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Procedure for the review and revision of European Union herbal monographs and European Union list entries

Final

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Procedure for the review and revision of European Union herbal monographs and European Union list entries

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Executive summary

The purpose of this procedure is to enable a consistent and proportionate process in reviewing and revising all European Union herbal monographs and European Union list entries adopted by the HMPC. This document describes how to identify the criteria/reasons that trigger the revision of European Union herbal monographs and list entries and the associated procedure and timelines for both the review and the revision.

Revision 1 pertained to clarify that minor changes of wording without safety implications should not trigger a revision of an European Union list entry.

Revision 2 pertains to streamline the review and revision of European Union herbal monographs and list entries. In particular, the revision aimed for improved clarity and transparancy by covering detailed guidance on the review process, including a new review template (i.e. Annex 1). In addition, the procedure for unscheduled review, i.e. review for specific reason in the Reflection paper on the reasons and timelines for revision of final European Union herbal monographs and European Union list entries (EMA/HMPC/326440/2007), has been included.

1. Introduction

1.1. Background, scope and objectives

The main tasks of the HMPC is to prepare a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (hereafter also referred to as ' European Union list' or ' list entry') and to establish European Union herbal monographs (hereafter also referred to as 'monographs') for traditional herbal medicinal products and for well-established herbal medicinal products (Article 16f(1)and Article 16h(3) of the Directive 2001/83/EC (1)).

If an application for traditional use registration relates to a herbal substance, preparation or a combination thereof contained in the European Union list, the data specified in Article 16c(1)(b)(c) and (d) do not need to be provided (i.e. details of authorisation or registration or refusal to grant authorisation or registration, evidence of long standing use and bibliographic review of safety data).

European Union herbal monographs for the application of both the traditional use and well-established use can serve as a basis for simplified registration or bibliographical marketing authorisation applications.

The HMPC and the European Commission pointed out in their respective reports (2, 3) that the monographs adopted by the HMPC need to be periodically updated through a procedure to be put in place for retrieving and evaluating new data. Because of constant scientific progress and evolution of regulatory frameworks, monographs should be re-evaluated in a continuous process. The periodic review and, if necessary, the subsequent revision processes are essential in order to prevent European Union herbal monographs from becoming outdated[1].

When a European list entry exists, revision of an EU herbal monograph can have consequences for relevant changes in the existing list entry as well. The need for revision of the list entry following the

1 In some cases the review part of this procedure may also be used to check for new data for substances for which the previous HMPC assessment did not lead to monograph establishment (see Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and/or combinations thereof are not established -EMA/HMPC/84530/2010 as revised). If new information allowing monograph establishment in line with Chapter 2a Directive 2001/83/EC is detected, the standard procedures for development of a new monograph are followed. Once adopted, the previous public statement and supporting documents will be superseded.

revision of an EU monograph should be carefully assessed, on a case by case basis, taking into account the nature of the changes and the presence of any safety concern.

1.2. Responsibilities

In principle, the Rapporteur in charge of the review/revision of a monograph and a list entry will be the HMPC/MLWP member, who did the primary assessment. When this is not possible, the HMPC will appoint a new Rapporteur. By the same principle, a Peer-reviewer should also be appointed.

The decision on the need for revision is taken by the HMPC, based on the review report and proposal by the Rapporteur, peer-reviewed and agreed by MLWP.

1.3. Main principle

To prevent monographs and list entries from becoming outdated a three-step procedure will be followed:

Step I) Review of new data

The review of new information (new scientific data or other findings), that could be relevant for the content of a monograph, is to be initiated by time elapsed since the previous published version (Periodic review) or by data submitted to HMPC at any time (Unscheduled review).

Step II) Decision on relevance of new data and the need of revision

The revision of a monograph is initiated upon decision by HMPC following review of new information and proposal by Rapporteur. The decision to start the revision procedure has to be justified by the relevance of the reviewed data.

Step III) Revision or no revision

a) HMPC decision that revision is needed - revision according to HMPC standard procedures (4, 5, 6).

b) HMPC decision that no revision is needed - an addendum is published to the existing assessment report

The details of the procedure for the review and revision of monographs is described in the sections below and illustrated in Figure 1. The HMPC voting and publication practice of finalised documents following the review and revision process is summarised in Table 1.

When appropriate, the revision of European Union list entries will take place in parallel to or shortly after the revision of related monographs. When a European Union list entry is revised according to Article 16f of Directive 2001/83/EC (1), the Comitology procedure will be followed at the European Commission level after transmission by the EMA in order to update an existing list entry.

Table 1. HMPC voting and publication practice of finalised documents following the review and revision process.

Relevant new information - Revision	**No relevant new information – No revision**
New final documents to be adopted for publication	
New monograph	Addendum to the already published assessment report based on the Rapporteurs review report
New Opinion	
New supporting documents (assessment report and list of references) and, if applicable, overview of comments	
What happens with the already published documents	
Existing monograph, assessment report, list of references, opinion and, if applicable, overview of comments, will be replaced by the revised monograph, assessment report, list of references, a new opinion and, if applicable, new overview of comments. Replaced documents will be labelled as 'Superseded'.	Existing monograph, assessment report, list of references, opinion and, if applicable, overview of comments, remain as 'current version' on the website.

3. Step I: Review of new data

The review of new data that could be relevant for the content of a monograph, is to be initiated by the time elapsed since the previous published version (Periodic review) or by new relevant data submitted to HMPC at any time (Unscheduled review).

3.1. Periodic review

The need for revision will be considered after every 5 years since publication date of the first version (or last revised version, if applicable) of the monograph or the publication date of the last addendum to the assessment report (in case a review has been previously performed not leading to a revision) in order to ensure that European Union herbal monographs and European Union list entries are up to date (scientific state of the art).

The HMPC decides annually on the prioritisation of substances for the periodic review when drafting the work plan for the following year. The selected monographs to undergo a periodic review are included in the MLWP work plan and tracked in the Overview of assessment work - Priority list (7). After adoption of the work plan a call for scientific data (EMA secretariat) (8) and a request for a new market overview (Rapporteur) (9) will be initiated.

Timelines

When a monograph has been included in the MLWP work plan for periodic review, the HMPC secretariat informs the Rapporteur about the deadline for the review (i.e. the date the review is expected to be discussed at the HMPC plenary). In parallel the HMPC secretariat issues a call for scientific data (with 3 months deadline), using the template 'Call for scientific data for the periodic review of the monograph on' (8) after decision by HMPC.

The Rapporteur should start the review within 3 months after receiving the scientific data. If the Rapporteur is not able to start the review, the Rapporteur should inform the HMPC secretariat and a new Rapporteur shall be appointed by the next HMPC meeting. The review should preferably be finalised within 6 months. At the start of the review, the Rapporteur should send a request for a new market overview using the template 'Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and European Union list entries' (9). The timelines are illustrated in Figure 1.

Scope

To determine whether a revision of a monograph is required, the Rapporteur shall examine new data and other aspects (e.g. consistency) not yet available/existing during the previous assessment of the monograph in accordance with the 'Review template' (Annex 1) for the periodic review.

3.2. Unscheduled review

An unscheduled review may be triggered in case new relevant data brought to the attention of the HMPC by other EMA Committees/Working parties, HMPC members, National Competent Authorities, Interested Parties.

Timelines

The HMPC Secretariat informs immediately the Rapporteur of the concerned monograph on the submitted data received. The HMPC Secretariat will also inform the Rapporteur about the deadline of the review (date of the HMPC plenary). The Rapporteur should start the review within 3 months, and the review should preferably be finalised within 6 months. If the Rapporteur is not able to start the review, the Rapporteur should inform the HMPC Secretariat and a new Rapporteur shall be appointed by the next HMPC meeting. The timelines are illustrated in Figure 1.

Scope

Only the new data provided will be reviewed by the Rapporteur. The Rapporteur shall use the 'Review template' (Annex 1) for the unscheduled review.

3.3. Rapporteur's review of new data

If the new data or other aspects (e.g. consistency) not yet available/existing during the previous assessment of the monograph are likely to lead to a relevant change of a monograph, then a revision of the monograph is recommended by the Rapporteur. If the new data/findings are of low relevance for the content of the monograph then no revision is recommended. The findings of the review and the proposal of the Rapporteur on the revision is to be presented to the HMPC plenary – peer-reviewed and agreed by MLWP - using the 'Review report' (template in Annex 1) by the Rapporteur. The agreement at MLWP/HMPC should not require more than 1 meeting. The Rapporteur is responsible for sending the document to the Peer-reviewer before the meeting. The Rapporteur and Peer-reviewer should agree upon on a reasonable time-table for the peer-review process.

In the following cases, the new data/findings can be considered as relevant and may trigger a revision:

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

A revision of an existing European Union herbal monograph can be initiated by the HMPC following pharmacovigilance actions resulting from assessment at national or European level.

A revision of an existing monograph can also be triggered by new safety data (e.g. safety data provided by interested parties/Member States or new relevant safety data in literature) or pharmacovigilance data which would lead to a change in the monograph (e.g. restriction in use, contraindication, adverse event).

Newly published genotoxicity data will be assessed by the Rapporteur, e.g. to assess if a list entry can be established. When the new data support the establishment of a list entry, the monograph is to be revised and a list entry drafted.

New clinical data can trigger a revision of an existing European Union herbal monograph if the new data could be relevant for introducing a possibility for a new WEU indication or preparation.

New safety or clinical data from studies in the paediatric population or during pregnancy and lactation which would lead to a change in the monograph (e.g. age range of children) can trigger a revision of an existing European Union herbal monograph.

- **Regulatory practice**

A Member State via its HMPC member may bring to the attention of the Committee any decision taken at national level that, in its view, is relevant for a final European Union herbal monograph and European Union list entry. The HMPC will consider the need to review/revise other monographs that may be affected if revision for the reviewed monograph is agreed.

The time elapsed since the first version/last revision may allow new herbal substances/preparations that did not meet the requirement for at least 30 years documented medicinal use or the requirement for 15 years of use in the European Union to now be eligible for inclusion in the monograph.

It is also possible that a herbal substance/preparation which did not meet the requirement for at least 10 years well-established medicinal use is now eligible for inclusion in the monograph.

The Rapporteur shall reconsider the eligibility of herbal substances/preparations which was previously not included on those grounds and, if applicable, the monograph shall be revised.

- **Consistency**

When reviewing, the Rapporteur shall consider the harmonisation to other monographs in the same therapeutic area as regards the wording of the various sections or with previous HMPC decisions (e.g. new or revised thresholds for constituents of concern e.g. thujone, pulegone).

The Rapporteur may identify inconsistencies with other monograph(s) that HMPC may consider appropriate to be timely amended, if the change is considered relevant. In this case the Rapporteur proposes that the concerned monograph should be revised to be consistent with other monographs and a justification should be added to the assessment report.

Insconsistencies of minor importance do not justify the revision of a monograph. If inconsistencies with other monographs are of minor importance and do not trigger a revison, it should be explained in the review report.

- **Referrals**

As part of the outcome of a referral to the HMPC, the Committee can include in its position regarding the need to revise relevant monographs and/or list entries taking into consideration the required action agreed for the specific herbal medicinal product(s) subject of the referral.

4. Step II: Decision on relevance of new information and the need of revision

Based on the proposal and justification provided by the Rapporteur provided in the 'Review report' (template in Annex 1) - peer-reviewed and agreed by the MLWP - the HMPC should decide whether there is a need for revision of the monograph or not.

The considerations are presented to HMPC and discussed in order to prepare a decision for one of the following pathways:

a. Relevant new data:

   HMPC decides a revision of the monograph and supporting documents is needed. Information about the decision is given in the HMPC meeting report and the HMPC minutes publically available at the EMA website. The revision procedure starts immediately. The Overview of assessment - Priority list (7) and the following annual work plan of MLWP/HMPC will be updated accordingly.

b. No relevant new data:

   HMPC decides that the content of the existing monograph is still valid. The monograph is not changed, neither the assessment report nor the list of references. Instead an addendum to the existing assessment report based on the review report is to be published. Information about the decision not to revise the monograph and supporting documents is given in the addendum to the assessment report, the HMPC meeting report and the HMPC minutes made public at the EMA website.

5. Step IIIa: Revision

5.1. Scope

After the HMPC decision to start a revision, the Rapporteur shall revise the monograph, supporting documents and, if applicable, the list entry according to HMPC standard procedure (4, 5, 6). In the revision special attention should be paid to safety issues, apart from the other items which are to be considered (see section 4).

5.2. Documents to be revised and adopted

All documents should be checked against the latest templates. Beyond the EMA identity features (logo, font, etc.) and the inclusion of the herbal substance common name in all EU official languages, attention should be paid to new elements of the templates, such as new headers (e.g. monograph's section 4.6 on Fertility, pregnancy and lactation) and new sections (e.g. benefit/risk statements in the assessment report's overall conclusions).

Monograph

The revised monograph will be adopted with a new document number, showing the date of the revision under section 7 of the monograph 'Date of compilation/last revision' and on the cover page.

List entry

When a revision of a European Union list entry is proposed according to Article 16f of Directive 2001/83/EC as amended, the Comitology procedure will be followed at the European Commission level after transmission by the EMA.

HMPC Opinion

A new HMPC opinion will be adopted. There are different scenarios:

a) Opinion of the HMPC on a monograph

b) Opinion of the HMPC on a new list entry

c) Opinion of the HMPC on changes to be introduced into a list entry

d) Opinion of the HMPC to recommend the withdrawal of a list entry

Supporting documents

Assessment report

When the assessment report is modified extensively throughout all sections, the Rapporteur should consider inserting a summary of the major modifications under a section 'Major changes introduced in the <first><number as appropriate> revision'.

When one or several section(s) of a monograph are modified, the relevant parts of the assessment report shall contain the new data and an explanation/justification for the changes introduced in the monograph and, if applicable, the list entry.

List of references

The list of references will be updated with the new literature taken into consideration and revised. All new references supporting the updated assessment report should be included in the updated list of references together with, if applicable, a separate section for the references which were read but do not support the assessment report.

Overview of comments

During the 3-month public consultation of a revised monograph and, where appropriate, a list entry, comments from interested parties shall be collected and assessed. An overview of comments received on the revised monograph during the public consultation shall be prepared accordingly.

5.3. Procedure and timelines

In case the revision was decided after an unscheduled review, the call for scientific data should be published within 1 month of the HMPC decision on revision.

The duration of the revision until public consultation should preferably not exceed 12 months. The timelines are illustrated in Figure 2.

1. Discussion at MLWP and peer-review

Once agreed by the majority of MLWP members (preferably 1-2 meetings), and the Peer-reviewer, the revised draft monograph/list entry and the revised draft supporting documents are transmitted to HMPC for adoption for public consultation.

2. Adoption by HMPC for public consultation

During the following HMPC meeting the revised draft monograph/list entry and the revised draft supporting documents are adopted for public consultation.

3. Public consultation

The revised draft monograph/list entry and revised draft supporting documents are published for 3 months public consultation.

4. Discussion at MLWP and peer-review

After public consultation, the received comments will be summarised in the Overview of comments by the Rapporteur and discussed at MLWP/HMPC (preferably 1-2 meetings). After peer-review the revised draft monograph/list entry and revised draft supporting documents are transmitted to HMPC for final adoption.

5. Final adoption by HMPC

The revised draft monograph/ list entry and revised draft supporting documents are adopted by the HMPC during the following HMPC meeting.

Additional steps for revision of European Union list entries: The revised draft list entry is translated in all EU official languages (HMPC). Subsequently, the revised draft European Union list entry together with the HMPC opinion on the draft revised list entry, the assessment report, list of references, justification for changes where relevant, are transmitted to the European Commission followed by the publication of the link to the European Commission page where to access the Commission Decision on the EMA website.

6. Step IIIb: No revision

After HMPC decision that no revision is needed, an addendum to the already published assessment report based on the Rapporteur's review report (template Annex 1) adopted by the HMPC will be published. The already published monograph and supporting documents will not be changed. No new opinion is adopted nor published.

The addendum containing a summary and conclusion on the review of new data and a list of key references (following the format provided in the template for list of references) will be published within 2 months after the HMPC decision.

7. Definitions

European Union list entry: document whose purpose is to provide structured information, including information laid down in Article 16f(1) of Directive 2001/83/EC, relating to specific herbal substances or herbal preparations or combinations of substances and preparations from a given plant for use in traditional herbal medicinal products.

European Union herbal monograph: document whose purpose is to provide a scientific summary of all data available on the safety and efficacy of a herbal substance/preparation intended for medicinal use, as referred to in Article 16h(3) of Directive 2001/83/EC as amended.

Review: examination of new data and other aspects not yet available/existing during the previous assessment of the monograph to determine whether there is a need for a revision of the monograph and supporting documents. There are two possible types with different scope and triggering sources:

Periodic review: the need for revision will be considered every 5 years in order to ensure that European Union herbal monographs and European Union list entries are up to date (scientific state of the art).

Unscheduled review: the need for revision considered in case of new relevant data are brought to the attention of the HMPC by other EMA Committees/Working parties, HMPC members, National Competent Authorities, Interested Parties etc. Only the new data provided will be reviewed by the Rapporteur.

Revision: the process of revising monograph/list entry and supporting documents, new data and other aspects (e.g. consistency) not yet available/existing during the previous assessment are added to assessment report / list of references and as appropriate changes introduced in monograph/ list entry; involves adaptation of previous content to new templates and sometimes reconsideration/ modification of old parts complemented by the new information

Addendum to the assessment report: based on the review report of the Rapporteur (template Annex 1); includes a summary of availability and relevance of new data and explanation for not revising the monograph/list entry; is published after the HMPC decision finalising the review procedure without revision of previously adopted published documents

Key references: new references considered by rapporteur to be relevant for the decision on the review outcome

8. References

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 relating to medicinal product for human use

2. HMPC Status report on the implementation of the provisions of chapter 2a of Directive 2001/83/EC as amended by Directive 2004/24/EC as regards traditional herbal medicinal products - October 2006, Final (EMEA/HMPC/187219/06)
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2010/09/WC500096377.pdf

3. Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products. http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A52008DC0584

4. Procedure for the Preparation of EU monograph for herbal medicinal products with well-established medicinal use (EMEA/HMPC/182352/2005)

5. Procedure for the Preparation of EU monograph for traditional herbal medicinal products (EMEA/HMPC/182320/2005)

6. Procedure for the preparation of an entry to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/57137/2007)

7. Overview of status of HMPC assessment work – Priority list (EMEA/HMPC/278067/2006)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf

8. Procedure for calls for scientific data for use in HMPC assessment works (EMA/HMPC/1004/2006 as revised)

9. Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and European Union list entries (EMA/HMPC/124695/2011)

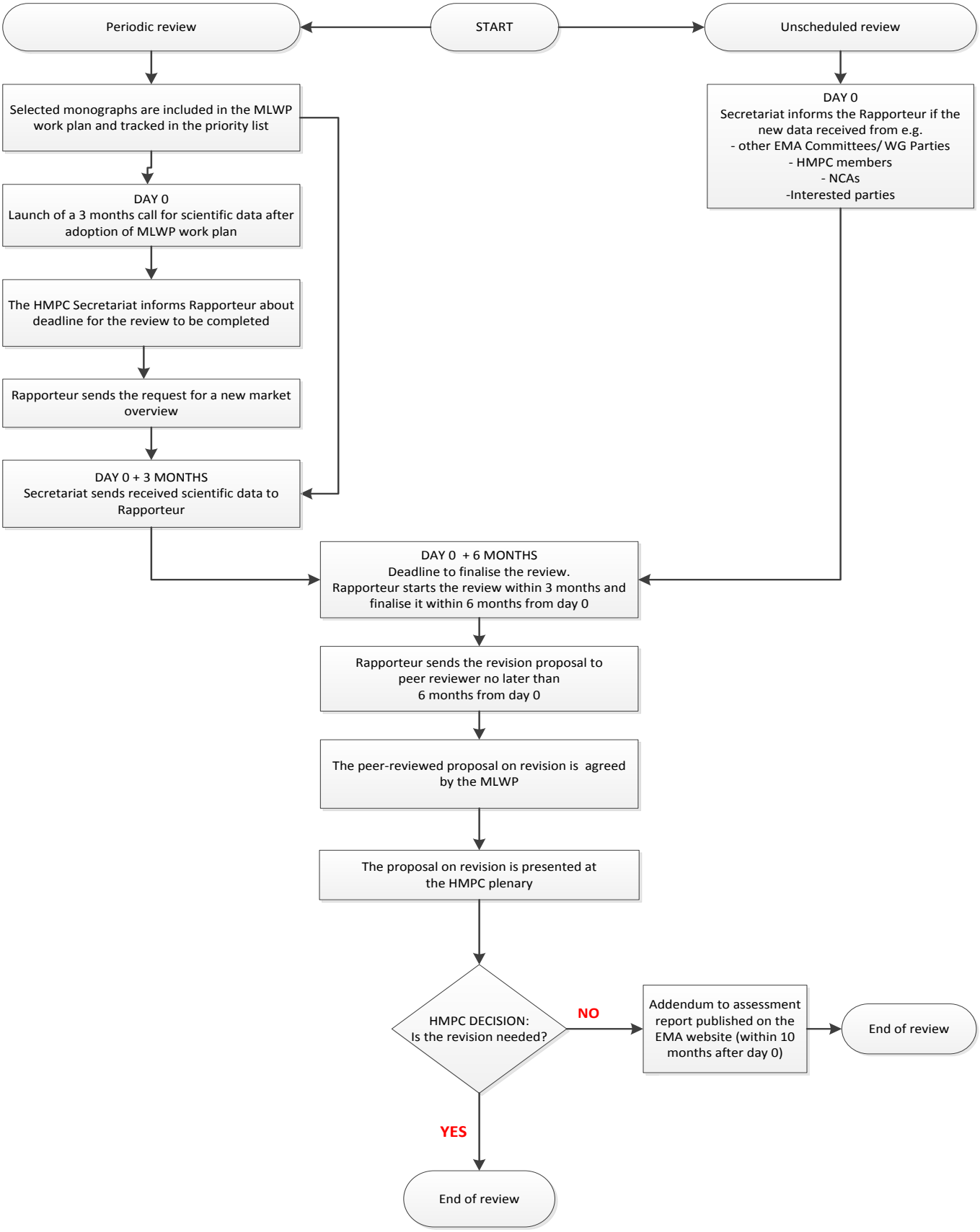

Figure 1. The process flow map of the procedure for the review of European Union herbal monographs.

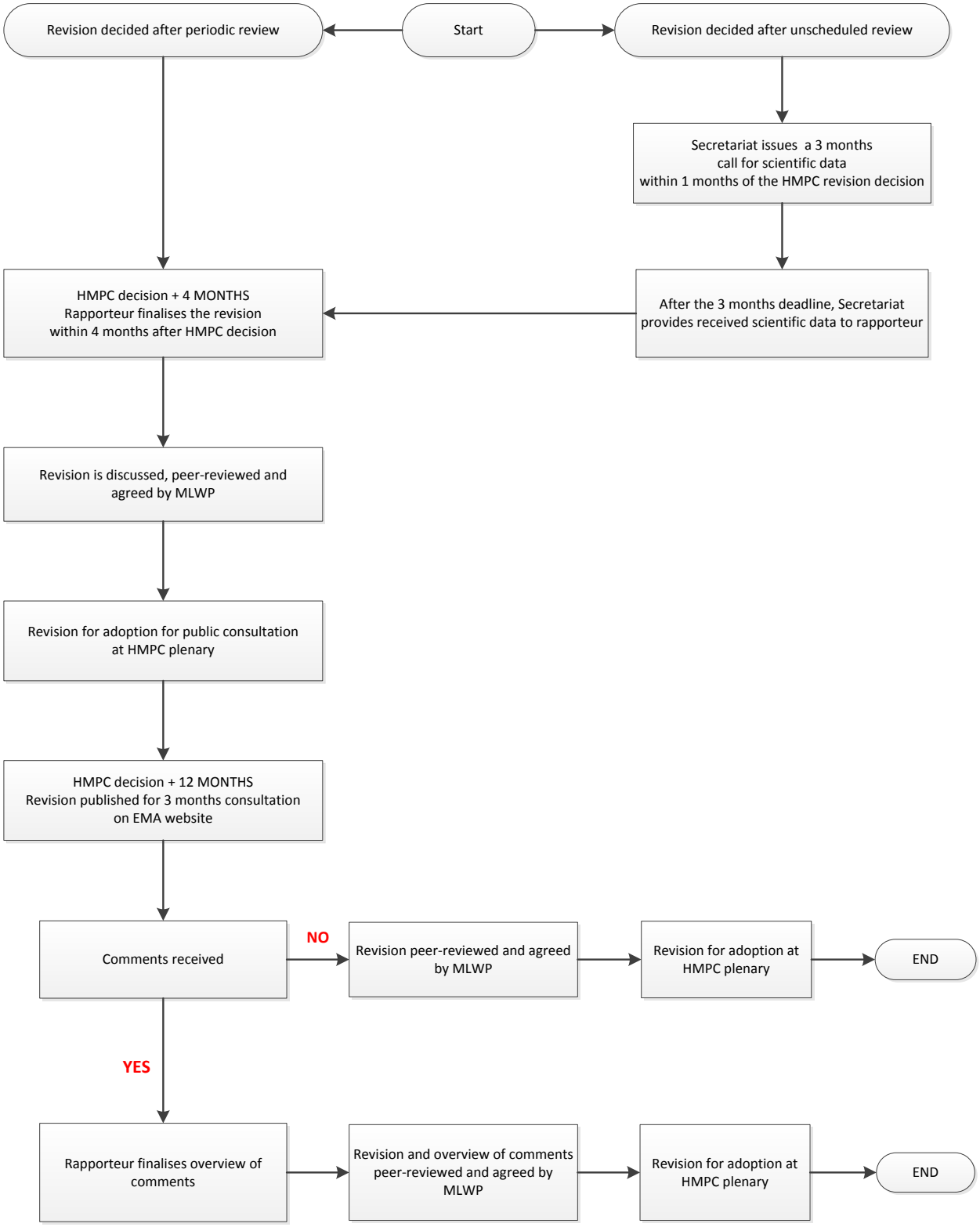

Figure 2. The process flow map of the procedure for the revision of European Union herbal monographs.

9. Annex 1 – Review report (Addendum to Assessment report) template (EMA/HMPC/568792/2017

<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	

HMPC decision on review of monograph <xxx> adopted on<date>	<date >
Call for scientific data (start and end date)	From<date > to <date>
Agreed by Working Party on European Union monographs and list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Review of new data on <plant, plant part >

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

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

- ☐ Pharmacovigilance data (e.g. data from EudraVigilance, VigiBase, national databases)
- ☐ Scientific/Medical/Toxicological databases <Rapporteur to include text, i.e. name of database, key words, search date, number of hits>
- ☐ Other <Rapporteur to include text>

Regulatory practice

- ☐ Old market overview in AR (i.e. products fulfilling 30/15 years on the market)
- ☐ New market overview (including pharmacovigilance actions taken in member states)
- ☐ Referral
- ☐ Ph.Eur. monograph
- ☐ Other <Rapporteur to include text>

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>

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

☐ Safety data

☐ Other scientific data <Rapporteur to include text>monograph

☐ Regulatory practice

☐ Referral

☐ Other <Rapporteur to include text>

Availability of new information (i.e. likely to lead to a relevant change of the monograph)

Scientific data	Yes	No
New non-clinical safety data likely to lead to a relevant change of the monograph	☐	☐
New clinical safety data likely to lead to a relevant change 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 likely to lead to a relevant change of the monograph	☐	☐
New clinical studies introducing a possibility for new WEU indication/preparation	☐	☐
Other scientific data likely to lead to a relevant change 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	☐	☐
Other regulatory practices likely to lead to a relevant change of the monograph	☐	☐
Referrals likely to lead to a relevant change of the monograph	☐	☐
New / Updated Ph. Eur. monograph likely to lead to a relevant change of the monograph	☐	☐
Consistency	Yes	No
New or revised public statements or other HMPC decisions likely to lead to a relevant change of the monograph	☐	☐
Relevant inconsistencies with other monographs within the therapeutic area that require a change of the monograph	☐	☐
Other relevant inconsistencies that require a change of the monograph	☐	☐
Other	Yes	No
<Rapporteur to include text>	☐	☐

Summary and conclusions on the review

During the review <Rapporteur to include number> new references not yet available during the first/previous assessment were identified.

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

<Rapporteur to include number> references were considered to be relevant for the assessment.

<Rapporteur to include number> references justify a revision of the monograph.

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

or < No revision is considered required because <Rapporteur to include text>

References

a) References relevant for the assessment:

<Rapporteur to list the key references>

b) References that justify the need for the revision of the monograph:

<Rapporteur to list references> or <None>

Rapporteur's proposal 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

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

Insert relevant extract from HMPC minutes:

The HMPC agreed <not> to revise the monograph, assessment report and list of references on <plant, plant part><, by consensus><, by majority>. . .

<The following members did not agree with the decision of the HMPC and were of the position that there are new data/findings of relevance for the content of the monograph and a revision is needed: <Insert name(s) of the members>.