KLH-10 version 1 TERMINOLOGY AND PRINCIPLES OF GOOD CLINICAL PRACTICE

This Guideline supersedes guideline KLH-10 with the effect from 9 June 2011.

Translation of the Chapter 1. of ICH Guideline for Good Clinical Practice (E6, May 1, 1996), which defines basic terms used in this guideline and in the Czech translation of the guideline, and of the Chapter 2, which specifies principles of good clinical practice. Text of the ICH guideline is slightly modified according to the Czech legislation: Decree No. 226/2008 Coll. on good clinical practice and detailed conditions of clinical trials on medicinal products, Act No. 378/2007 Coll. on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals).

There are eight explanatory notes added to the ICH Guideline text:

1. Term 1.1 - Adverse Drug Reaction: New use of a marketed product means e.g. use in new indication, new dosage form, for new qroup of patients, in new fixed combination or new dosage schedule. Also added explanation of Serious Adverse Drug Reaction, Unexpected Adverse Drug Reaction and Unexpected Serious Adverse Drug Reaction.

2. Term 1.27 - Independent Ethics Committee: Section 34 of the Act No. 79/1997 Coll., on Pharmaceuticals is the legal basis for ethics committees in the Czech Republic; further specification will be in the Decree of Ministry of Health on good clinical practice and detailed conditions for clinical trials on pharmaceuticals, which is under preparation.

3. Term 1.5 and 1.31 – Institutional Review Board is analogical to Czech Local Ethic Committee

4. Term 1.45 – Protocol Amendment: Added term Substantial Amendment to Protocol

5. Term 1.49 - Regulatory Authorities: According to the Section 9 of the Act No. 79/1997 Coll., on Pharmaceuticals State Institute for Drug Control is the competent authority in the Czech Republic.

6. Principles of GCP - 2.6 - According to the Section 35 of the Act No. 79/1997 Coll., on Pharmaceuticals the consent of the ethics committee of the health care facility and approval of / notification to State Institute for Drug Control are necessary for conducting a clinical trial.

7. Principles of GCP - 2.9 - According to the Section 35 of the Act No. 79/1997 Coll., on Pharmaceuticals the written informed consent is necessary for conducting a clinical trial.

8. Principles of GCP - 2.12 - Legal basis for principles of good manufacturing practice is the Decree of Ministry of health No. 355/1997 Coll., on good manufacturing practice, good distribution practice and detailed conditions for licensing of manufacture and distribution of pharmaceuticals.