KLH-9 Investigator's brochure

This provision is valid as of June 1, 1998.

Translation of Chapter 7. of ICH Guideline for Good Clinical Practice (E6, May 1, 1996), which represents requirements of SUKL for investigator's brochure submitted with the application for approval / notification of clinical trial. Text of the guideline is not modified or changed.

There are added three explanatory notes to second paragraph of the chapter 7.1. - Introduction, specifying requirements of SUKL:

1. In the cases, where the investigational product is registered and is used in compliance with the registration decision, Summary of Product Characteristics represents for SUKL and ethics committees sufficient substitution for Investigator's Brochure.

2. New use of a marketed product should be understood as use which is not in compliance with registration decision issued for this product.

3. In the Czech Republic the relevant new information should be reported to SUKL as well as to relevant ethics committees.