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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.

Information

Outline of notifications on the use of non-authorized 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 (EMA)

A list of new documents issued by the EMA 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.

Information on authorised medicinal products and approved specific therapeutic programmes

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