**National Procedure**

**The applicant’s** **<joint>/****<Quality>/****<Non-Clinical>/****<Clinical>/****<Module 1>response**

**Responses to the questions raised by national competent authority**

**<Invented Name>**

**<(Active Substance)>**

**Case number:**

**Applicant:**

Tick boxes:

 [ ]  This is a LoQ 1 joint response document

 [ ]  This is a LoQ 2 joint response document

[ ]  This is a LoQ 3 joint response document

[ ]  Confirmation that all questions from the NCA have been transferred into this template without any amendments

 [ ]  Confirmation that word document and pdf document are identical

# Responses to Questions of NCA

The applicant loads the joint response template from [sukl link](https://www.sukl.sk/hlavna-stranka/slovenska-verzia/registracia-humannych-liekov/podavanie-ziadosti-a-dokumentacie-na-srl/tlaciva?page_id=5476).

The applicant prepares the responses to NCA (LoQ 1 – LoQ 3) questions as they have been introduced, by compiling them verbatim into the joint response template. Similarly, the responses in further steps of the procedure are filled in.

All sections (i.e. question, the applicant’s response, assessment of the applicant’s response, and overall summary and conclusion) should be replicated as many times as questions under each relevant topic (i.e. DP, DS; pharmacology, PK, toxicology; PK, PD, efficacy, safety, PhV; module 1). ASMF related questions are answered separately from joint response template. The applicant may choose whether one joint response document or several separate response documents are prepared. Adequate title on the front page is picked up.

The questions should follow the same order as included in the respective LoQ. Each question should be clearly identified and responded to. Questions are not allowed to be combined.

Applicant’s responses to clinical, nonclinical, quality and Module 1 issues should be provided in one joint document or as separate documents per Module. The response document(s) should be provided both in pdf format in Module 1 and in current Word format in the working doc folder, with a confirmation on the cover page that both versions are identical. This document will not be used for supporting technical documentation which will be included in the relevant Modules.

The applicant should use this template for each response prepared throughout each LoQ round of the national procedure.

## Quality aspects

NB: This document should only address responses to questions not related to the ASMF.

*Responses to questions on the Applicant’s Part and Restricted Part of the ASMF can be found in a separate document*

**Drug substance (related to additional data provided by applicant only)**

Question

The applicant prefills the NCA questions (LoQ1-3) as they have been introduced, i.e. verbatim. Numbering of the questions must be according to the respective LoQ.

The applicant’s response:

The applicant prefills their complete responses concerning each question. It is not acceptable to just refer to annexes. However, annexes may be used and referred to if large data packages, new data, space consuming tables or pictures need to be included to support the responses. Annexes referred to should be easily identified into the response.

Assessment of the applicant’s response:

Overall summary and conclusion:

These sections are to be filled by the NCA only, the fields may not be deleted by the applicant.

**Drug product**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Non-clinical aspects

**Pharmacology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Toxicology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Toxicology**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Clinical aspects

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacodynamics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Efficacy**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Safety**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacovigilance**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacokinetics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacodynamics**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Efficacy**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Clinical Safety**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

**Pharmacovigilance**

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Module 1 aspects

Question

The applicant’s response:

Assessment of the applicant’s response:

Overall summary and conclusion:

## Additional remarks from the applicant:

The changes proposed by the Applicant should be listed here, e.g. change of MAH, change of names, change of authorised persons, etc.

**LIST OF QUESTIONS <2, 3>**

To be filled-in by the NCA after assessment of the respective LoQ round.

**Quality aspects**

Question

**Non-clinical aspects**

Question

**Clinical aspects**

Question

**Module 1 aspects**

Question