

Most important regulatory news as occurred in the Czech Republic

1. Content of SUKL Bulletin 5/2008

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

1.1 SUKL guidelines

Guidelines of the State Institute for Drug Control cancelled as of May 1, 2008

List of guidelines valid as of May 1, 2008

UST-23 version 1-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 as of May 1, 2008.

1.2 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 March 27, 2008 to April 23, 2008

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

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

1.3 Information

Inspection of documents in relation to administrative proceedings on setting of maximum ex-factory price levels and levels and conditions of reimbursement of pharmaceuticals

All the information is available on the SUKL website.

1.4 Regular columns

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

The information on evaluated notifications in the month of April 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 April 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 March 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.

Overview of data on applications submitted in the first quarter of 2008 – clinical trials

Overview of data on basic activities of the Section of Pharmacy and Distribution Control in the first quarter of 2008

Overview of data on basic activities of the Inspection Section in the first quarter of 2008

Overview of data on activities of the Surveillance Branch in the area of medical devices in the first quarter of 2008

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

List of medicinal products whose marketing authorisation will expire in July 2008

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

List of medicinal products with expired marketing authorisation

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

2. 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>

3. Content of Pharmacotherapeutical Information 5/2008

Treatment of the bites of vipera snakes: serum yes or no?

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

petra.kerkova@sukl.cz