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

# 1. Important information

21.2.2008 State Institute for Drug Control (SUKL) informed that the European Medicines Agency (EMEA) had recommended the authorisation of the first 'pre-pandemic vaccine' for humans against influenza caused by the H5N1 virus.
http://www.sukl.cz/uploads/Dalsi_upozorneni/Press_Release_EMEA.pdf

25.2.2008 SUKL published on its web sites information about a Commission´s public call for expressions of interest related to the appointment by the European Commission of members and alternates representing clinicians and patients' associations at the Committee for Advanced Therapies of the European Medicines Agency (EMEA).
http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/docs/2008_01/2008-01_advther_en.pdf

# 2. Content of SUKL Bulletin 2/2008

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

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

## 2.1 SÚKL guidelines

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

**REG 77 version 2- Application for variation to a marketing authorisation of a medicinal product**
The application form for variation to a marketing authorisation has been updated to reflect the changes introduced by the new Act on Pharmaceuticals. The new version of REG-77 superseding the existing version with effect from February 1, 2008.

## 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 December 20, 2007 to January 23, 2008**

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

## 2.3 Regular columns

**Outline of notifications on the use of non-authorised medicinal products in the month of January 2008**
The information on evaluated notifications in the month of January 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 January 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 (EMEA)**
A list of new documents issued by the EMEA in December 2007 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.

**Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the fourth quarter of 2007**

**Overview of data on basic activities of the Inspection Branch in the fourth quarter of 2007**

**Overview of data on activities of the Medical Devices Branch in the fourth quarter of 2007**

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

**List of medicinal products whose marketing authorisation will expire in April 2008**
The validity of marketing authorisations of the listed products will expire during April 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 January 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

- List of distributors of pharmaceuticals (only of APIs) up to the March 1, 2008
- List of Subjects distributing medicinal products in the Czech Republic on the basis of a distribution license granted by another EU Member State up to the March 1, 2008

### The list of manufacturers

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

- List of manufacturers of the medicinal products and control laboratories (up to the March 1, 2008)
- List of blood transfusion centres which are holders of manufacturing licence (up to the March 1, 2008)
- Holders of GMP Certificate of API manufacture (up to the March 1, 2008)

## 4. Content of Pharmacotherapeutical Information 2/2008

**The role of physician and pharmacist resulting from the new Act on Pharmaceuticals**

If you do not wish to receive this SUKL Monthly Regulatory Update in future, please notify us on e-mail:
petra.kerkova@sukl.cz