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

SÚKL guidelines

List of guidelines valid as of October 1, 2008

UST-11 version 2-Reporting form for use of a non-authorised medicinal product

According to Act No. 378/2007 Coll., on Pharmaceuticals, as amended, and according to Decree No. 228/2008 Coll., physicians are obliged to report the use of non-authorised medicinal products to SUKL. This special form includes all requested information and should facilitate these reports. Version 2 is valid as of September 1, 2008.

UST-35 version 1-Non-interventional post-authorisation studies

In accordance with Section 92 (12) of Act No. 378/2007 Coll., on Pharmaceuticals and Amendments to Some Related Acts, as amended, every Marketing Authorisation Holder is obliged to inform the State Institute for Drug Control on the launch and close-out of all non-interventional studies in the Czech Republic in advance. This guideline replaces UST-35 as of October 1, 2008.

REG-84-Electronic submission of applications for marketing authorisation

Decree No 228/2008 Coll., on the marketing authorisation of medicinal products in its Section 3, paragraph 1 provides that applications and other documentation concerning human medicinal products submitted to the SUKL, must be in electronic format, unless otherwise agreed with the SUKL in special cases. The applications and other documentation shall be processed in the eCTD electronic format. This guideline sets up types of application and related documentation and the procedure for their submitting.

PHV-3 version 2-Non-interventional post-authorisation safety studies with medicinal products for human use

This guideline sets out terms and conditions for conducting non-interventional post-authorization safety studies with products for human use that are partly or fully sponsored by pharmaceutical industry or by organizations or persons supported by pharmaceutical industry. The guideline also contains new rules for reporting to the public register of these studies via web form and is coming into force on 11th September 2008.

Information on drug consumption

Team of authors: Drug consumption in the Czech Republic in the 2nd 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

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

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

The validity of marketing authorisations of the listed products will expire during November 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 August 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 July 24, 2008 to August 20, 2008

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

List of specific therapeutic programmes approved in the period from July 1, 2008 to August 31, 2008