STATE INSTITUTE FOR DRUG CONTROL

Bulletin of SUKL - List of Contents - Archives 2000

SUKL Bulletin 12/2000

Content

Koblihová I.: Use of authorised and non-authorised medicinal products in the light of the amended Act on Pharmaceuticals
In the text addressed especially to physicians basic principles of performance of clinical trials in the Czech Republic and the possibility, responsibilities and obligations of physicians concerning use of non-authorised medicinal products (named patient use) as they arise from the amended Act on Pharmaceuticals (Act No.79/1997 Coll., as amended by the Act No. 149/2000 Coll.) are published.

Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of November 2000 Information on reported adverse incidents of medical devices

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

Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 2000
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 New Declaration of Helsinki (Ethical Principles for Medicinal Research Involving Human Subjects)
Czech translation of the New Declaration of Helsinki amended by the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000 is published.

Test facilities complying with GLP requirements - changes

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.

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List of medicinal products where the registration decision will be no longer valid in May 2001
Registration decision of above mentioned products will be no longer valid during May 2001 and it will be indicated in SUKL database by "Z" and published in Věstník SÚKL.

List of medicinal products where the registration decision is no longer valid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 November 30, 2000.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of November 2000

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

November 2000

SUKL Bulletin 11/2000

Content

Šmíd M.: Basic principles of marketing authorisation of medicinal products, evaluated information on product, use of non-authorised products and liability of physicians in the light of the amended Act on Pharmaceuticals

In the paper addressed to physicians basic principles of marketing authorisation of innovative and generic products are discussed, as they arise from the amended Act on Pharmaceuticals (Act No.79/1997 Coll., as amended by the Act No. 149/2000 Coll.). The concept of Summary of Product Characteristics and its content is explained as well as the role of Patient Information Leaflet. Liability of prescribing physician is demonstrated in situations of use of an authorised product, non-authorised product (named patient use) and product exempted from the authorisation by the Ministry of Health.

Front page news

Measures taken in case of defects or adverse reactions of medicinal products in the month of October 2000

Information on reported adverse incidents of medical devices

Pharmacopoeia activities

National Chemical Reference Substances established by the Czech Pharmacopoeia Commission

Information

Information on the change of symbols describing the registration status in the SUKL database of medicinal products

The use of symbols "A", "B", "N" and "R" describing the registration status is explained.

Information on the rules for providing of drug consumption data

State Institute for Drug Control collects drug consumption data according to the Section 18 par. 1 letter e) of the Act No 79/1997 Coll., as amended by the Act No 149/2000 Coll., on Pharmaceuticals. Rules for providing these data by the SUKL are described.

Information on the project for transfer of approved information on medicinal products into electronic form

The registration decision holders are repeatedly asked to send already approved texts of Summary of Products Characteristics, Patient Information Leaflets and Labelling on diskettes or CD-ROMs.

Announcement for operators of supply points of medical devices

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.

Quarterly evaluation of pharmacies activity

Results of the inspection activities of SUKL in pharmacies during the third quarter of 2000 are published.

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

Registration decision of above mentioned products will be no longer valid during April 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 October 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 October 2000
List of exemptions from registration granted by Ministry of Health during the month of October 2000

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Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of September 2000
Information on reported adverse incidents of medical devices

SÚKL provisions
Survey of provisions valid as of November 1, 2000
VYR-13-Shelf life extension of a batch of medicinal product manufactured before the approval of the appropriate variation to the marketing authorisation
The extension of the shelf-life of a medicinal product batch manufactured before the approval of the appropriate variation to the terms of marketing authorisation is in the responsibility of the marketing authorisation holder. Conditions to be fulfilled in such cases are given. This guideline replaces the SUKL guideline REG-15.

Information
List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the third quarter of 2000
List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the third quarter of 2000
Information on sanctions
List of sanctions inflicted on regulated subjects by SUKL in the months of January to September 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 July is enclosed. 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 medicinal products where the registration decision will be no longer valid in March 2001
Registration decision of above mentioned products will be no longer valid during March 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 September 30, 2000.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of September 2000
List of exemptions from registration granted by Ministry of Health during the month of September 2000

Bulletin SUKL 09/2000

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Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of August 2000
Information on reported adverse incidents of medical devices
Information of the State Institute for Drug Control on the method of supply of medicinal

products containing pseudoephedrine
All the medicinal products containing not more than 30 mg of pseudoephedrine in a dosage form have got the OTC legal status again. The more detailed information is available on the SUKL website.

SÚKL provisions
Survey of provisions valid as of October 1, 2000
UST-5-Permanent service of the State Institute for Drug Control for cases requiring urgent measures from safety reasons for pharmaceuticals and medical devices
As of October 1, 2000 the permanent service for solving urgent safety problems of pharmaceuticals and medical devices is established in the SUKL. Contact phone, fax and e-mail are provided as well as definitions of urgent and non-urgent cases.

Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 1st half of the year 2000
Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.

Information
A few sentences to activities of the Medical Devices Branch of SUKL
Since July 1, 2000 the Medical Devices Branch is covering a new agenda, as already mentioned in Věstník SUKL No.7/2000. The Branch has a new organisational structure (see SUKL website www.sukl.cz).

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 is enclosed. 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 medicinal products where the registration decision will be no longer valid in February 2001
Registration decision of above mentioned products will be no longer valid during February 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 August 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 August 2000
List of exemptions from registration granted by Ministry of Health during the month of August 2000

Bulletin SUKL 08/2000

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Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of July 2000
Information on reported adverse incidents of medical devices

SÚKL provisions
Survey of provisions valid as of September 1, 2000
Information on changes in issuing of SUKL guidelines

Those European Commission/EMEA/CPMP guidelines that are addressed to narrow range of users will not be translated and will be used as SUKL guidelines in English language. English text will be available on the SUKL web site and on request in the SUKL mail room.

KLH-18-Clinical Study Report
The provision represents requirements of SUKL for the structure and content of the clinical study report. SUKL takes over requirements of the ICH Guideline E3 – Structure and Content of Clinical Study Reports (E3, November 30, 1995), CPMP/ICH/137/95 as standards for assessment without translating this guideline. Reference to the guideline is provided. This provision is valid as of September 1, 2000.

SLP-2-OECD Documents of Good Laboratory Practice
Test facilities which are in compliance with "OECD Principles of Good Laboratory Practice (as revised in 1997)" should follow in the conducting of their studies OECD Consensus Documents. These documents are available on the following web site: http://www.oecd.org//ehs/glp.htm.

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

Information
Information on seminars prepared by SUKL during the 2nd half of 2000 – 1st part
The list of seminars and the application form are included.

Information for registration decision holders and for applicants for registration of medicinal products
The project for transfer of all the approved texts of Summary of Products Characteristic, Patient Information Leaflet and Labelling of medicinal products into electronic form is under preparation in the State Institute for Drug Control with the aim to publish them on the SUKL web site. The registration decision holders are requested to send already approved texts of above mentioned documents on diskettes to SUKL. The applicants for registration are asked to send above mentioned texts during final stages of approval process. Instructions and format are included.

Information for physicians and pharmacists on the possible use of an unregistered medicinal product
According to the Czech Law No 149/2000, valid since August 1, 2000, the State Institute for Drug Control recommends a described procedure to a physician who decides to use the unregistered medicinal product on his own responsibility for individual patient and also the procedure for wholesalers and pharmacists in such a case. The content of the information which is necessary to be forthwith notified to SUKL (it means up to 15 days) is also specified.

Information on differentiation between medicinal and other products
According to the Czech Law No 149/2000 Coll. (Amendment of the Law No 79/1997 Coll.), since August 1, 2000 the State Institute for Drug Control is the authority responsible for the decision, whether a product is classified as a medicinal product or not. The aim is to achieve differentiation between medicinal and other products in a way compatible with the EU. A written application is required. The specification of the documents to be attached to the application are presented. Detailed guideline will be published until the end of the year 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 is enclosed. Documents are available in SUKL library.

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

Quarterly evaluation of pharmacies activity
Results of the inspection activities of SUKL in pharmacies during the second quarter of 2000 are published.

Information for pharmacies concerning analysis performed by stations of hygienic service

List of medicinal products where the registration decision will be no longer valid in January 2001
Registration decision of above mentioned products will be no longer valid during January 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 July 31, 2000.

List of disinfectants approved by the Chief Health Officer to June 30, 2000

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of July 2000
List of exemptions from registration granted by Ministry of Health during the month of July 2000

Bulletin SUKL 07/2000

Contents

Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of June 2000
Information on reported adverse incidents of medical devices
Statement of the State Institute for Drugs Control On Legislative Changes with Regard to Medical Devices
SUKL hereby announces, that on June 30, 2000, its activities stemming from Sections 62 and 63, of the People´s Health Act No. 20/1966 Coll., as amended, will be terminated. Therefore applications with related documentation, which had been submitted under this Act (particularly applications for approvals of the use of medical devices in the course of medical care), will not be solved after this date and, if after above mentioned term required, will be returned by the Medical Devices Branch of the Institute to the applicant. Unsolicited applications will be archived for the period of six months, documentation relating to the applications will be archived for the period of five years.

From July 1, 2000, when the new Medical Devices Act No. 123/2000 Coll. comes into forceeffect, SUKL will, through its Medical Devices BranchSection of Medical Devices, cover new agenda, bestowed upon the Institute under Section 40 of this Act. This agenda comprises especially inspections of providers of medical care (for example administration and filing of documentation related to medical devices, records on installationstrainings, on periodical check-ups of medical devices, on adverse incidents irregular eventsetc.) and initial investigation of adverse incidents.

SÚKL provisions
Survey of provisions valid as of August 1, 2000
REG-52 - Colouring matters permitted for use in medicinal products - amendment
This provision amends the SUKL provision REG-40 as of August 1, 2000. Based on the scientific opinions of the Scientific Committee on Medicinal Products and Medical Devices of the European Commission and on the conclusions of the Pharmaceutical Committee meeting held on March 22-23, 2000 the following colorants are now included in the list of colorants permitted for use in medicinal products: E 123 Amaranth, E 127 Erythrosin, E 161g Canthaxanthin and E 173 Aluminium. The provision REG-40 is valid with this exemption and will be completely revised after the change of EU legislation.

Pharmacopoeia activities
Changes to the Czech Pharmacopoeia 1997 and the Czech Pharmacopoeia Supplement 1999
Changes were made according to the European Pharmacopoeia 3rd Edition Supplement 2000 Articles („corrected 2000“) and according to other changes reported by the European Pharmacopoea Commission, both are designed („E“). In the Czech Pharmacopoeia Supplement 2000 are also included Czech changes without specific designation.

Information
Forthcoming publication – list of OTC medicinal products and products containing narcotic and psychotropic substances
List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the second quarter of 2000
List of manufacturers and wholesalers of pharmaceuticals in the CR approved in the second 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 is enclosed. 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 medicinal products where the registration decision will be no longer valid in December 2000
Registration decision of above mentioned products will be no longer valid during December 2000 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, 2000.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of June 2000
List of exemptions from registration granted by Ministry of Health during the month of June 2000

Bulletin SUKL 06/2000

Contents

Front page news
Measures taken in case of defects or adverse reactions of medicinal products in the month of May 2000
Information on reported adverse incidents of medical devices

SÚKL provisions
Survey of provisions valid as of July 1, 2000
REG-49-Requirements on stability studies in registration dossier
The guideline, which is based on the translation of Note for Guidance CPMP/QWP/556/96, 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. As regards requirements on stability studies of new active substances and related finished products and stability studies of biotechnological/biological products SUKL takes over requirements of Note for guidance CPMP/ICH/380/95, STABILITY TESTING OF NEW DRUG SUBTANCES AND PRODUCTS and Note for Guidance CPMP/ICH/138/95, STABILITY TESTING OF BIOTECHNOLOGICAL/BIOLOGICAL PRODUCTS as standards for assesment without translating these guidelines. The guideline is valid as of September 1, 2000.

REG-50-Reduced stability testing – bracketing and matrixing
The guideline, which is based on the translation of Note for Guidance CPMP/QWP/157/96, REDUCED STABLITY TESTING PLAN – BRACKETING AND MATRIING, specifies in detail the possibility of reducing the scheduled stability tests. The guideline is valid as of September 1, 2000.

REG-51-Stability testing for a Type II variations
The guideline, which is based on the translation of Note for Guidance CPMP/QWP/576/96, STABILITY TESTING FOR A TYPE II VARIATION TO A MARKETING AUTORISATION, gives information on data to be submitted with application for a Type II variation. The guideline is valid as of September 1, 2000.

Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 1st quarter of the year 2000
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 seminar prepared by SUKL in the 2nd half of 2000
The programme of the seminar and the application form are included. The event will take place in the State Institute for Drug Control in August 25, 2000.

Test facilities complying with GLP requirements - changes
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 is enclosed. 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 medicinal products where the registration decision will be no longer valid in November 2000
Registration decision of above mentioned products will be no longer valid during November 2000 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, 2000.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of May 2000

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

Bulletin SUKL 05/2000

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Front page news

Measures taken in case of defects or adverse reactions of medicinal products in the month of April 2000
Information on reported adverse incidents of medical devices

SÚKL provisions
Survey of provisions valid as of May 1, 2000
LAB-9-Notice for applicants for the Batch Certificate of an active substance/excipient
Applicants are fully responsible for the sampling of active substances/excipients. State Institute for Drug Control considers delivered samples to be representative and homogeneous. The information on the Institute´s policy of analyses costs is provided.

Pharmacopoeia activities
Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic
Announcement of certification of suitability of monographs of the European Pharmacopoeia
Isotonization of aqueous solutions of the medicinal products prepared in pharmacies

The document sets out a general recommendation for isotonization of aqueous solutions of the medicinal products prepared in pharmacies.

Stabilization of medicinal products prepared in pharmacies
The document sets out a general recommendation for stabilization of the medicinal products prepared in pharmacies.

Information
Pharmacovigilance symposium and workshop
The event will take place in the State Institute for Drug Control in June 20 and 21, 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 is enclosed. Documents are available in SUKL library.

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

Quarterly evaluation of pharmacies activity
Results of the inspection activities of SUKL in pharmacies during the first quarter of 2000 are published.

List of medicinal products where the registration decision will be no longer valid in October 2000
Registration decision of above mentioned products will be no longer valid during October 2000 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, 2000.

Information on registered drugs and drugs with exemptions from registration
Recently registered medicinal products and variations to registrations approved during the month of April 2000
List of exemptions from registration granted by Ministry of Health during the month of April 2000

Bulletin SUKL 04/2000

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Front page news

Measures taken in case of defects or adverse reactions of medicinal products in the month of March 2000

Information on a reported adverse incidents of medical devices

Pharmacy activities

Control of pharmacies in the year 1999
Out of the total number of 9 787 samples taken from pharmacies 16,9 % of samples were found to be non-compliant and 8,5 % 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 been improving moderately.

Information on drug consumption

Team of authors: Drug consumption in the Czech Republic in the year 1999
This article is focused on drug consumption in the Czech Republic in the year 1999 and on the comparison with previous years. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses. A comparison with total health care expenditures is also presented. Consumption of several ATC groups with highest level of consumption is discussed.

Information

Information on seminar prepared by SUKL in the 1st half of 2000
The programme of the seminar and the application form 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 is enclosed. 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 medicinal products where the registration decision will be no longer valid in September 2000
Registration decision of above mentioned products will be no longer valid during September 2000 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, 2000.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of March 2000

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

Bulletin SUKL 03/2000

Contents

Front page news

Measures taken in case of defects or adverse reactions of medicinal products in the month of February 2000

Information of the State Institute for Drug Control on measures concerning medicinal products containing pseudoephedrine and other precursors of methamphetamine
Measures of SUKL concerning legal status and the method of supply of above mentioned medicinal products are valid since March 1, 2000.

Information on a reported adverse reaction of medical devices

Data on registration of medicinal products in SÚKL in the year 1999
Basic data on performance of registration process in the Czech Republic, including management of applications for registration, variations and renewals are presented. In sake of better understanding, there is also provided introduction to principles of registration procedure as well as overall data on the amount of registered products and administrative fees obtained during 1999. Dramatic increase of

performance is seen in all types of agendas, there is obvious benefit from adoption of "Common simplified procedure" on granting registrations of centralised products. Registration process is largely influenced by acceptance of EU regulatory standards. More demanding registration process is, because of still large amount of "outdated" submissions, frequently finalised by negative decision (59 %). Despite of increasing effort, there is still seen the lack of capacity especially in the area of variations and renewals.

SÚKL provisions

UST-4-Standard terms for pharmaceutical dosage forms, routes of administration and containers

Czech terms for dosage forms, routes of administration and containers drawn up by the Czech Pharmacopoeia Commission are listed. The provision includes also terms for non-professional users in lay language and abbreviations of dosage forms and of routes of administration. Date for coming into operation is July 1, 2001.

Pharmacopoeia activities

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

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 is enclosed. 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 medicinal products where the registration decision will be no longer valid in August 2000

Registration decision of above mentioned products will be no longer valid during August 2000 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 29, 2000.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of February 2000

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

Bulletin SUKL 02/2000

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Front page news

Measures taken in case of defects or adverse reactions of medicinal products in the month of January 2000

Information on changes in processing approvals of medical devices

By December 31, 1999 the agenda of certification of manufacture, import and distribution, which SUKL had been responsible for, has been terminated. Unresolved applications submitted by this date will be returned to applicants gradually. From February 1, 2000 on, SUKL is no more responsible for the agenda connected with granting and withdrawing approvals for the use of medical devices. From February 1, 2000 on this agenda has been passed on to the Ministry of Health, Department of Pharmaceuticals. Applications submitted to SUKL by January 31, 2000 will be solved in normal way.

Information on a reported adverse reaction of medical devices

SÚKL provisions
Survey of provisions valid as of March 1, 2000

REG-47-Procedure for application for registration and subsequent variations of medicinal product that has been registered in the EU Member States by Mutual Recognition Procedure - pilot phase
New registration procedure is applicable to medicinal products that were granted registration by the Mutual Recognition Procedure in the EU - Member States based on the evaluation of full dossier (including bibliographic applications). This new procedure can also be applied to line extensions to the product, which already passed this simplified procedure in the Czech Republic. The aim of the procedure is to achieve in the Czech Republic harmonised status of medicinal products that passed EU MRP. The application can be submitted any time after day 90 of the respective MRP, when all necessary documents are available. The guideline defines basic principles and prerequisites, procedure to be followed and documentation to be submitted both for application for registration and variations. All necessary forms are included. Guideline considers already known principles and documents agreed during PERF meetings and is proposed as the pilot phase to gain experience before common procedure of CADREAC countries will be discussed. The guideline is valid as of March 2000.

REG-48-Simplified procedure for registration of some essentially similar products (procedure for "non-problem generics")

New registration procedure is applicable to referenced applications where proposed SPC and PIL are with the exception of administrative data identical with those of the reference medicinal product and essential similarity is documented by bioequivalence study or there exists the possibility to derive it from pharmaceutical data only. The guideline is valid as of March 2000.

Information

Invitation to an annual meeting and report on SUKL°s activities in the year 1999

Announcement of the State Institute for Drug Control and the Ministry of Finance destinated for applicants for registration, registration decision holders and manufacturers of medicinal products

Change in granting codes of SUKL to registered medicinal products has been proposed and is published for comments.

Validity of the manufacturing and wholesaling licences

Measures accepted for smooth issuing of manufacturing and wholesale licences in the year 2000 because of the time limited manufacturing licences that had been issued by the Ministry of Health in 1997 are described.

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 is enclosed. 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 1999 are published.

List of medicinal products where the registration decision will be no longer valid in July 2000

Registration decision of above mentioned products will be no longer valid during July 2000 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, 2000.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of January 2000

List of exemptions from registration granted by Ministry of Health during the month of December 1999 - 2nd part

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

Bulletin SUKL 01/2000

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Measures taken in case of defects or adverse reactions of medicinal products in the month of December 1999
Information on a reported adverse reaction of medical devices
Information on a reported unapproved medical device
SÚKL provisions
VYR-12-Sterilization procedures
The document sets out the interpretation of GMP and Pharmacopoeias requirements for the heat sterilization procedures. It contains procedures of calibration, qualification, process validation, monitoring, revalidation and preventive maintenance for the heat sterilization.
Information on drug consumption
Team of authors: Drug consumption in the Czech Republic in the 3rd quarter of the year 1999
Comparison with the situation in previous period is given. Figures are expressed in the number of packages, Czech crowns and Defined Daily Doses.
Pharmacopoeia activities
Announcement of texts of the European Pharmacopoeia becoming official standards in the Czech Republic
Information
Information for applicants for registration of medicinal products
Two new registration procedures concerning registration of some generic products and registration of medicinal products following the Mutual Recognition Procedure in the European Union will be published in the next issue of Vestnik SUKL and even before they will be available on the SUKL web site (www.sukl.cz) under the heading "News". Procedures will be applicable as of March 1, 2000.
Information for applicants for an approval for manufacture, distribution and import of medical devices and for applicants for an approval of medical devices for use in provision of health-care
Proposed changes to the current regulatory systems are about to be finalized by the Ministry of Health. Any changes, when finalized, will be announced on the homepage of the State Institute for Drug Control (www.sukl.cz).
Information for applicants for registration, renewal of registration and changes of manufacturing site
Additional information to the SUKL provision REG-42 and REG-43 concerning submission and languages required for documents confirming GMP compliance in the registration dossier are given.
Notice to applicants for a fatty oils certificate
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 is enclosed. 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 wholesalers of medicinal products - amendment to December 31, 1999

List of medicinal products where the registration decision will be no longer valid in June 2000

Registration decision of above mentioned products will be no longer valid during June 2000 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, 1999.

Information on registered drugs and drugs with exemptions from registration

Recently registered medicinal products and variations to registrations approved during the month of December 1999

List of exemptions from registration granted by Ministry of Health during the month of December 1999