STATE INSTITUTE FOR DRUG CONTROL

Bulletin of SUKL - List of Contents - Archives 2001

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SLP-3-Monitoring procedures for good laboratory practice and guidance for the conduct of test facility inspection and study audits
Czech translation of the annexes to the Commission Directive 1999/12/EC adapting to technical progress for the second time the Annex to Council Directive 88/320EEC on the inspection and verification of good laboratory practice.

SLP-4-National GLP Programme - Components of Procedures for GLP Monitoring
Joint document for both GLP Monitoring Authorities in the Czech Republic for pharmaceuticals (SÚKL) and chemicals (NIO). All components of the Part A of the Annex of Commission Directive 1999/12/EC are described in this document.

Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 2001
Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.

Information
Information for applicants for registration of medicinal products: Acceptability of new dossier format CTD (Common Technical Document) in SUKL
SUKL declares that because of harmonisation with EU countries it is possible to submit registration applications in both formats (as described in the decree No. 473/2000 of the register or in CTD format).

Reminder: TSE risk and medicinal products

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 enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of November 2001
The information on evaluated notifications in the month of November 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Data on applications submitted to SUKL
Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in May 2002
Registration decision of above mentioned products will be no longer valid during May 2002 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of November 30, 2001.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of November 2001

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VYR-19-Qualification and validation
The text of this SUKL guideline is the Czech translation of the EU Guide "Annex 15 to the EU Guide to Good Manufacturing Practice - Qualification and validation" which is in the EU Member States valid since September 1, 2001.

Information
Results of a survey on knowledge of physicians about adverse drug reactions reporting, principles of use of non-registered medicinal products and information sources on drugs
The survey was conducted on a representative sample of 500 physicians (388 out-patient physicians and 112 hospital ones), covering all the basic fields of medicine uniformly in individual regions of CR.

Joint packaging of medicinal products/other products
The information describes legal conditions for placing on the market of such joint packaging in the Czech Republic.

Information on the tracking mechanism of batches of medicinal products during their distribution
Conditions for control of medicinal products and evidence of batches at wholesalers are described.

Responsible person in a pharmacy (according to the Act No.79/1997 Col., on Pharmaceuticals, as amended)

Information for laboratories (cancelling the SUKL provisions LAB-4 and LAB-5)

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 enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of October 2001
The information on evaluated notifications in the month of October 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Quarterly evaluation of pharmacies activity
Results of the inspection activities of SUKL in pharmacies during the third quarter of 2001 are published.

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 Inspection Branch in the third quarter of 2001
Data on numbers of various types of inspection activities including terms are published.

List of medicinal products where the registration decision will be no longer valid in April 2002
Registration decision of above mentioned products will be no longer valid during April 2002 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of October 31, 2001.

Information on registered drugs and drugs with exemptions from registration
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Measures taken in case of defects or adverse reactions of medicinal products in the month of September 2001

Statement of the State Institute for Drug Control on the risk of venous thromboembolism associated with the use of "third generation" of combined oral contraceptives

Information
Release of approved information on medicinal products to SUKL website
Approved texts of Summaries of Product Characteristics, Patient Information Leaflets and Labelling sent by registration decision holders on diskettes/CD-ROMs or processed recently during the registration procedure in electronic form have been placed on SUKL website.

Announcement for vendors of selected medicinal products

List of selected medicinal products
Valid as of October 1, 2001

Information on documents issued by the European Agency for the Evaluation of Medicinal Products (EMEA)
The list of new documents issued by EMEA in June is enclosed. Documents are available in SUKL library.

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 September 2001
The information on evaluated notifications in the month of September 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the third quarter of 2001

List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the third quarter of 2001

Data on applications submitted to SUKL
Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in March 2002
Registration decision of above mentioned products will be no longer valid during March 2002 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of September 30, 2001.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of September 2001

List of exemptions from registration granted by Ministry of Health during the month of September 2001

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UST-12-Reporting of adverse drug reactions of human medicinal products during the course of clinical trials and in the common medical practice
The provision of SUKL establishing terminology used in pharmacovigilance, extent and rules of reporting of adverse drug reactions, including the contact addresses and obligations of all subjects involved in pharmacovigilance procedures.

VYR-18-Qualified Person in the Manufacture of Medicinal Products
Requirements for qualified person in the manufacture of medicinal products and for execution of its function, i.e. position, responsibilities, education and training of qualified person are given. Issues assessed within evaluation of the execution of the function of a qualified person in the Czech Republic and documents to be submitted with the application for manufacturing authorisation or a change to manufacturing authorisation connected with qualified person are described.

Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 2nd quarter of the year 2001
Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.

Information
Information on seminars prepared by SUKL in the 2nd half of 2001
The programme of six planned seminars organised by SUKL for regulated subjects and the application form are included.

Information on relation of the PECA protocol to export of medicinal products to the EU Member States

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 August 2001
The information on evaluated notifications in the month of August 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Data on applications submitted to SUKL
Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in February 2002
Registration decision of above mentioned products will be no longer valid during February 2002 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of August 31, 2001.

Information on registered drugs and drugs with exemptions from registration
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List of exemptions from registration granted by Ministry of Health during the month of August 2001

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PZT-14-Inspection of medical devices with health care providers
This guideline

- describes the system of inspections with providers of medical care, including activities of the State Institute for Drug Control concerning e.g. checking performance of preventive inspections, maintenance and repair of medical devices, verification of measurement accuracy, technical condition and compliance with the intended purpose of the use of such devices, keeping and maintenance of records and documentation related to medical devices, instructions for their use,
- is aimed at all professional staff responsible for the supply, use, maintenance and servicing of medical devices in hospitals, clinics, etc.,
- identifies other literature (e.g. European directives and standards, Czech legislation).

PZT-15-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 reporting, evaluation and investigation of adverse incidents known as the Medical Devices Vigilance system,
- is intended to facilitate the uniform application and implementation of the requirements laid down in the Czech Act No. 123/2000 Coll. on medical devices,
- covers the activities of the State Institute for Drug Control, Czech Notified Bodies, manufacturers (including their authorised representatives or distributors responsible for placing on the market), users and others concerned with the continuing safety of medical devices,
- identifies other literature (e.g. European directives and standards, Czech legislation).

PZT-16-Inspection of the clinical evaluation of medical devices with health care providers
This guideline

- describes the system and requirements for inspections of clinical evaluation and of conduct of clinical trials with health care providers,
- provides information which can be used to prepare and design clinical evaluation or clinical trial documentation,
- is aimed at all professional staff responsible for carrying out these clinical evaluation or clinical trials (e.g. sponsor, investigator, ethics committee, etc.),
- identifies other literature (e.g. European directives and standards, Czech legislation)

Information
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 May is enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of July 2001
The information on evaluated notifications in the month of July 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Quarterly evaluation of pharmacies activity
Results of the inspection activities of SUKL in pharmacies during the second quarter of 2001 are published.

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 Inspection Branch in the second quarter of 2001
Data on numbers of various types of inspection activities including terms are published.

List of medicinal products where the registration decision will be no longer valid in January 2002
Registration decision of above mentioned products will be no longer valid during January 2002 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of July 31, 2001.

Information on registered drugs and drugs with exemptions from registration
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LEK-5-Recommended shelf-lives of medicinal products prepared in pharmacies
Shelf-lives and storage conditions for eye drops and other medicinal products prepared in pharmacies and stored in a finished packaging or prepared in bulk to be stored and used later are specified.

Pharmacopoeia activities
Draft of changes 2001 - Changes in the Czech Pharmacopoeia 1997, Czech Pharmacopoeia 1997-Supplement 1999 and Czech Pharmacopoeia 1997-Supplement 2000

Information
Information for manufacturers of medicinal products
Educational requirements for qualified persons in the manufacture of medicinal products are given. The way how to reach the equivalency with EU Directives (No. 75/319/EEC and 81/851/EEC) is described. The EU requirements for qualified person are included.

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 April is enclosed. Documents are available in SUKL library.

List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the second quarter of 2001

List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the second quarter of 2001

Overview of notifications on the use of non-registered medicinal products in the month of June 2001
The information on evaluated notifications in the month of June 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Data on applications submitted to SUKL
Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in December 2001
Registration decision of above mentioned products will be no longer valid during December 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of June 30, 2001.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of June 2001

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UST-11-Reporting form for use of a non-registered medicinal product
According to the Act No. 79/1997 Coll., on Pharmaceuticals, as amended and according to the Decree No. 473/2000 Coll., physicians are obliged to report the use of non-registered medicinal product to SUKL. This special form includes all requested information and should facilitate these reports.

REG-61-Procedure for application for registration and subsequent variations of medicinal product that has been registered in the EU Member States by Mutual Recognition Procedure
Revision of the SUKL guideline REG-47 to be in compliance with the adopted common CADREAC procedure (Procedure on the Granting of Marketing Authorisations by CADREAC Drug Regulatory Authorities for Human Medicinal Products Already Authorised in EU Member States Following the Decentralised Procedure). The difference from the pilot phase is that the procedure now can be used also for line extensions of MR products which are in the Czech Republic already harmonised with the EU (but had not been registered in the CR by this simplified procedure). The requirements on the documentation to be submitted and all necessary forms are included.

VYR-17-Shelf life extension of a batch of medicinal product manufactured before the approval of the appropriate variation to the registration
The extension of the shelf-life of a medicinal product batch manufactured before the approval of the appropriate variation to the terms of registration is in the responsibility of the registration decision holder. Conditions to be fulfilled in such cases are given. This guideline replaces the SUKL guideline VYR-13.

Pharmacy activities
Results of a survey focused on fulfilling conditions of supply in pharmacies
Survey was conducted by SUKL employees and was concluded by the statement that in case of medicinal products with possible risk to the patient's health the conditions of supply specified in the registration decision are complied with.

Results of a survey of view of mothers with children aged under three years focused on the availability of medicinal products and information on them
It was concluded that most of surveyed mothers were satisfied with information given in pharmacies and about a half of them wish to buy some medicinal products for common illnesses out of pharmacies.

Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 1st quarter of the year 2001
Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.

Information
Information on the project for transfer of approved information on medicinal products into electronic form
Numbers of approved texts of Summary of Products Characteristics, Patient Information Leaflets and

Labelling sent by registration decision holders on diskettes/CD-ROMs or approved during the registration procedure in electronic form are given. List of registration decision holders that took part in this project is published with acknowledgement.

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 March is enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of May 2001
The information on evaluated notifications in the month of May 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Data on applications submitted to SUKL
Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in November 2001
Registration decision of above mentioned products will be no longer valid during November 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of May 31, 2001.

Information on registered drugs and drugs with exemptions from registration
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List of exemptions from registration granted by Ministry of Health during the month of May 2001

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UST-9-Provision to minimise the risk of transmission of animal spongiform encephalopathies directed to pharmacies, manufacturers and wholesalers of active pharmaceutical ingredients and excipients for preparation of medicinal products in pharmacies
The steps to be taken by manufacturers and wholesalers of active pharmaceutical ingredients and excipients and also by pharmacies during the preparation of medicinal products to guarantee TSE/BSE safety are described. In particular the need of evaluation of data on all active pharmaceutical ingredients and excipients supplied to the pharmacies by their manufacturer and the obligation of pharmacies to use only active pharmaceutical ingredients and excipients which are marked by information about TSE/BSE risk are stressed.

UST-10-Arrangements of the State Institute for Drug Control for the application of new

pharmacopoeial standards
According to the Convention and Protocol on the Elaboration of a European Pharmacopoeia the Czech Republic should take necessary measures to ensure that all the changes, corrections and rapid implementations shall become the official standards on the date fixed by the Public Health Committee. Therefore SUKL publishes information on these changes, corrections and rapid implementations including the time limits in the Věstník SUKL and on the Institute´s website and as of the specified date applies the standards for assessment of dossiers, inspections of operators and laboratory control, as appropriate.

REG-60-Requirements for the registration of medicinal products manufactured using material derived from human blood or blood components
Specific requirements for the registration of medicinal products containing material derived from human blood or blood components as an active ingredient or excipient are provided in the guideline which replaces SUKL guideline REG-34. The requirements are based on the number of European documents tabled in the Annex which this way become the official standards for assessment of registration dossier without translation in the Czech language. English texts are available on request in the SUKL library. With respect to the validity of the Decree on registration No. 473/2000 Coll., the requirements are being already applied to applications for registration submitted since January 1, 2001. Because of the legal obligation of marketing authorisation holders to assure safety of their products, the marketing authorisation holders are requested to amend the specified data (in particular data on the origin of the material used and the plasma master file) till November 30, 2001, if they had not been submitted yet.

VYR-16-Manufacture of Products Derived from Human Blood or Human Plasma
Czech translation of Annex 14 to GMP Guide for Medicinal products (Volume IV of the Rules governing Medicinal Products in the European Union) which is in the EU valid since September 1, 2000 is published. This document sets the rules for the manufacture of products derived from human blood or human plasma and for blood service centres collecting blood or blood plasma and replaces the Annex 3 to Recommended Procedures for Implementation of Good Manufacturing and Good Distribution Practice published in Special Issue of Věstník SUKL in 1998.

KLH-19-Documentation submitted with the application for approval of a clinical trial
This guideline replaces SUKL guideline KLH-13 and is valid as of June 1, 2001. KLH-19 reflects requirements of the Act No. 79/1997, on Pharmaceuticals, as amended and of the Decree No. 472/2000 Sb., on good clinical practice and detailed conditions of conduct of clinical trials, and specifies in detail documentation submitted with the application for approval of a clinical trial, including pharmaceutical data on investigational products covering also assurance of safety of the product with respect to the risk of TSE transmission. Specific requirements on bioequivalence studies, clinical trials with radiopharmaceuticals, immunologicals and medicinal products containing or consisting of genetically modified organisms are included.

Information

Information on seminars prepared by SUKL in the 1st half of 2001 - 2nd part
The programme of seminar and the application form are included.

Information for applicants / holders of registration decision
SUKL is updating the databases of addresses of holders of registration decision, persons authorised by the registration holder to communicate with SUKL, persons responsible for pharmacovigilance and contact addresses for provision of information on medicinal products to the public in the CR. This activity is performed through the SUKL homepage (www.sukl.cz) and is connected with the process of documenting the minimisation of risk of transmission of TSE agents for each medicinal product. For more information see SUKL guideline REG-59.

Information about the new possibility concerning the application for database extracts of adverse drug reactions reported to SUKL

Information on forthcoming publications
List of OTC medicinal products and products with narcotic substances and List of pharmacies, manufacturers and wholesalers of medicinal products in CR will be 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 February is enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of April 2001
The information on evaluated notifications in the month of April 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Quarterly evaluation of pharmacies activity
Results of the inspection activities of SUKL in pharmacies during the first quarter of 2001 are published.

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 Inspection Branch in the first quarter of 2001
Data on numbers of various types of inspection activities including terms are published.

List of medicinal products where the registration decision will be no longer valid in October 2001
Registration decision of above mentioned products will be no longer valid during October 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of April 30, 2001.

Information on registered drugs and drugs with exemptions from registration
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REG-59- Registration requirements on medicinal products derived from organs or tissues from ruminants and proof of safety of medicinal products in respect of transmission of animal spongiform encephalopathies
There are provided requirements on application for registration as well as the way how to demonstrate the TSE/BSE safety of products existing on the market and the relevant deadlines. TSE/BSE safety should be demonstrated for all products authorised before 1.1.2001. The requirements are based on the EMEA/410/01 guideline and similar procedure as in the EU is adopted.

Vyr-14-Provision to minimise the risk of transmission of animal spongiform encephalopathies directed to manufacturers of medicinal products
The steps to be taken by manufacturers to guarantee TSE/BSE safety are described. Mainly the needs of evaluation of data on all starting materials and tracebility of all starting materials during the production are stressed.

Vyr-15-The procedure of issuing manufacturing licences for blood service centres
The document describes the administrative procedures concerning issuing manufacturing licences for blood centres and it contains the necessary information for this procedure including application forms and questionnaires.

Pharmacy activities
Control of records kept on individual medicinal products in pharmacies

Control of pharmacies in the year 2000
Out of the total number of 7 975 samples taken from pharmacies 15,9 % of samples were found to be non-compliant and 16,6 % of samples were found "non-compliant with adjustment". The number of non-compliant samples from pharmacies continues to be relatively high, but since 1995 the quality of medicinal products and purified water prepared in pharmacies has slightly improved.

Information
Information of SUKL on current status of evaluation of risk of transmission of TSE/nvCJD by medicinal products
Information of SUKL on initiatives taken in respect of TSE/BSE safety, as well as nvCJD safety of medicinal products. Complex measures were or are being taken concerning new applications for registration of medicinal product, including blood derivatives, all medicinal products already registered, official batch release, investigational medicinal products, manufacture of medicinal products and starting material and certification and use of starting materials in pharmacies.

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 January is enclosed. Documents are available in SUKL library.

Information on sanctions
List of sanctions inflicted on regulated subjects by SUKL in the months of October 2000 to March 2001.

Overview of notifications on the use of non-registered medicinal products in the month of March 2001
The information on evaluated notifications in the month of March 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

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 2001

List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the first quarter of 2001

List of medicinal products where the registration decision will be no longer valid in September 2001
Registration decision of above mentioned products will be no longer valid during September 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of March 31, 2001.

Information on registered drugs and drugs with exemptions from registration
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UST-8 Basic principles of differentiation of human pharmaceuticals from other products, including specification of medicinal products requiring registration

This provision specifies the "borderline products", defines rules for their categorisation and offers guidance for applicants concerning the "borderline product" evaluation procedure (list of required documents, description of evaluation process). It contains the main definitions related to this area.

REG-58 Annual variation in composition of human influenza vaccine

This guideline describes the way how to apply for the annual update of influenza vaccine composition as type II variation. This provision is based on the Regulation (EC) No. 541/95 as amended by Regulation (EC) No. 1146/98 and on the European Commission "Guideline on Fast Track Procedure for Human Influenza Vaccines".

Pharmacy activities

Control cards in pharmacies - exchange in 2001 and the amendment of 2001

Cards for income control of pharmaceutical substances and excipients in pharmacies were renewed and amended.

Survey of information given together with supplied OTC medicinal products in pharmacies conducted by employees of regional departments of SUKL

Survey was conducted in 200 selected pharmacies and was concluded by the statement that the level of spontaneously given information was very good, information given on request should be improved.

Pharmacopoeia activities

Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic

Announcement of technical secretariat of the Czech Pharmacopoeial Commission to the monographs Aqua purificata and Aqua pro iniectione

Aqua pro iniectione (correction of the pharmacopoeial monograph)

Information on drug consumption

Team of authors: Drug consumption in the Czech Republic in the year 2000

This article is focused on drug consumption in the Czech Republic in the year 2000 and on the comparison with previous years. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses. Consumption of several ATC groups with highest level of consumption is discussed.

Information

Information on 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 December is enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of February 2001

The information on evaluated notifications in the month of February 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Data on applications submitted to SUKL

Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in August 2001

Registration decision of above mentioned products will be no longer valid during August 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid

Above mentioned products are indicated by "Z" in SUKL database as of February 28, 2001.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of February 2001

List of exemptions from registration granted by Ministry of Health during the month of February 2001

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REG-57 Requirements on the information on the packaging material of medicinal products
This regulation replaces former REG-10 and REG-30 and defines the conditions for creation of Czech labelling and data, which are to be stated on the packaging materials. Further it describes the exemptions when the packaging material in Czech is not required.

Information
Invitation to the annual meeting and report on SUKL's activities in the year 2000

Information on the project for transfer of approved information on medicinal products into electronic form
Numbers of approved texts of Summary of Products Characteristics, Patient Information Leaflets and Labelling sent by registration decision holders on diskettes/CD-ROMs or approved during the registration procedure in electronic form are given. List of registration decision holders that took part in this project is published with acknowledgement.

List of test facilities included in national GLP programme in the field of medicinal products

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 November is enclosed. Documents are available in SUKL library.

Overview of notifications on the use of non-registered medicinal products in the month of January 2001
The information on evaluated notifications in the month of January 2001, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

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 2000 are published.

List of medicinal products where the registration decision will be no longer valid in July 2001
Registration decision of above mentioned products will be no longer valid during July 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of January 31, 2001.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of January 2001

List of exemptions from registration granted by Ministry of Health during the month of January 2001

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Content

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Petráček J.: Drug safety monitoring
Pharmacovigilance system is based on the cooperation of Registration Decision Holder, Regulatory Authority, and health professionals. Obligations of all these participants are described. Finally, the system of ADRs spontaneous reports in the Czech Republic is explained, and meanings of basic terms are set down.

Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of December 2000.

SÚKL provisions
Survey of provisions valid as of January 1, 2001

UST-6-Price list of the State Institute for Drug Control
Based on new legislation the Institute provides revised price list of some of its activities. The provision, which is valid as of January 1, 2001, includes also principles of pricing.

UST-7-Payment procedure applicable to administration fees
As of February 1, 2001 revised procedure for payment of administration fees is applicable, which is based on the interaction with the Institutes database via Internet prior to the submission. This database generates the unique variable symbol which is then used for the payment and as the consequence allows the Institute planning of applications processing.

REG-53-Specific requirements for electronic submission
Besides the submission of hard copies (i.e. paper copies) of the dossier, the submission of partial or complete copies using electronic storage media - a suitable PC-compatible medium - is encouraged by the State Institute for Drug Control. This document provides applicants with specific requirements, e.g. format, number of copies of dossier.

REG-54-Variations to registration
This guideline specifies in detail procedures and requirements for the application for variation which are based on the new Czech legislation (Act No. 79/1997 Coll., as amended, and Registration Decree No. 473/2000 Coll.) and on the EU documents (Regulations Nos. 541/95, as amended by 1146/98, and 542/95, as amended by 1069/98, and the Guideline on Dossier Requirements for Type I Variations, November 1999).

REG-55-Variation to registration of the medicinal product - Application for approval of Type II variation / notification of Type I variation
Following entering into force of the new Registration Decree (No. 473/2000 Coll.) the revised form is applicable to applications for the approval of Type II variation and for the notification of Type I variation. This form replaces the form REG-37 as of January 1, 2001.

REG-56-Categorisation of Medicinal Products as Selected Pharmaceuticals
This regulation describes both the way, how to apply for the legal status of a "selected pharmaceutical" concerning already registered products or new applications, and required documentation for this category of medicinal products.

Information
Information on seminars prepared by SUKL in the 1st half of 2001
The programme of seminars and the application form are included.

Information for vendors of selected medicinal products

The information of the State Institute for Drug Control (SUKL), concerning medical devices whose permission for providing health care, granted by SUKL, expired on December 31, 2000

List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2000

List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the fourth quarter of 2000

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 October is enclosed. Documents are available in SUKL library.

The evaluation of notifications on the use of non-registered medicinal products
The information on evaluated notifications in the period from August 1 till December 31, 2000, in particular numbers of notifications, patients, health care facilities and used medicinal products are published.

Data on applications submitted to SUKL
Data on numbers of various types of applications submitted monthly to SUKL.

List of medicinal products where the registration decision will be no longer valid in June 2001
Registration decision of above mentioned products will be no longer valid during June 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid
Above mentioned products are indicated by "Z" in SUKL database as of December 31, 2000.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of December 2000

List of exemptions from registration granted by Ministry of Health during the month of December 2000