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

SÚKL guidelines

List of guidelines valid as of March 1, 2008

REG 77 version 2- Application for variation to a marketing authorisation of a medicinal product

The application form for variation to a marketing authorisation has been updated to reflect the changes introduced by the new Act on Pharmaceuticals. The new version of REG-77 superseding the existing version with effect from February 1, 2008.

Information

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

The information on evaluated notifications in the month of January 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 January 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 December 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.

Overview of data on basic activities of the Branch of Pharmacy and Distribution Control in the fourth quarter of 2007

Overview of data on basic activities of the Inspection Branch in the fourth quarter of 2007

Overview of data on activities of the Medical Devices Branch in the fourth quarter of 2007

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

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

The validity of marketing authorisations of the listed products will expire during April 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 January 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 December 20, 2007 to January 23, 2008

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