UST-35 version 1

Non-intervention post-marketing studies.

The guideline takes effect on September 1 2008

This guideline supersedes the original guideline UST-35.

In compliance with the provision of Section 92, paragraph 12 of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, **the marketing authorisation holder is obliged to inform the Institute in advance of the commencement and, thereafter, of the completion of all non-intervention studies in the Czech Republic.**

The Guideline provides more detailed definitions of terms, stipulates the conditions governing the conduct and the provision of information and source materials to SÚKL for the purposes of control in the area of non-intervention post-marketing studies on human medicinal products, which are completely or partially sponsored by the pharmaceutical industry or organisations and individuals supported by the pharmaceutical industry and which **are not intended to monitor the safety.**

Related regulations:

- Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended
- Act No 40/1995 Coll., on Advertising Regulation, as amended (hereinafter referred to as the "Act on Advertising Regulation")
- Decree No 228/2008 Coll., on Marketing Authorisation of Medicinal Products

Statutory authority:

- Section 13, paragraph 3, letter i) of the Act on Pharmaceuticals;
- Section 92, paragraph 12 of the Act on Pharmaceuticals;
- Section 2, paragraph 1, letters c) and d) of the Act on Advertising Regulation;
- Section 5, paragraph 1 of the Act on Advertising Regulation;
- Section 17 of the Decree on Marketing Authorisation of Medicinal Products.

1. Definition of terms

A non-intervention study shall mean an investigation within the scope of which medicinal products are used in a regular manner and in compliance with the terms and conditions of their marketing authorisation (Section 51, paragraph 1 of the Act on Pharmaceuticals).

A non-intervention post-marketing safety study shall mean a pharmaco-epidemiological study or clinical trial conducted in compliance with the marketing authorisation in order to identify or quantify the safety risks associated with the authorised medicinal products. For more details please refer to SÚKL Guideline PhV-3.

2. Legislative authority

Decree No 228/2008 Coll. imposes upon the marketing authorisation holder the duty to electronically inform the Institute of the intention to conduct a non-intervention post-marketing study and to provide the following details:

- Name(s), surname and the 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 object of the study by means of the code allocated to the product by the Institute (Section 32, paragraph 5 of the Act);
- Study title;
- Identification number of the study under which the study related documents of the marketing authorisation holder are maintained;
- The purpose, design, blinding, scope, and target parameters of the study;
- Start date of the study, expected date of data collection completion, completion of analyses and submission of the final report.

3. Method of informing SÚKL

The website www.sukl.cz, section Reports for SÚKL, contains the relevant forms for reporting non-intervention post-marketing studies and their completion. Once the form is completed, the reporter, i.e. the authorised person of the marketing authorisation holder or agent shall send the notification with a certified electronic signature.

The notification of commencement of non-intervention post-marketing studies form and method of completion

Information on the medicinal product

- **SÚKL code**
  If the SÚKL code of the medicinal product to be studied is, for example, 0000702, when completing the form enter the code of the pharmaceutical either in the format, i.e. as 702, or i.e. as 0000702.

On the basis of the code entered, the form will be automatically loaded with other identification details of the medicinal product and of the marketing authorisation holder.
If the study is conducted on more than one medicinal product, the form allows for the addition of other codes by repeating the entry procedure.

Information on the study

- **Type of study**
  Select one of the listed options.
  Thereafter, complete the **Study title, Study ID under which the holder's study-related documents are maintained, Purpose of the study and Study description** (e.g. quantitative research, poll-based method (Face to Face or other), telephone research)**.**

Dates

- Complete the date of study **commencement, expected data collection closure date, expected date of completion of analyses, and expected date of final report submission** in the dd.mm.yyyy format.

Once the form is fully completed, reporter's electronic signature attached, and the form posted, the details you have entered will be loaded to the SÚKL database and a new page will be generated - "Confirmation of receipt of data regarding a non-intervention post-marketing study". **The confirmation contains essential data regarding your notification and the identifier allocated to the notified NPS**, which is to be used afterwards for the Study Completion Notification. Under this identifier your study will be maintained also in the SÚKL Registry.

Non-intervention post-marketing study completion notification form

This form is intended for the notification of study completion, which has to be made within 150 days of the study completion date.

SÚKL identifier

- Enter the **SÚKL identifier** generated upon study commencement notification. Once you enter the identifier, data entered into the system upon the study commencement notification will be retrieved.

Date

- Complete the **date of study completion** and attach the **final report** in the pdf, doc, xml format.

Study site and cost reimbursements

- Enter the **Identification number of the site representative** (IČPP) **or Identification number of the healthcare site** (IČP).
- Enter the **name and surname of the doctor responsible for the conduct of the study** in the healthcare facility.
- Enter the **method of reimbursement** of investigator's costs.
- Enter the **amount of reimbursement** of investigator's costs.

These fields are to be completed for individual healthcare facilities or investigators. To repeat the process, press the "Repeat this Section" button.