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#### **UST-24 version 1-Waivers and refund of costs reimbursement for expert activities performed on request**

Basic rules and procedure for waivers and refund of costs reimbursement for expert activities performed on request is provided. This Revision No. 1 supersedes the original version of the guideline from November 1, 2003 and is valid as of October 20, 2008

#### **UST-27 version 2- Regulation of Advertising on human medicinal products and human tissues and cells**

The revision of the guideline provides all participants with SUKL's attitude to advertising of medicinal products in any type of communication media (except for radio and TV broadcasting). This guideline is in compliance with Act No. 40/1995 Coll., on Regulation of Advertising, as amended, and with Act. No. 296/2008 Coll., on Human Tissues and Cells.

#### **UST-36-Administration fees and costs reimbursement for activities performed on request under Act No. 296/2008, Quality and Safety Assurance of Human Tissues and Cells for Human Application**

Basic rules and procedure of costs reimbursement for expert activities performed on request is provided. The guideline is valid as of October 20, 2008.

#### **REG-75 version 1-Categorisation of Medicinal Products as Selected Pharmaceuticals**

This guideline replaces guideline REG-75 and describes the categories of "selected pharmaceuticals", provides instructions how to apply for this legal status in case of medicinal products that have already been authorised and in case of new applications for marketing authorisation.

#### **KLH-12 version 2- Requirements on Good Manufacturing Practice (GMP) documents supporting the request for authorisation/notification of clinical trials**

This revision of guideline supersedes the original version of the guideline from 1. 1. 2008 and is valid from November 1, 2008. The revised version of guideline defines GMP documents which are to be submitted together with the request for authorization/notification of clinical trials.

#### **KLH-19 version 1-Documents Needed for Approval of Clinical Trials - Requirements on Pharmaceutical Part of Dossier**

The revision of KLH-19 guideline contains requirements on quality part of dossier (IMPD) which should be provided together with the Request for Authorization of Clinical Trials. The requirements on medicinal products of chemical and biological/biotechnological origin as well as on advanced therapy medicinal products and radiopharmaceuticals are presented.

#### **KLH-20 version 4-Application for Approval/Notification of a Clinical Trial**

The guideline replaces KLH-20 version 3 and is valid since November 1, 2008. It contains detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, Annex 1 specifies the requirements for summary of the protocol.

#### **VYR-37-Good manufacturing practice in the manufacture and distribution of blood components**

The aim of this guideline is to provide further information on GMP principles in the manufacture and distribution of blood components including handling of these preparations in blood banks of healthcare facilities. The guideline elaborates requirements of the Act No 378/2008 Coll., on Pharmaceuticals, as amended, and Decree No 143/2008, on Human Blood with the emphasis on requirements of control and quality assurance.

#### **VYR-38-Specification of requirements on quality and safety of human tissues and cells intended for human application**

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**

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#### **Information on documents issued by the European Medicines Agency (EMA)**

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#### **Data on applications submitted to SUKL –marketing authorisations and variations thereto**

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