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

Information on adverse event of a medical device

SÚKL guidelines

List of guidelines valid as of June 1, 2008

LEK-9 version 1-Handling of medicinal products in healthcare facilities

Commentary on the new decree No. 84/2008 Coll., laying down details on handling of medicinal products, especially conditions of storage, dilution of preparations etc. in hospitals. The commentary has been prepared to assist healthcare professionals in understanding and implementation of this decree.

Information on drug consumption

Team of authors: Drug consumption in the Czech Republic in the 1st quarter of the year 2008

Comparison with the situation in the previous period is given. Figures are expressed in number of packages, Czech crowns and Defined Daily Doses.

Information

Information on controls made in healthcare facilities in the year 2007 – the 1st part

Controls were focused on treatment with medicinal products and were conducted as initial ones.

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

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

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

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

The validity of marketing authorisations of the listed products will expire during August 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 May 31, 2008.

Information on authorised medicinal products and approved specific therapeutic programmes

Authorised medicinal products and variations to marketing authorisations approved in the period from April 24, 2008 to May 21, 2008

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