<date>

<doc ref>

Committee on Herbal Medicinal Products (HMPC)

Report on <Periodic><Unscheduled> review of European Union herbal monograph <(Addendum to Assessment report)> on <plant, plant part>

 *Insert botanical name of the plant according to the binomial system (genus, species, variety and author), [comma] the plant part in Latin.*

|  |  |
| --- | --- |
| Rapporteur(s) |       |
| Assessor(s) |       |
| Peer-reviewer(s) |       |

| HMPC decision on review of monograph <xxx> adopted on <date> | <date >*[to be filled by Secretariat]* |
| --- | --- |
| Call for scientific data (start and end date) | From<date > to <date> *[to be filled by Secretariat]* |
| Discussion in Committee on Herbal Medicinal Products (HMPC) |      *[to be filled by Secretariat]* |
| Adoption by Committee on Herbal Medicinal Products (HMPC)  |      *[to be filled by Secretariat]* |

Note:

* *In general, none of the main headings should be deleted or changed during the preparation of the Review report. If a heading is not used, please insert ‘not applicable’*
* *Any text should be written in the provided text boxes <Rapporteur to include text> only*
* *All instruction notes (in green) must be deleted before finalising the report*

**Review of new data**

**<Periodic review (from <****year > to <year >)>**

*In this section, the most important sources of new data are specified with tick boxes. The rapporteur should tick each box after checking the source for new data. If no new relevant data is available, the box should still be ticked after the rapporteur checked the source. In general, all boxes listed below should be ticked as part of the appropriate review process.*

* *Examples of scientific databases to be searched are presented in the* *HMPC AR template (EMA/HMPC/418902/2005)*
* *For the search in different databases the rapporteur should take into consideration as starting point for the search the last data search according to existing assessment report, or, if not available, date of first discussion of the previous assessment*
* *Extensive explanation on search is not needed; please add only relevant information, i.e. name of the database, key words used, search date and if applicable the filters used*
* *Examples of pharmacovigilance databases to be searched are EudraVigilance, VigiBase, and national databases. In general, the rapporteur in collaboration with pharmacovigilance colleagues, should at least check data from the EudraVigilance database*
* *A new market overview should be conducted using the Template for information exchange for the preparation of the assessment report supporting the establishment of EU herbal monographs and EU list entries (EMEA/HMPC/137093/2006 Rev.2). Medicinal products on the EU market can also be found in the Article 57 database:* [*Public data from Article 57 database | European Medicines Agency (europa.eu)*](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/public-data-article-57-database)
* *The rapporteur should check the* [*EURD-list*](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/periodic-safety-update-reports-psurs) *if a PSUSA-procedure has been finalised during the review period. If so, the rapporteur should liaise with Lead Member State (LMS) for the outcome of the PSUSA*
* *The rapporteur should check if feedback from experiences with the monograph during MRP/DCP procedures is available (internal HMPC document), see in MMD ‘The feedback form EU procedure/national experiences’ (located in the folder: Internal HMPC guidance documents)*
* *To assist the rapporteur to check consistency with other monographs within the therapeutic area, there is a regularly updated file in MMD ‘Final monograph overview’ (located in the folder: 7.2 Documents for information)*

**Sources checked for new information:**

Scientific data (e.g. non-clinical and clinical safety data, clinical efficacy data)

[ ]  Scientific/Medical/Toxicological databases
<Rapporteur to include the name of database, the period covered, search date, and if applicable the filters used>

[ ]  Pharmacovigilance databases

[ ]  data from EudraVigilance

[ ]  from other sources (e.g. data from VigiBase, national databases)

[ ]  Other <Rapporteur to include text>

Regulatory practice

[ ]  Old market overview in AR (i.e. check products fulfilling 30/15 years of TU or 10 years of WEU on the market)

[ ]  New market overview (including pharmacovigilance actions taken in member states)

[ ]  PSUSA

[ ]  Feedback from experiences with the monograph during MRP/DCP procedures

[ ]  Ph. Eur. monograph

[ ]  Other <Rapporteur to include text i.e. referral, data submitted by the IP>

Consistency (e.g. scientific decisions taken by HMPC)

[ ]  Public statements or other decisions taken by HMPC

[ ]  Consistency with other monographs within the therapeutic area

[ ]  Other <Rapporteur to include text>

Other

[ ]  <Rapporteur to include text>

**<Unscheduled review>**

*This section should only be used in case an unscheduled review has been triggered or otherwise should be deleted.*

Data submitted by <Insert text> to HMPC on <Insert date>

[ ]  Safety data

[ ]  Other scientific data <Rapporteur to include text>

[ ]  Regulatory practice

[ ]  Referral

[ ]  Other <Rapporteur to include text>

**Availability of new information that could trigger a revision of the monograph**

*In this section, the rapporteur should indicate if there are new information available from the review of new data that could trigger a revision of the monograph. The tick box “yes” should be ticked if new relevant data is available. The new data should be further presented in the sections specified below. A “yes” in this section means that data will be further presented in the sections below but doesn’t necessarily mean that the conclusion of the rapporteur and HMPC will be that a revision is needed.*

*For example, if new genotoxicity data is available, “yes” for both “New non-clinical safety data that could trigger a revision of the monograph” and “New data introducing a possibility of a new list entry” should be ticked. In the section “Scientific data” below, the new study will be summarised and assessed.*

*If “no” is ticked, no further information is needed in the sections below.*

|  |  |  |
| --- | --- | --- |
| *Scientific data* | Yes | No |
| New non-clinical safety data that could trigger a revision of the monograph  | [ ]  | [ ]  |
| New clinical safety data that could trigger a revision of the monograph | [ ]  | [ ]  |
| New data introducing a possibility of a new list entry | [ ]  | [ ]  |
| New clinical data regarding the paediatric population or the use during pregnancy and lactation that could trigger a revision of the monograph | [ ]  | [ ]  |
| New clinical studies introducing a possibility for new WEU indication/preparation | [ ]  | [ ]  |
| Other scientific data that could trigger a revision of the monograph | [ ]  | [ ]  |
| *Regulatory practice* | Yes | No |
| New herbal substances/preparations with 30/15 years of TU  | [ ]  | [ ]  |
| New herbal substances/preparations with 10 years of WEU  | [ ]  | [ ]  |
| New recommendations from a finalised PSUSA | [ ]  | [ ]  |
| Feedback from experiences with the monograph during MRP/DCP procedures that could trigger a revision of the monograph | [ ]  | [ ]  |
| New/Updated Ph. Eur. monograph that could trigger a revision of the monograph | [ ]  | [ ]  |
| Other regulatory practices that could trigger a revision of the monograph | [ ]  | [ ]  |
| *Consistency* | Yes | No |
| New or revised public statements or other HMPC decisions that could trigger a revision of the monograph | [ ]  | [ ]  |
| Relevant inconsistencies with other monographs within the therapeutic area that could trigger a revision of the monograph | [ ]  | [ ]  |
| Other relevant inconsistencies that could trigger a revision of the monograph  | [ ]  | [ ]  |
| *Other* | Yes | No |
| <Rapporteur to include text> | [ ]  | [ ]  |

**Summary of new references**

*In this section, the rapporteur summarises the number of new references found that were not yet available during the first/previous assessment. If further selection criteria/filters were used (e.g. PRISMA), this will be indicated. References considered to be relevant for the monograph should be full text references that have been assessed by the rapporteur. References that could trigger a revision of the monograph are references that justified a “yes” in the table above. These references should be further presented in the section “Assessment of new data”.*

During the review <Rapporteur to include number> new references not yet available during the first/previous assessment were identified. Out of these new references <Rapporteur to include number> references were considered to be relevant for the monograph and <Rapporteur to include number> references that could trigger revision of the monograph.

<Rapporteur to include number> references were provided by Interested Parties during the Call for data.

**Assessment of new data**

*In the following sections, the rapporteur should present the new information* *that could trigger a revision of the monograph (the data that justified a “yes” in the table above) and include the assessment of the data. If there is no “yes”-box ticked, there is no information to include under the headings below and the rapporteur should state “Not applicable”.*

**New scientific data** **that could trigger a revision of the monograph**

<Rapporteur to include text> or <Not applicable>

*<Assessor's comment:>*

*Data that could trigger a revision of the monograph should be briefly presented with an appropriate reference. An assessor’s comment should also be included.*

 *Examples of new scientific data that could trigger a revision of the monograph:*

* *Ames test*
* *Animal reproductive and developmental toxicity study*
* *Adverse event(s) or other safety data not included in the monograph from e.g. published case reports, clinical studies, or case reports from pharmacovigilance database assessed to be relevant to be included in the monograph (for guidance see e.g.* *Screening for adverse reactions in EudraVigilance EMA/849944/2016). In the assessment of new adverse events, MedDRA terminology and classification system should be used*
* *New efficacy data from randomised, controlled, clinical trial in indication(s) where there is a medicinal product on the EU market for more than 10 years*

*In general, unless data that could trigger a revision of the monograph, phytochemical and analytical data on the herbal substance/preparation, non-clinical pharmacological data, or pharmacokinetic data should not be presented in the Review report.*

**New regulatory practice that could trigger a revision of the monograph**

New herbal substances/preparations with 30/15 years of TU or 10 years of WEU

*In this section new preparations identified during the review should be specified. Information about MS with no products on their market should not be included in this section.*

| **Active substance** | **Indication** | **Pharmaceutical form Strength (where relevant)PosologyDuration of use** | **Regulatory Status (date, Member State)** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

This overview is not exhaustive. It is provided for information only and reflects the situation at the time when it was established.

<Rapporteur to include text> or <Not applicable>

*<Assessor's comment:>*

*Data that could trigger a revision of the monograph should be briefly presented with an appropriate reference. An assessor’s comment should also be included.*

*Pharmacovigilance actions taken in member states should also be included in this section.*

*In the case of an updated Ph. Eur. monograph, the rapporteur should check if it leads to a relevant change of the EU herbal monograph.*

* *Example that triggered the revision: The updated Hippocastani semen Ph. Eur. monograph contains a new method (LC assay), a new marker (protoaescigenin) and a new limit (min. 1.5%). Extracts included in the EU herbal monograph are standardised according to the previous Ph. Eur. monograph (aescin) and refer in content and posology to the marker. A conversion factor is available to revise EU herbal monographs accordingly.*
* *Example that did not trigger a revision: The updated Hamamelidis cortex Ph. Eur. monograph contains a higher limit than before, min. 5% tannins instead of min. 4% based on a new method. However, the HMPC monograph uses Ph. Eur. solely as quality standard reference but does not contain standardised preparations referring explicitly to a marker in content and posology.*

**Inconsistency that could trigger a revision of the monograph**

<Rapporteur to include text> or <Not applicable>

*<Assessor's comment:>*

*Data that could trigger a revision of the monograph should be briefly presented with an appropriate reference. An assessor’s comment should also be included.*

* *Rapporteur should objectively identify relevant inconsistencies with other monographs within the therapeutic area and other HMPC guidance documents*
* *Rapporteur should be careful to avoid transferring the conclusions or indications, which were based on specific data and assessment from one monograph to another*

**Other issues that could trigger a revision of the monograph**

<Rapporteur to include text> or <Not applicable>

*<Assessor's comment:>*

*Other reasons that could trigger a revision of the monograph should be briefly presented with an appropriate reference. An assessor’s comment should also be included.*

**New information not considered to trigger a revision at present but that could be relevant for the next review**

<Rapporteur to include text> or <Not applicable>

*<Assessor's comment:>*

*In this section the rapporteur could present information that is considered not to trigger a revision at the moment but that could be relevant for the next review when further information is available, e.g. a clinical study in a new indication. It refers to data that are usually relevant and included in the assessment report but do currently not change any conclusions for the existing monograph. Once a revision procedure is started in the future, they should be taken into account.*

*The rapporteur should carefully select the references, and no more than the 10 most important references should be included, to keep the Review report short and concise.*

**References**

*The rapporteur should carefully select the references as these are relevant for the decision on the review outcome.*

*If more than 20 references that could trigger a revision are found, the rapporteur may mention it and present only the 10 most important references, to keep the Review report short and concise. The list of references may exceptionally be omitted when the Review report’s content clearly points to the need for revision and evidence for new relevant information is made transparent for committee discussion and decision.*

**Rapporteur’s proposal on revision**

[ ]  Revision needed, i.e. new data/findings of relevance for the content of the monograph

<The revision is recommended because of <Rapporteur to include text>>

*If revision needed is ticked, the rapporteur should include a short summary of the most important* *findings likely to lead to a relevant change of the monograph.*

[ ]  Revision likely to have an impact on the corresponding list entry (if applicable)

*Rapporteur to check list entry (if available). And tick the box if there are findings likely to lead to relevant changes of list entry.*

[ ]  No revision needed, i.e. no new data/findings of relevance for the content of the monograph

**HMPC decision on revision**

[ ]  Revision needed, i.e. new data/findings of relevance for the content of the monograph

[ ]  No revision needed, i.e. no new data/findings of relevance for the content of the monograph