - LEK-6- Recommended shelf-lives of medicinal products prepared in pharmacies - amendment
    - LEK-7- Requirements for clean rooms in pharmacies
- **Pharmacopoeia activities**
    - Information on weighing of Belladonnae folii extractum siccum normatum in pharmacies
- **Information**
    - Invitation to the meeting summarizing SUKL activities
    - Information for users of data on registration, variations and renewals of registration released by the State Institute for Drug Control
    - Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
    - Overview of notifications on the use of non-registered medicinal products in the month of January 2002
    - Data on applications submitted to SUKL
    - Quarterly evaluation of pharmacies activity
    - Overview of data on basic activities of the Inspection Branch in the fourth quarter of 2001
    - List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the month of January 2002
    - List of test facilities included in national GLP programme in the field of medicinal products
    - List of new control laboratories with a GMP certificate of SUKL issued during the period of 1.1.2001 - 31.1.2002
    - List of medicinal products where the registration decision will be no longer valid in July 2002
    - List of medicinal products where the registration decision is no longer valid

- **Information on registered drugs and drugs with exemptions from registration**
    - Recently registered medicinal products and variations to registrations approved during the period of December 19, 2001 to January 9, 2002
    - List of exemptions from registration granted by Ministry of Health during the period of December 20, 2001 to January 11, 2002

SUKL Bulletin 01/2002

- **Content**
- **PF 2002**
- **Front page news**
    - Measures taken in case of defects or adverse reactions of medicinal products in the month of December 2001
- **SÚKL provisions**
    - Survey of provisions valid as of February 1, 2002
    - DIS-7-Monitoring and control of storage and transportation temperatures for pharmaceuticals by manufacturers and wholesalers
    - VYR-20-Certification by a Qualified Person and Batch Release
    - VYR-21-Parametric Release
    - VYR-22-Manufacture of medicinal gases
- **Pharmacopoeia activities**
    - Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic
- **Information**
    - Evaluation of the Czech population approach to usage of patient information leaflets and their interest to buy medicinal products without medical prescription
    - Information on termination of the pre-operational phase of PECA for good manufacturing practice and batch certification of human medicinal products
    - Electronic mail-room of SUKL
    - Announcement of change of a phone number of the regional department in Brno
    - 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)
    - Overview of notifications on the use of non-registered medicinal products in the month of December 2001
    - List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2001
    - List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the fourth quarter of 2001
    - Data on applications submitted to SUKL

- List of medicinal products where the registration decision will be no longer valid in June 2002
- List of medicinal products where the registration decision is no longer valid

- **Information on registered drugs and drugs with exemptions from registration**
  - Recently registered medicinal products and variations to registrations approved during the month of December 2001
  - List of exemptions from registration granted by Ministry of Health during the month of December 2001