UST-35 Version 2 Non-interventional Post-authorisation Studies, Method of Reporting

This guideline supersedes Guideline UST-35 Version 1 as of 12 January 2015.

In compliance with the provision of Section 59a, paragraph 1 of Act No 378/2007 Coll., Act on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals) (hereinafter referred to as the "Act on Pharmaceuticals"), as amended, a sponsor of a non-interventional post-authorisation study (hereinafter referred to as "NPS") not referred to by Sections 93j and 93k of this Act shall be obliged to forthwith notify the Institute of the commencement and termination of the non-interventional post-authorisation study and, within 180 days of data collection completion, submit a final report to the Institute. Sections 93j and 93k of the Act on Pharmaceuticals set forth basic principles governing the organisation of non-interventional post-authorisation safety studies.

The guideline provides more details on the definition of terms, stipulates conditions governing the conduct, provision of information and source materials to SÚKL for the purposes of potential controls in the sphere of non-interventional post-authorisation studies on human medicinal products completely or partially sponsored by the pharmaceutical industry or organisations or individuals supported by the pharmaceutical industry **which are not focused upon the monitoring of safety.**

Related regulations:

- Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended
  - Section 13, paragraph 3, letter a), item 1 and letter i), and Section 59a
- Decree No 228/2008 Coll., on the marketing authorisation of medicinal products
  - Section 17

1. Definition of terms

A non-interventional study shall mean a trial within the scope of which medicinal products are used in a regular manner and in compliance with the conditions of their marketing authorisation. Section 3a, paragraph 2 of the Act on Pharmaceuticals stipulates that for the purposes of this Act, a non-interventional post-authorisation study on a human medicinal product shall mean any study in which an authorised medicinal product is used in a regular manner and in compliance with the conditions of its marketing authorisation and in which the use of the medicinal product is not determined by the inclusion of the patient into such study, but by the decision of the attending doctor, and no additional diagnostic or monitoring procedures are applied in respect of the patients and the analysis of the collected data is carried out by means of epidemiological methods; non-interventional post-authorisation studies include, in particular, epidemiological, pharmacoeconomic, and research studies.

A more detailed specification of **non-interventional post-authorisation safety studies** is provided by Section 93j of the Act on Pharmaceuticals. More details are stipulated by guideline SÚKL PhV-3.

2. Legislative requirements

Decree No 228/2008 Coll. stipulates that the marketing authorisation holder shall be obliged to inform the Institute in electronic format about their intention to carry out a non-interventional post-authorisation study, providing the following details: :

- the name(s), surname and place of business of the marketing authorisation holder, where a natural person is concerned; or the business name and registered office of the marketing authorisation holder where a legal person is concerned;

- the identification of the product which is to be the subject of the study, by the code allocated to the product by the Institute (Section 32, paragraph 5 of the Act);
- study title;
- study identifier under which documents of the marketing authorisation holder pertaining to the study are maintained;
- the purpose, design, blinding, scope and target parameters of the study;
- study start date, anticipated date of data collection completion, analyses completion, and final report submission.

3. Method of informing SÚKL

Website www.sukl.cz, section Reports to SÚKL, contains relevant forms for the reporting of non-interventional post-authorisation studies and their completion. The notifier, i.e. the authorised person of the investigator, having completed the form, shall submit the report with attached certified electronic signature.

Non-interventional post-authorisation study initial notification form and method of its completion

Information on the medicinal product

- **SÚKL code** If the SÚKL code for the medicinal product in the study is e.g. 0000702, when completing the data into the form, enter the code of the pharmaceutical in a numerical format, i.e. 702, or in text format, i.e. 0000702.

On the basis of the entered code, further identification data about the medicinal product and about the marketing authorisation holder will be automatically defaulted in the form. If the study is conducted with several medicinal products, the form will allow for the addition of other codes through the repetition of the entry procedure.

Information on the study

- **Type of study** Select one of the provided options. Thereafter, complete the **study title, study ID according to MAH's documents, objectives of the study, and study description** (such as quantitative research, questionnaire method (Face to Face or another one), telephone research)**.**

Dates

- Complete the **study start date, expected end date of data collection, expected analysis end date, and expected date of final report submission** in the dd.mm.yyyy format.

Once you complete the entire form, attach the electronic signature of the notifier and submit the form; the data you have entered will be recorded in SÚKL's registry and a new page – "Confirmation of receipt of data regarding a non-interventional post-authorisation study" will be generated. **The confirmation contains basic data pertaining to your report and SÚKL identifier for the notified NPS**, which is to be used for the End-of-Study Notification. Your study will be also filed in SÚKL's registry under this identifier.

Non-interventional post-authorisation study end-of-study notification form

This form is intended for the notification of study completion and shall be submitted within 180 days of the completion of the study.

SÚKL identifier allocated to the study:

- Enter the **SÚKL identifier** generated when the study start was notified. After the entry of the identifier, data entered into the system during notification of the study start will be generated.

Date

- Enter the **study end date** and attach the **final report** in the pdf, doc, xml format.

Where the study was conducted and costs of healthcare professionals

- enter the identifier of the employee within the site (**IČPP**) or the identifier of the institution (**IČP**);
- the name(s), surname and address, including telephone number of the institution of the doctor who was responsible for medical decisions at the trial site;
- enter the **method of reimbursement** of the investigator's costs;
- enter the **amount of reimbursement** of the investigator's costs.

Complete these fields for individual institutions or for the investigator.