Information for sponsors of clinical trials on pharmaceutical data submission for new clinical trials with already assessed drug products and the possibility to refer to data submitted in the past

The information was given on clinical trials seminar on December 9th, 2003. It concerns new clinical trials when the sponsor refers to an already assessed clinical trial with the same product and therefore it is not necessary to submit pharmaceutical data to be assessed (i. e. the cases when pharmaceutical data are not submitted and there is a reference in the application form to a trial already assessed; or the cases when pharmaceutical data are submitted but the sponsor declares in the application form that the pharmaceutical data were assessed in submitted clinical trial file submitted in the past).
The information requested in Appendices 1 and 2 are submitted by every **sponsor** of clinical trial (according to the Application for approval/notification of clinical trial form) who wants to refer to already assessed clinical trial.
The purpose of the information requested is to identify investigational drug product already assessed in the past, to distinguish if the product is really the same without any changes and variations that could have been made during its development and helps to reveal these variations and changes.
The data are submitted in tabular format similar to the marketing authorisation variation table, i. e. "current status" and "proposed status" (which means product already assessed/newly assessed product) – see Appendix 1.

!! NOTE !!

- For the product without reference – i. e. submitted for the first time in the Czech Republic or with implemented variation or change – complete pharmaceutical data according to SÚKL guideline KLH-19 are requested by SÚKL.
- KLH-19 is mandatory also for every comparator product.
- For products with marketing authorisation – i. e. both in the Czech Republic and/or EEA (European Economic Area) – is KLH-19 mandatory as well.
- KLH-19 is still valid for all other cases – i. e. also for blinding or modifications of authorised products for clinical trial purpose. Only drug products already assessed in the past are affected by this document.
- For biological/biotechnological products different procedure applies:
  In case any variation or change was implemented – complete pharmaceutical data are requested together with the list of variations and changes.
  In case no variation or change was implemented – then there is no need to submit complete pharmaceutical data, but a binding statement must be submitted declaring that no changes were implemented.

Appendix 1:

Characteristics of investigational drug product for clinical trial	
Current status (approved product)	Proposed status (drug product for new clinical trial)
1. Investigational product	

Active substance:	**Active substance:**
• Name	• Name
• Structural formula	• Structural formula
• Manufacturer	• Manufacturer
• Specification	• Specification
Finished product:	**Finished product:**
• Name, dosage form, strength	• Name, dosage form, strength
• Complete composition	• Complete composition
• Specification of excipients (e. g. reference to Pharmacopoeia)	• Specification of excipients (e. g. reference to Pharmacopoeia)
• Manufacturer	• Manufacturer
• Specification	• Specification
• Container	• Container
• Shelf-life	• Shelf-life
2. Comparator product	
Data requested for comparator product are to be found in SÚKL guideline KLH-19. In case the comparator product was assessed in the past as well and the sponsor refers to already assessed clinical trial, the same data as for the investigational product are requested.	

Appendix 2:

Statement:

Sponsor of clinical trial ……*(company, address)*

We declare that from last clinical trial

……*(protocol number of previous clinical trial)*
……*(date of submission of Application for approval/notification of clinical trial for previous clinical trial to SÚKL)*
……*(reference number of SÚKL)*
……*(number and date of approval – for biological/biotechnological product only)*

with the drug product
……*(name, stregth, dosage form)*

[*]no changes and variations to drug product quality and its manufacturing process were implemented.

*these changes and variations to drug product quality and its manufacturing process were implemented: (*describe*)

[**]no changes occured:

1) regarding TSE safety – for all material of animal origin
2) regarding virogogical safety of all material of human and animal origin

**these changes and variations were implemented:

1) regarding TSE safety – for all material of animal origin: (*describe*)
2) regarding virogogical safety of the material of human and animal origin: (*describe*)

Date, stamp and signature of responsible person of the sponsor:

[*] delete if not applicable
[**] delete if not applicable