## *Annex 3*

## Requirements for the Submission of Pharmaceutical Data for IMPs Previously Assessed by SÚKL

If the investigational medicinal product has already been assessed by the State Institute for Drug Control (hereinafter referred to as “SÚKL”), it is necessary to submit a sponsor's declaration specifying whether any changes have or have not been made to the pharmaceutical documentation (IMPD) compared to the previously approved version. The declaration (see Annex 1) has to contain a reference to the previously assessed pharmaceutical documentation (product name, EudraCT number of the clinical trial, SÚKL file no.).

In case no changes have been made, the following shall be submitted:

1. Sponsor's declaration (Form 1 refers);
2. For the active substance(s), finished medicinal product(s), comparator(s), and placebo: a list of all manufacturers, including Good Manufacturing Practice documents, specifications, shelf-life and storage conditions; where a protocol of autonomous shelf-life extension has been approved, this approved plan shall be also submitted (Form 2 refers).

In case changes have been made, the following shall be submitted:

1. Sponsor's declaration (Form 1 refers);
2. A list of all changes in IMPD – either in the form of a list of amended chapters and a summary of the individual changes made, or in a “now/then” table comparing the current and previous version;
3. The entire IMPD, or only those chapters that have been amended (so called “simplified IMPD”).
4. For the active substance(s), finished medicinal product(s), comparator(s), and placebo: a list of all manufacturing sites, including Good Manufacturing Practice documents, specifications, shelf-life and storage conditions; where a protocol of autonomous shelf-life extension has been approved, this approved plan shall be also submitted (Form 2 refers).

Form 1

## Sponsor’s declaration regarding the status of pharmaceutical documentation compared to the previously assessed version

Sponsor of the clinical trial



 *(company name and address)*

           

This is to declare that since the last clinical trial

|  |  |  |
| --- | --- | --- |
|  |  |  |
| *(EudraCT number)* |  | *(SÚKL file no.)* |

on medicinal product

|  |
| --- |
|  |
| *(name, strength, pharmaceutical form)* |

[[1]](#footnote-1)\*no changes to the quality of the product and its manufacturing process have been made.

[[2]](#footnote-2)\*the following changes to the quality of the product and its manufacturing process have been made: *(please specify)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Date |  | Signature of sponsor's responsible person |  | Stamp |







Form 2

## Requirements governing the submitted summary of pharmaceutical data

### Active substance

1. **Manufacturer(s)**

Specify the complete manufacturing chain (manufacturing as well as testing sites).

### Specification

Specify the current version of the specification.

### Shelf-life

Specify the approved shelf-life and storage conditions for the active substance. In case an autonomous extension protocol has been approved, provide the approved plan.

### Investigational medicinal product

1. **Manufacturer(s)**

Specify the complete manufacturing chain (manufacturing as well as testing sites, packaging and labelling sites), including Good Manufacturing Practice (GMP) documents (for requirements, please refer to the current version of guideline KLH-12).

### Specification

Specify the current version of the specification.

### Shelf-life

Specify the approved shelf-life and storage conditions for the IMP. In case an autonomous extension protocol has been approved, provide the approved plan.

### Comparator / Placebo

1. **Manufacturer(s)**

Specify the complete manufacturing chain (manufacturing as well as testing sites, packaging and labelling sites), including GMP documents (for requirements, please refer to the current version of guideline KLH-12), if the comparator/placebo has not been authorised.

### Specification

Specify the current version of the specification, if the comparator/placebo has not been authorised.

### Shelf-life

Specify the approved shelf-life and storage conditions for the comparator/placebo. In case an autonomous extension protocol has been approved, provide the approved plan.

                     

Date Signature of sponsor's responsible person

Stamp

1. \* Delete as appropriate [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)