Monthly Regulatory Update 03/08

Most important regulatory news as occurred in the Czech Republic

1. Important information

21.3.2008 State Institute for Drug Control informed the European Medicines Agency (EMEA) had recommended that Velcade (bortezomib) should not be used in patients with certain severe pulmonary or heart problems (acute diffuse infiltrative pulmonary and pericardial disease).
http://www.emea.europa.eu/humandocs/PDFs/EPAR/velcade/PR_Velacade_13944308en.pdf

2. Content of SUKL Bulletin 3/2008

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

2.1 SÚKL guidelines

List of guidelines valid as of April 1, 2008

UST-34-Projects of laboratory control and taking samples of medicinal products from the market
The guideline describes the procedure for collecting samples of medicinal products from pharmacies and wholesale by inspectors of the Institute in order to control their quality in SUKL laboratories and determines compensation for the samples to wholesalers by MAHs.

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 January 24, 2008 to February 20, 2008

Medicinal products authorised under the EU centralised procedure and entered in SUKL database in the period from February 1, 2008 to February 29, 2008

List of specific therapeutic programmes approved in the period from February 1, 2008 to February 29, 2008

2.3 Information

Information on seminars held by SUKL in 1st half of 2008- 2nd part
The overview of seminars and the application form are included.

2.4 Regular columns

Outline of notifications on the use of non-authorised medicinal products in the month of February 2008
The information on evaluated notifications in the month of February 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 February 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 January 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 manufacturers and distributors of pharmaceuticals in the CR approved in the month of February 2008

List of medicinal products whose marketing authorisation will expire in May 2008
The validity of marketing authorisations of the listed products will expire during May 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 February 29, 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 3/2008

Vaccination, immunization and antimalarial prophylaxis by travelling abroad – completion
Arterial „prehypertension“, a useful concept for drug companies, useless for patients

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