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**Measures taken in the case of quality defects or adverse reactions to medicinal products in the month of June 2008**

### SÚKL guidelines

**List of guidelines valid as of August 1, 2008**

#### **UST-23 version 2-Providing of free samples of medicinal products for human use for promotional purposes**

According to the amendment to Act on Advertising (No. 40/1995 Coll.) providing of free samples of medicinal products is considered to be advertising. SUKL as the authority responsible for monitoring of medicinal products advertising sets up revised rules for providing free samples of medicinal products in this guideline, which replaces UST-23 version 1 as of August 1, 2008.

#### **UST-28 version 1-Approval procedure for parallel import of a medicinal product**

The revised guideline summarizes conditions for parallel import of a medicinal product, including obligations of a parallel importer and provides detailed instructions for parallel import authorisation application and the description of approval procedure according to the Act on Pharmaceuticals No. 378/2007 Coll.

#### **UST-35-Non-interventional post-authorisation studies**

In accordance with Section 92 (12) of Act No. 378/2007 Coll., on Pharmaceuticals and Amendments to Some Related Acts, as amended, every Marketing Authorisation Holder is obliged to inform the State Institute for Drug Control on the launch and close-out of all non-interventional studies in the Czech Republic in advance.

#### **LEK-5 version 1-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 according to the Czech Pharmacopoeia 2005 and its Supplements.

### Pharmacopoeia activities

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**Announcement of texts of the European Pharmacopoeia being recognized as official standards in the Czech Republic**

### Information

#### **Information on controls of pharmacies in the year 2007 - 2nd part**

Out of the total number of 1.324 samples taken from pharmacies 7,7 % were found non-compliant in some parameters. The number of non-compliant samples from pharmacies is the lowest one since 2002, the quality of medicinal products and purified water prepared in pharmacies has considerably improved.

**Information for pharmacy owners concerning their duty to inform SUKL about launch and closedown of a pharmacy activity and the SUKL's position on announcements of on-site controls in pharmacies**

**Information for Marketing Authorisation Holders of herbal medicinal products on transitional provisions of Section 113(6) of Act No 378/2007 Coll. (i.e. harmonisation of herbal medicinal products with valid authorisations with the statutory requirements for registration of traditional herbal medicinal products) and consequent duties of Marketing Authorisation Holders**

#### **Information on forthcoming publications**

List of pharmacies, manufacturers and wholesalers of medicinal products in the CR and List of OTC medicinal products and products with narcotic substances will be published.

**Information on sanctions imposed by SUKL in 2008 for breaches of Act No. 378/2007 Coll., on Pharmaceuticals, as amended, and under Act No. 40/1995 Coll., as amended**

**Outline of notifications on the use of non-authorized medicinal products in the month of June 2008**

**List of authorised medicinal products where placing on the market of individual batches with the labelling in a foreign language was approved in the month of June 2008**

**List of medicinal products whose authorisation for parallel import was granted in the month of June 2008**

**Information on Czech standards relating to medical devices published in the Bulletin of the COSMT**

**Information on documents issued by the European Medicines Agency (EMA)**

A list of new documents issued by the EMA in May 2008 is published. Documents are available in SUKL library.

**Data on applications submitted to SUKL –marketing authorisations and variations thereto**

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

**List of new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the second quarter of 2008**

**List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of June 2008**

**List of medicinal products whose marketing authorisation will expire in September 2008**

The validity of marketing authorisations of the listed products will expire during September 2008 and the products will be marked in SUKL database by "Z" and published in Věstník SÚKL.

**List of medicinal products with expired marketing authorisation**

The listed products are marked by "Z" in SUKL database as of June 30, 2008.

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

**Authorised medicinal products and variations to marketing authorisations approved in the period from May 22, 2008 to June 25, 2008**

**Medicinal products authorised under the EU centralised procedure and entered in SUKL database in the period from June 1, 2008 to June 30, 2008**

**List of specific therapeutic programmes approved in the period from June 1, 2008 to June 30, 2008**