Monthly Regulatory Update 01/08

Most important regulatory news as occurred in the Czech Republic

1. Important information

The new Act No. 378/2007 on Pharmaceuticals came in force on December 31st 2007.

Since 1st January 2008, the State Institute for Drug Control is the national competent authority for setting maximum prices and levels and conditions of reimbursement of medicinal products and foods for special medical purposes and also the authority responsible for price control of medicinal products, foods for special medical purposes and medical devices .
State Institute for Drug control (SUKL) has got new web sites (www.sukl.cz) since 1st January 2008.

30. 1. 2008 State Institute for drug control informed that the European Medicines Agency (EMEA) had recommended updating the product information for rosiglitazone-containing antidiabetic medicinal products. Rosiglitazone is available in the Czech republic as Avandia (rosiglitazone maleate) and Avandamet (rosiglitazone maleate/metformin).
http://www.emea.europa.eu/pdfs/human/press/pr/4223208en.pdf

2. Content of SUKL Bulletin 1/2008

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

Measures taken in the case of quality defects or adverse reactions to medicinal products in the month of December 2007

2.1 SÚKL guidelines

List of guidelines valid as of February 1, 2008

KLH-12 version 1- Requirements on Good Manufacturing Practice (GMP) documents supporting the request for authorisation/notification of clinical trials
This revision of Guideline KLH-12 supersedes the original version of the guideline from 1. 1. 1999 and is valid from February 1, 2008. The revised version of Guideline KLH-12 defines GMP documents which are to be submitted together with the request for authorization/notification of clinical trials. The manufacture and import of Investigational Medicinal Products (IMPs) is subject to manufacturing authorisation. This guideline specifies documents which prove compliance with GMP conditions for IMPs.

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 November 22, 2007 to December 19, 2007

Medicinal products authorised under the EU centralised procedure in the period from December 1, 2007 to December 31, 2007

List of specific therapeutic programmes approved in the period from December 1, 2007 to December 31, 2007

2.3 Regular columns

Outline of notifications on the use of non-authorised medicinal products in the month of December 2007
The information on evaluated notifications in the month of December 2007, 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 December 2007

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 November 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.

List of new pharmacies and detached departments for dispensing pharmaceuticals and medical devices approved by SUKL in the fourth quarter of 2007

List of manufacturers and distributors of pharmaceuticals in the CR approved in the month of December 2007

List of medicinal products whose marketing authorisation will expire in March 2008
The validity of marketing authorisations of the listed products will expire during March 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 December 31, 2007.

3. Distributors and Manufacturers in the Czech Republic

The list of distributors

http://www.sukl.cz/list-of-distributors-of-medicinal-products

- List of distributors of pharmaceuticals (only of APIs) up to the February 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 February 1, 2008

The list of manufacturers

http://www.sukl.cz/list-of-manufacturers-of-the-medicinal-products-and-control

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

4. Content of Pharmacotherapeutical Information 1/2008

Vaccination, immunization and antimalarial prophylaxis by travelling abroad