# STATE INSTITUTE FOR DRUG CONTROL

## Bulletin of SUKL - List of Contents - Archives 1999

## SUKL Bulletin 12/1999

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**KLH-17-Investigator**
Translation of the Chapter 4 of Guideline for Good Clinical Practice (International Conference on Harmonization, E6, May 1, 1999) which represents responsibilities and obligations of the investigator of clinical trial. The text of the quideline is compared with the Czech legislation (Law on Pharmaceuticals No. 79/1997 Coll. and Decree on Good Clinical Practice No. 230/1999 Coll.) and several comments are given.
**DIS-6-Reporting of deliveries of distributed drugs**
The provision defines more exactly the way of reporting drug deliveries from wholesalers or manufacturers to health care facilities or vendors of selected drugs. Each wholesaler has to set up a system, which enables to provide the SUKL with drug consumption data as well as to establish a responsible person.
**VYR-11-Updating of the Site Master File and Questionnaires for manufacturers of medicinal products and pharmaceutical active ingredients**
The document sets out requirements for updating of questionnaires for manufacturers of medicinal products, pharmaceutical active ingredients (including medicinal gases) and quality control laboratories and in addition establishes the specific questionnaire for inspection of computer systems working in the field of GMP.
**LEK-4-Hygienic principles and their application in pharmacies**
The provision is valid as of January 1, 2000.
**Information**
**Information for users of data on registration, variations and renewals of registration released by the State Institute for Drug Control**
The SUKL releases information on issued decisions before they come into force. The reason is to make information available as soon as possible. In case of appeal of an applicant against the decision the SUKL makes necessary corrections in published list of decisions.
**Information about a course of pharmaceutical medicine**
**List of control laboratories with a GMP certificate of SUKL**
**Information for pharmacies concerning analysis performed by stations of hygienic service**
**Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**
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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 May 2000**
Registration decision of above mentioned products will be no longer valid during May 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 November 30, 1999.
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**REG-45-Names of the products manufactured under the licence**
The conditions under which the medicinal product manufactured under the licence can have the same name as the original already registered medicinal product and documents to be submitted together with such an application are set out in the guideline.
**REG-46-Maximum shelf-life for sterile products after first opening or after reconstitution**
The guideline, which is based on the translation of Note for Guidance CPMP/QWP/159/96, MAXIMUM SHELF-LIFE FOR STERILE PRODUCTS FOR HUMAN USE AFTER FIRST OPENING OR FOLLOWING RECONSTITUTION, gives information on data to be submitted with the application and recommendations on texts to be provided in summary of product characteristics, package leaflet and labelling, if appropriate. The guideline is valid as of January 1, 2000.
**Information on drug consumption**
**Team of authors: Drug consumption in the Czech Republic in the 1st half 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.
**Information**
**Statement by the State Institute for Drug Control concerning Y2K**
English translation of the statement is included.
**Prepared change to the guideline REG-36-Variations**
Until the amendment of the Law on Pharmaceuticals and consequently the amendment of the Decree on Registration are valid, applications for both Type I and Type II variations are processed according to the Decree on Registration No. 289/1998 through the approval procedure and the applicant has to wait till the decision on the variation is issued. According to the present legislation also more variations can be applied for using one application form but in the case that both Types of variations are included, the Type I variation could be delayed by a more detailed assessment of Type II variation.
**A change in the date of GMP and GDP seminars announced to be in December 1999**
The seminars will be held on January 7 and 8, 2000.
**Information on sanctions**
List of sanctions inflicted on regulated subjects by SUKL in the months of January to October 1999.
**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 third quarter of 1999 are published.
**List of medicinal products where the registration decision will be no longer valid in April 2000**
Registration decision of above mentioned products will be no longer valid during April 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**
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**LEK-2-Comment to the Decree No.90/1999**
The Decree laying down details on preparation and supply of medicinal products and conditions of pharmacy operation is valid as of May 1999. The comment has been worked out to help pharmacists in understanding of the Decree.
**LEK-3-Recommended shelf-lives of medicinal products prepared in pharmacies**
Shelf-lives and storage conditions for eye drops and other preparations stored in a finished packaging or prepared in bulk to be stored and used later are given.
**Information on drug consumption**
**Team of authors: Drug consumption in the Czech Republic in the 2nd 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.
**Information**
**Information on seminars prepared by SUKL during the 2nd half of 1999 - amendment**
Invitation for a medical devices seminar and a change in the date of Pharmacopoeia seminar 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 March 2000**
Registration decision of above mentioned products will be no longer valid during March 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 September 30, 1999.
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**SLP-1-Rules of controlling activities of the State Institute for Drug Control**
**Pharmacopoeia activities**
**Chemical Reference Substances established by the Czech Pharmacopoeia Commission**
**Information**
**Presentation of the web sites of the State Institute for Drug Control**
Short information about contents of the web sites http://www.sukl.cz is given.
**Information on seminars prepared by SUKL during the 2nd half of 1999**
The list of seminars and the application form is 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**
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**List of medicinal products where the registration decision will be no longer valid in February**

**2000**
Registration decision of above mentioned products will be no longer valid during February 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**
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**Information on a reported adverse reaction of medical devices**
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**Survey of provisions valid as of September 1, 1999**
**REG-44-Application for registration of the medicinal product**
The new version of the application form reflecting recent changes and development in registration process has been issued. The application for registration of medicinal product using this new form should be preferably submitted immediately and the old version (REG-38) will be accepted till October 1, 1999 at latest. The form is available in SUKL both in paper and electronic version and could be downloaded from the SUKL homepage on the address www.sukl.cz.
**KLH-16-Sponsor**
Translation of Chapter 5 of the Guideline for Good Clinical Practice of International Conference on Harmonisation (E6, Step 4 of May 1, 1996) which represents responsibilities and obligations of the sponsor of clinical trial. The text of the guideline is neither modified or adapted to the Czech legislation and should serve as a guidance for sponsors of clinical trials.
**Information on drug consumption**
**Team of authors: Drug consumption in the Czech Republic in the 1st 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.
**Information**
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**List of medicinal products where the registration decision is no longer valid**
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Information on a reported adverse reaction of medical devices
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UST-3-Notification of selected medicinal products to SUKL before beeing placed on the Czech market
There is the obligation in the registration decision of selected medicinal products to notify SUKL on the intention to place every batch on the Czech market and these products have to be released by SUKL. The procedure and documentation to be submitted for the batch release are given.
**Pharmacopoeia activities**
Aqua purificata
Aqua pro iniectione
**Information**
Information for applicants for marketing authorisation / registration decision holders and wholesalers of drugs concerning EAN codes
Contact adresses are included.
List of test facilities complying with the GLP requirements
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.
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Defects of medicinal products in the month of May 1999
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Survey of provisions valid as of July 1, 1999
REG-43-Applications for registration of medicinal product processed administratively
Some applications for registration, e.g. second name of the registered product, transfer of the registration decision holder (MAH) and/or products manufactured under licence agreement, can be processed without detailed assessment by administrative procedure. This applies to products that can be, with the consent of MAH, fully referenced to already registered product. Presumptions of this procedure are the identity of registered medicinal product (i.e. raw materials and their sources, manufacturing process and type of equipment, specifications, testing methods and packaging are identical) and referenced documentation in compliance with requirements for registration valid at the time of submission of new application. Documents to be submitted with this application are listed. This provision is valid as of September 1, 1999.
**Information**
Consultation Day organized by Branch of Clinical Trials and Pharmacovigilance - May 18th, 1999
SÚKL organized the Consultation Day which was attended by 40 representatives from 23 farmaceutical companies. The aim of the Consultation Day was to give an opportunity to discuss questions concerning Clinical Trials, Applications for Renewal of the Registration Decision, Periodic Safety Update Reports, OTC Drugs and Reporting of Adverse Reactions.
Information for pharmacies concerning analysis performed by stations of hygienic service
Forthcoming publication - survey of pharmacies, manufacturers and wholesalers of drugs in the CR
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.
Information on Czech standards relating to medical devices published in the Bulletin of the COSMT
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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 1999

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

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**105 years from Prof. PhDr. PhMr. Eduard Skarnitzl's birth**

**Front page news**

Change of the telephone numbers of the State Institute for Drug Control

New telephone numbers are valid since May, 1999.

Defects of medicinal products in the month of April 1999

Information on a reported adverse reaction of medical devices

**SÚKL provisions**

Survey of provisions valid as of June 1, 1999

UST-2-Payment procedure applicable to administration fees

Due to the change of the Institute's bank account number, the guidance for the procedure for administration fees payment is revised. The details on the procedure and the form "Proof of administration fee payment" are included. The provision replaces provision UST-1 as of June 1, 1999.

PZT-13- Minimum data set to be reported to the State Institute for Drug Control by a medical device manufacturer/importer/holder of an "Approval to use", in the case of occurance of medical device-related adverse event

The provision is valid as of June 1, 1999

**Pharmacy activities**

Control of pharmacies in the year 1998

On the basis of 9 320 controlled samples taken from pharmacies medicinal products prepared in pharmacies were found to be unsatisfactory, but a slight improvement in comparison with the previous years has been detected. 30,1 % of samples examined have not met quality requirements.

**Information**

Announcement for pharmacies concerning preparation of medicinal products

Forthcoming publication - list of OTC medicinal products and products with narcotic and psychotropic substances

List of control laboratories with a GMP certificate of SUKL

Amendment valid as of April 30, 1999.

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 1999 are published.

List of medicinal products where the registration decision will be no longer valid in October 1999

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

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Information on a reported adverse reaction of medical devices

**Inspection activities**

Annex to the recommended procedures of application of Good Manufacturing Practice in regional blood transfusion centre

**Information on drug consumption**

Team of authors: Drug consumption in the Czech Republic in the year 1998

This article is focused on drug consumption in the Czech Republic in the year 1998 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**

Common declaration of the State Institute for Drug Control and the Institute for State Control of Veterinary Immunologicals and Medicaments

Information of the State Institute for Drug Control on the "year 2000" problem

Problems associated with the year 2000 concerning medical devices are mentioned. The advice for health professionals both on software embedded in medical equipment and medical software which runs on a general-purpose computer is given.

Information for companies distributing active pharmaceutical ingredients

Criteria for sorting of excipients and active pharmaceutical ingredients are described. SUKL requires that all companies which do not posses the licence for manufacturing and distribution of pharmaceutical active ingredients have to apply for this licence till 30.9.1999.

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

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List of medicinal products where the registration decision will be no longer valid in September 1999

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

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