**<Type II> <group of> variation<s>**

**Final Variation Assessment Report**

**<Invented Name>**

**<(Active Substance)>**

**<AB/H/{nnnn}/II/{nnn}>**

**<AB/H/{nnnn}/II/{nnn}/G>**

**<AB/H/xxxx/WS/{nnn}>**

**Marketing Authorisation Holder:**

**Date:**

*This report is effectively an update of the Preliminary Variation Assessment Report and thus retains the core structure of the initial report.*

*It is not mandatory to use this template. As alternative approach, the PVAR can be used in which amendments based on the response document have been included*

|  |  |
| --- | --- |
| Deadline for Comments by CMS (Day 80) |  |

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**ADMINISTRATIVE INFORMATION**

|  |  |
| --- | --- |
| Name of the medicinal product(s) in the RMS |  |
| Name of the active substance (INN, common name): |  |
| Pharmaco-therapeutic group (ATC code) |  |
| Pharmaceutical form(s) and strength(s) |  |

|  |  |  |
| --- | --- | --- |
| Procedure number |  | |
| Member States concerned |  |

|  |  |
| --- | --- |
| RMS contact person | **Name**  Tel:  E-mail: |
| Name(s) of the assessors | **Quality:**  **Name**  Tel:  Email:  **Nonclinical:**  **Name**  Tel:  Email:  **Clinical:**  **Name**  Tel:  Email:  **Pharmacovigilance:**  **Name**  Tel:  Email |

|  |  |
| --- | --- |
| Nature of change/s requested |  |

|  |  |
| --- | --- |
| Active Substance Master File (ASMF) Assessment Report/s  <Active substance> - <ASM> - <ASMF reference number> <ASMF holder’s version> | Attached as separate document/s <including confidential Annex 1> N/A |

# Recommendation

Based on the review of the data on ,  , the RMS considers that the <group of> variation<s> < following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008> for <medicinal product invented name> (<INN>), in the treatment of <indication>, for the following proposed changes <scope of variation>

<is approvable.>

<is not approvable unless the MAH can provide satisfactory responses to the <X> request for supplementary information. The details of these/this objections/request for supplementary information are provided in section V.>

<is not approvable since major objections (see section V.1) have been identified which preclude a recommendation for such variation and recommend that the variation to the terms of the Marketing Authorisation should be refused.>

*<The section below should only be filled out in case of variation(s) with impact on the conditions to the Marketing Authorisation>*

Conditions to Marketing Authorisation pursuant to Article 21a, 22 or 22a of Directive 2001/83/EC

*Please choose one of the following options and delete the ones not applicable*

For the condition(s)/ to the Marketing Authorisation that have been lifted as a result of the variation assessment, see section IV.

For the previously agreed condition(s) to the Marketing Authorisation that remain(s) valid and is/are still outstanding, see section IV.

For the **new condition(s)** to the Marketing Authorisation that has/have been agreed as a result of the variation assessment, see section IV.

# EXECUTIVE SUMMARY

## II.1 Scope of the variation

<Text>

# Assessment of the responses to the Member State(s) Request for supplementary information

## <Quality aspects>

<Text below relevant subheadings as detailed below> <N/A>

<III.1.1 **Major objections**>

**< III.1.1.1 Active substance (related to additional data provided by the applicant only)>**

|  |
| --- |
| The assessment of the active substance in this FVAR should only address responses to questions concerning additional information provided by the applicant, which is not included in the ASMF. In case a full Module 3.2.S for the Active Substance is provided by the applicant, assessment of responses to questions regarding the active substance should be included in this FVAR.  The assessment of the responses to questions on the Applicant’s Part and Restricted Part of the ASMF should be provided in the separate AR on the ASMF. |

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

**<III.1.1.2 Medicinal product>**

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

<III.1.2 Other concerns>

<III.1.2.1 **Active substance (related to additional data provided by the applicant only)>**

|  |
| --- |
| The assessment of the active substance in this FVAR should only address responses to questions concerning additional information provided by the applicant, which is not included in the open part as provided by the ASMF holder. In case a full dossier for the Active Substance is provided by the applicant the full assessment of the active substance should be included in this FVAR.  The assessment of the responses to questions on applicant’s part and restricted part of the ASMF should be provided in the separate AR on the ASMF. |

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

**<III.1.2.2 Medicinal product>**

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

## <Non-clinical aspects>

<Text> <N/A>

### <II.2.1 Major objections>

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

**<**II.2.2 Other concerns >

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

## <Clinical aspects (including RMP)>

<Text> <N/A>

<III.3.1 Major objections>

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

**<**III.3.2 Other concerns>

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

## <Product information>

<Text> <N/A>

<Harmonisation of PL and labelling is included as part of this procedure.>

<PL and labelling are harmonised for this product.>

<III.4.1 Major objections>

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

**<**III.4.2 **Other concerns**>

<Text> <N/A>

Question

Summary of the Applicant’s response

Assessment of the Applicant’s response

# Updated discussion <OVERALL CONCLUSION><AND BENEFIT-RISK Assessment> <AND GROUNDS FOR REFUSAL the <group OF> <VARIATION<s>>

Please also indicate

- if existing conditions to the Marketing authorisation pursuant to Article 21a, 22 or 22a of Directive 2001/83/EC remain valid or can be lifted,

-if new conditions to the Marketing authorisation pursuant to Article 21a, 22 or 22a of Directive 2001/83/EC should be imposed,

or that no conditions to the Marketing authorisation are applicable.

Please also provide a justification, by e.g. referring to other parts of the FVAR.

# <further Request for supplementary information as proposed by the RMS >

|  |
| --- |
| Questions must be divided into ‘ major objections’ and/or ‘other concerns’, which are defined as follow:  ‘ Major objections’, preclude a recommendation to the variation to the term of the marketing authorisation. In principle, one ‘ major objection’ may entail more than one question and the use of bullet points or subheadings is encouraged. It is vital that the structure and content of the objection are clear and understandable to the reader. Detailed comments may be necessary along with a reference to guidance documents  Ideally, the objection should include a clarification as to what kind of response/action by the MAH could be considered to solve the problem.  ‘Other concerns’, may affect the proposed conditions to the variation to the terms of the marketing authorisation and product information. |

## V.1 < Major objections>

<Text below relevant subheadings as detailed below> <N/A>

### <V.1.1 Quality aspects>

**<V.1.1.1 Active Substance (related to additional data provided by the applicant only)>**

|  |
| --- |
| In case the ASMF procedure is used the following should be stated in case major objections are being raised on the restricted or applicant’s part of the ASMF:  *‘For major objections on the restricted or applicant’s part of the ASMF see separate AR on the ASMF’* |

<**V.1.1.2 Medicinal Product**>

### <V.1.2 Non clinical aspects>

### <V.1.3 Clinical efficacy>

### <V.1.4 Clinical safety>

### <V.1.5 RMP>

### <V.1.6 Product information>

## V.2 < Other concerns>

<Text below relevant subheadings as detailed below> <N/A>

### <V.2.1 Quality aspects>

< **V.2.1.1. Active Substance (related to additional data provided by applicant only)**>

|  |
| --- |
| In case the ASMF procedure is used the following should be stated in case other concerns are being raised on the restricted or applicant’s part of the ASMF:  *‘For other concerns on the restricted or applicant’s part of the ASMF see separate AR on the ASMF’.* |

< **V.2.1.2. Medicinal Product**>

### <V.2.2 Non clinical aspects>

### <V.2.3 Clinical efficacy>

### <V.2.4 Clinical safety>

### <V.2.5 RMP>

### <V.2.6 Product information>

# Annex: Proposed changes to the <SmPC>, <PL>, <Labelling> ANNOTATED with THE RMS’s comments AFTER EACH SECTION>