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### SÚKL guidelines

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#### **REG-84 version 1-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. Version<sup>o</sup>1 of this guideline is valid as of October 1, 2008.

#### **VYR-10-version 1 Validation of Aseptic Procedures**

The aim of this guideline is to acquaint drug manufacturers with the requirements of SUKL for the validation of aseptic procedures. The guideline is intended particularly for manufacturers of medicinal products, but it can be also used by manufacturers of active pharmaceutical ingredients having aseptic procedures included in their production processes. The guideline includes also criteria for evaluation of validation results.

#### **VYR-36 Clean rooms**

The aim of this guideline is to provide drug manufacturers with interpretation of current GMP requirements on clean rooms. These requirements are defined in SUKL guideline VYR-32 Annex 1 version 1 "Manufacture of sterile medicinal products". Methods published in ISO standard 14644 Clean rooms can be used for monitoring.

### Laboratory control

#### **Outcomes of projects finished by the Laboratory Control Section**

The Laboratory control section performed, based on the specific projects, controls on medicinal products taken from the Czech market by inspectors of the Institute. Outcomes of the following projects are included in this report: Verification of quality of generics: a) *products containing atenolol*, b) *products containing diclofenac*, c) *products containing fenofibrate*, d) *products containing ranitidine hydrochloride* (survey of quality and comparison with an original product) and *Radiopharmaceuticals – kits and generators* (project verifying the quality of the products using different methods).

### Information

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#### **List of medicinal products whose marketing authorisation will expire in December 2008**

The validity of marketing authorisations of the listed products will expire during December 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 September 30, 2008.

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**Authorised medicinal products and variations to marketing authorisations approved in the period from August 21, 2008 to September 24, 2008**

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