April 2022

EMA/CMDh/438/2022

*(Adopted June 2018)*

HaRP Assessment Report

[active substance]

[date assessment report]

**Recommendation\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Safety specifications** | **Additional PhV activities** | **Additional Risk minimisation measures** | **Essential Targeted Questionnaires** |
| **Important Identified risk** |  |  |  |
| 1. |  |  |  |
| 2. |  |  |  |
| …. |  |  |  |
| ***Important potential risk*** |  |  |  |
| 1. |  |  |  |
| 2. |  |  |  |
| ….. |  |  |  |
| ***Missing information*** |  |  |  |
| 1. |  |  |  |
| 2. |  |  |  |
| ….. |  |  |  |

\* The following products are included in the assessment based on the Excel table dated: dd/mm/yyyy

A)

B)

….

**Summary of assessment per safety concerns (not mandatory)**

***Safety concern #1***

| *EU Procedure Number* |  |  |  |  |  |  |  | *Ongoing aRMM\** | *Ongoing aPhV\** | *Essential TQ in place\** | ***Conclusion*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Category#* | I | I | P | P | M | N | N |  | | | |
| *Wording^* | S | S | A | A | A | n/a | n/a |  | | | |
| *Safety Concern* |  | | | | | | | No ☐ | No ☐ | No ☐ | **Remove** |
| Yes ☐ | **Remain** |
| Yes ☐ | |
| Yes ☐ | | |
| *Comments* | In absence of any management plan for the risk (ongoing aRMM, aPhV or essential TQ) the safety concern is removed, unless there is a strong and compelling scientific arguments why it should remain. | | | | | | | | | | |

\* aRMM = Additional Risk Minimisation Measures; aPhV = Additional Pharmacovigilance Activities; TQ = Targeted Questionnaire   
# Category: I = Important Identified; P = Important Potential; M = Missing Information; N = None   
^ Wording: S = Similar; A = Altered; n/a = Not Applicable

***Safety concern #2***

| *EU Procedure Number* |  |  |  |  |  |  |  | *Ongoing aRMM\** | *Ongoing aPhV\** | *Essential TQ in place\** | ***Conclusion*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Category#* | I | I | P | P | M | N | N |  | | | |
| *Wording^* | S | S | A | A | A | n/a | n/a |  | | | |
| *Safety Concern* |  | | | | | | | No ☐ | No ☐ | No ☐ | **Remove** |
| Yes ☐ | **Remain** |
| Yes ☐ | |
| Yes ☐ | | |
| *Comments* | *<In absence of any management plan for the risk (ongoing aRMM, aPhV or essential TQ) the safety concern is removed, unless there is a strong and compelling scientific arguments why it should remain>* | | | | | | | | | | |

Etc….