

### Most important regulatory news as occurred in the Czech Republic

## 1. Important information

2.4.2008 To ensure the safety of heparin products in the Czech Republic market, the State institute for Drug Control (SUKL) has asked companies that manufacture heparin-containing products to test the heparin active pharmaceutical ingredient used in those products.

9.4.2008 SUKL informed about FDA's warning of unapproved drugs marketed as "Natural Supplements", products had contained active ingredients in prescription erectile dysfunction drugs.  
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01817.html>

17.4.2008 SUKL discovered that medicinal product Kamagra Gold was offered via the Internet. This medicinal product indicated for the treatment of erectile dysfunction is not authorised in the Czech Republic.

## 2. Content of SUKL Bulletin 4/2008

<http://www.sukl.cz/contents-2008>

### 2.1 SUKL guidelines

List of guidelines valid as of May 1, 2008

**CAU-01-Instructions for filling in the Application form for maximum ex-factory price of pharmaceuticals according to Act No. 48/1997 Coll.**

**CAU-02-Instructions for filling in the Application form for levels and conditions of reimbursement of pharmaceuticals according to Act No. 48/1997 Coll.**

**CAU-03-Instructions for filling in the Application form for maximum ex-factory price and levels and conditions of reimbursement of pharmaceuticals according to Act No. 48/1997 Coll.**

### 2.2 Information on authorised medicinal products and approved specific therapeutic programmes

<http://www.sukl.cz/databaze-zmen-v-registracich-lp>

**Authorised medicinal products and variations to marketing authorisations approved in the period from February 21, 2008 to March 26, 2008**

**Medicinal products authorised under the EU centralised procedure and entered in SUKL database in the period from March 1, 2008 to March 31, 2008**

**List of specific therapeutic programmes approved in the period from March 1, 2008 to March 31, 2008**

### 2.3 Information

#### **Changes of secondary packaging of medicinal products („repackaging“)**

Information for manufacturers of medicinal products on main principles governing changes in secondary packaging („repackaging“) is published. The information covers all medicinal products including investigational medicinal products, parallel importation and quality defects of products

### 2.4 Regular columns

**Outline of notifications on the use of non-authorised medicinal products in the month of March 2008**

The information on evaluated notifications in the month of March 2008, in particular numbers of notifications, patients, health care facilities and used medicinal products is published.

**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 March 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 February 2008 is published. 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 new pharmacies and separate departments for dispensing pharmaceuticals and medical devices approved by SUKL in the first quarter of 2008**

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

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

The validity of marketing authorisations of the listed products will expire during June 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 March 31, 2008.

### **3. Distributors and Manufacturers in the Czech Republic**

**The list of distributors**

<http://www.sukl.cz/list-of-distributors-of-medicinal-products?lchan=1&lred=1>

**The list of manufacturers**

<http://www.sukl.cz/list-of-manufacturers-of-the-medicinal-products-and-control?lchan=1&lred=1>

### **4. Content of Pharmacotherapeutical Information 4/2008**

Treatment of age-related macular degeneration

Information to safety of the medicinal product Gardasil

If you do not wish to receive this SUKL Monthly Regulatory Update in future, please notify us on e-mail:

[petra.kerkova@sukl.cz](mailto:petra.kerkova@sukl.cz)