HaRP Assessment Report
[active substance(s) / combination of substances]
[date assessment report]

*If appropriate also include:*

Only applicable to the indication(s): xxx,

Only applicable to the formulation(s): yyy,

Only applicable to the strengths: zzz.

**Recommended list of safety concerns, and reasons for maintaining each safety concern**

|  |  |  |  |
| --- | --- | --- | --- |
| **List of safety concerns (LoSC)**  | Additional PhV activities (e.g., PASS studies) | Additional RMM | Other reason for maintaining safety concern**\*** |
| **Important Identified risk** |
| 1.\*\* | [ ]  | [ ]  | [ ]  |
| 2. | [ ]  | [ ]  | [ ]  |
| …. | [ ]  | [ ]  | [ ]  |
| ***Important potential risk*** |
| 1.\*\* | [ ]  | [ ]  | [ ]  |
| 2. | [ ]  | [ ]  | [ ]  |
| ….. | [ ]  | [ ]  | [ ]  |
| ***Missing information***  |
| 1.\*\* | [ ]  | [ ]  | [ ]  |
| 2. | [ ]  | [ ]  | [ ]  |
| ….. | [ ]  | [ ]  | [ ]  |

***\**** *Other reasons may include (1) routine pharmacovigilance (PhV) activities beyond adverse reaction reporting and signal detection such as follow-up questionnaires, and (2) specific clinical measures (excluding clinical measures which have been implemented in the past and can be considered well-integrated in clinical practice).*

***\*\**** *In case of no remaining safety concern, please state:* ***“none”*** *and checkboxes are unchecked.*

**The safety concerns from the following RMPs are included in the HaRP assessment:**

1. <product name> RMP version xx (<date>), approved under < EU Procedure Number >
2. …

**In addition, the following regulatory procedures are reviewed for HaRP assessment:**

1. < Procedure Number >
2. …

**Note: Each safety concern should be assessed separately, in a stepwise manner (next pages)**

For an adequate HaRP assessment, to conclude on the (un)likely impact on the B/R of a risk, it is needed to screen available SmPC(s) and recent PSUSA procedure(s), as well as other available sources if deemed relevant, such as referrals, Epitt signals, variations etc...

**Safety concern #1 - <*wording*>**

Alternative Wordings of safety concern #1 (if any): *<Alternative wording>*

Category*: <Important Identified>; <Important Potential>; or <Missing Information>*

*(In case a safety concern is categorized differently across RMPs, more than one category can be stated)*

**Step 1) Assessing the need for maintaining a safety concern in the RMP (to be filled in first)**

|  |
| --- |
| **Table 1** Possible argument(s) for maintenance of safety concern, in line with GPV Module V |
| Ongoing routine PhV activities beyond adverse reaction reporting and signal detection, such as FU questionnaires. | [ ]  |
| Ongoing additional pharmacovigilance activities in place, such as PASS study | [ ]  |
| Specific clinical measures in place (routine RMM), excluding clinical measures which have been implemented in the past and can be considered well-integrated in clinical practice | [ ]  |
| Ongoing additional risk minimisation measures  | [ ]  |
| Other strong and compelling scientific argument(s) as to why it should remain, in line with GPV Module V, namely [to be filled in by assessor] … | [ ]  |

**In case one (or more) of the above checkboxes are checked, the safety concern should be maintained in the RMP, and the assessment of this safety concern is completed.**

**If none of the above checkboxes are checked, please proceed with the assessment below.**

**Step 2) Assessing the need for removal of safety concern (to be filled in secondly, if needed)**

|  |
| --- |
| **Table 2** Possible argument(s) for removal of safety concern in line with GPV Module V |
| Not a likely impact on B/R and the risk is not considered for risk management planning, considering the following arguments: |
| This risk is sufficiently described in the product information (SmPC, PIL) and is considered well-known in clinical practice | [ ]  |
| Based on available information in latest PSUSA(s) and/or other procedures such as referrals, EPITT signal (if relevant), the risk is not considered ‘important'.  | [ ]  |
| Further justification for removal, in line with GPV Module V, namely [to be filled in by assessor]:..For example: *there is wide post-marketing experience with the substance (more than 10 years).* | [ ]  |

**Safety concern #2 - <*wording*>**

Alternative Wordings of safety concern #2 (if any): *<Alternative wording>*

Category*: <Important Identified>; <Important Potential>; or <Missing Information>*

*(In case a safety concern is categorized differently across RMPs, more than one category can be stated)*

**Step 1) Assessing the need for maintaining a safety concern in the RMP (to be filled in first)**

|  |
| --- |
| **Table 1** Possible argument(s) for maintenance of safety concern, in line with GPV Module V |
| Ongoing routine PhV activities beyond adverse reaction reporting and signal detection, such as FU questionnaires. | [ ]  |
| Ongoing additional pharmacovigilance activities in place, such as PASS study | [ ]  |
| Specific clinical measures in place (routine RMM), excluding clinical measures which have been implemented in the past and can be considered well-integrated in clinical practice | [ ]  |
| Ongoing additional risk minimisation measures  | [ ]  |
| Other strong and compelling scientific argument(s) as to why it should remain, in line with GPV Module V, namely [to be filled in by assessor] … | [ ]  |

**In case one (or more) of the above checkboxes are checked, the safety concern should be maintained in the RMP, and the assessment of this safety concern is completed.**

**If none of the above checkboxes are checked, please proceed with the assessment below.**

**Step 2) Assessing the need for removal of safety concern (to be filled in secondly, if needed)**

|  |
| --- |
| **Table 2** Possible argument(s) for removal of safety concern in line with GPV Module V |
| Not a likely impact on B/R and the risk is not considered for risk management planning, considering the following arguments: |
| This risk is sufficiently described in the product information (SmPC, PIL) and is considered well-known in clinical practice | [ ]  |
| Based on available information in latest PSUSA(s) and/or other procedures such as referrals, EPITT signal (if relevant), the risk is not considered ‘important'.  | [ ]  |
| Further justification for removal, in line with GPV Module V, namely [to be filled in by assessor]: ..For example: *there is wide post-marketing experience with the substance (more than 10 years).* | [ ]  |