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

SÚKL guidelines

List of guidelines valid as of January 1, 2009

UST-29 version 4-Administration fees and costs reimbursement for professional activities, costs reimbursements for activities connected with providing information and costs reimbursements for other activities

This revision of the guideline UST-29 version 3 brings changes in payment of costs reimbursement with effect from 18 November 2008. The guideline includes a list of fees and relevant forms.

REG-80 version 1-Inclusion of a medicinal product already authorised in the CR into Mutual Recognition Procedure or into Decentralised Procedure

This guideline replaces guideline REG-80 as of November 10, 2008. The guideline provides information on conditions under which a medicinal product already authorised in the CR can be included into Mutual Recognition Procedure or Decentralised Procedure and its marketing authorisation number can be maintained.

LEK-12-Conditions for clinical trial of pharmaceuticals in pharmacies

This provision specifies condition under which clinical trial of pharmaceuticals can take place in pharmacies. Requirements for conducting of clinical trials of pharmaceuticals are laid down by **Act No 378/2007 Coll.**, on pharmaceuticals and by **Decree No 229/2008 Coll.**, on the manufacture and distribution of pharmaceuticals, **Decree No 84/2008 Coll.**, on good pharmaceutical practice, detailed conditions of handling pharmaceuticals in pharmacies, healthcare facilities and other operators and facilities supplying medicinal products and **Decree No 226/2008 Coll.**, on good clinical practice, detailed conditions of clinical assessment of pharmaceuticals.

Information on drug consumption

Team of authors: Drug consumption in the Czech Republic in the 3rd 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

Counterfeit and illegal products analyzed by Laboratory Control Section

A short report about counterfeit drugs and illegal products which were analyzed recently by Laboratory Control Section on the request of the Institute's Enforcement and Advertising Regulation Dept. The report informs about concrete analyzed products, mainly anabolics and "Life-Style" products obtained from internet sales. Information about results of analysis was forwarded to EDQM.

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

List of medicinal products whose authorisation for parallel import was granted in the month of November 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 November 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 November 2008

List of medicinal products whose marketing authorisation will expire in February 2009

The validity of marketing authorisations of the listed products will expire during February 2009 and the products will be marked in SUKL database by "Z" and published in Věstník SUKL.

List of medicinal products with expired marketing authorisation

The listed products are marked by "Z" in SUKL database as of November 30, 2008.

Information on authorised medicinal products and approved specific therapeutic programmes

Authorised medicinal products and variations to marketing authorisations approved in the period from October 26, 2008 to November 26, 2008

Medicinal products authorised under the EU centralised procedure and entered in SUKL database in the period from November 1, 2008 to November 30, 2008

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