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Front page news

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

SÚKL guidelines

List of guidelines valid as of September 1, 2008

UST-21 version 1-Notification of selected medicinal products to SUKL before their placing on the Czech market (Official batch release)

The revised guideline summarizes the procedure and documentation to be submitted according to the Act on Pharmaceuticals No. 378/2007 Coll. and the guidelines for Official Control Authority Batch Release of blood medicinal products and vaccines in the EC/EEA are given.

UST-23 version 2-Providing of free samples of medicinal products for human use for promotional purposes

According to the amendment to Act on Advertising (No. 40/1995 Coll.) providing of free samples of medicinal products is considered to be advertising. SUKL as the authority responsible for monitoring of medicinal products advertising sets up revised rules for providing free samples of medicinal products in this guideline, which replaces UST-23 version 1 as of August 1, 2008.

VYR-32 version 2-Guidelines on Good Manufacturing Practice

The EU Commission has published revision of chapter 1 to the EU GMP Guide which includes important information regarding risk assessment approach in manufacture and quality control of medicines. SUKL is publishing the translation of changes only. The translation of the new EU GMP Annex 20 (Quality Risk Management) is published on the SUKL website.

Information

Information about excessive consumption and sales of medicinal products containing pseudoephedrine up to 30 mg

Controls have been performed in 22 pharmacies with excessive sales of medicinal products containing pseudoephedrine up to 30 mg, list of these pharmacies is published. .

Websites of the State Institute for drug control

Information on a new content of the website.

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

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 July 2008

List of medicinal products whose authorisation for parallel import was granted in the month of July 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 June 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.

Overview of data on applications submitted in the second quarter of 2008 – clinical trials

Overview of data on basic activities of the Section of Pharmacy and Distribution Control in the second quarter of 2008

Overview of data on basic activities of the Inspection Section in the second quarter of 2008

Overview of data on activities of the Surveillance Branch in the area of medical devices in the second quarter of 2008

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

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

The validity of marketing authorisations of the listed products will expire during October 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 July 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 June 26, 2008 to July 23, 2008

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