Contents

Under Act No 296/2008 Coll., on Quality and Safety of Human Tissues and Cells Intended for Human Application, the State Institute for Drug Control is responsible for surveillance in the field covered by this act and for licensing of activities of tissue establishments and diagnostic laboratories.
The State Institute for Drug Control has prepared this guideline to substitute the pending decree stipulating requirements of EC directives on tissues and cells. The guideline includes also traditional national requirements arising from Decree No 437/2002 Coll.

Information

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

List of medicinal products whose authorisation for parallel import was granted in the month of October 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 September 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 third quarter of 2008 – clinical trials

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

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

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

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

List of medicinal products whose marketing authorisation will expire in January 2009
The validity of marketing authorisations of the listed products will expire during January 2009 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 October 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 September 25, 2008 to October 22, 2008

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

List of specific therapeutic programmes approved in the period from September 1, 2008 to September 30, 2008