Contents

Front page news

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

<u>SÚKL guidelines</u>

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 acording to Act No. 48/1997 Coll.

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

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

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 (EMEA)

A list of new documents issued by the EMEA 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.

<u>Information on authorised medicinal products and approved specific therapeutic programmes</u> 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