Guidance document on the content of the <co->rapporteur's day 80 critical assessment report for generic medicinal products (Article 10.1 only)

Overview and list of questions – generic medicinal products

<Invented name>

<(Active substance)>

EMEA/H/C/<xxx>

Applicant:

This template is aimed for generic applications. If, apart from bioequivalence studies, other (non)-clinical data have been submitted, the template should be supplemented with relevant headings from the general templates of assessment report for non-clinical and clinical data.

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Rapporteur:	
Co-rapporteur:	
EPL:	
PM :	
Start of the procedure:	
Date of this report:	
Deadline for comments:	

Administrative information

<Invented> name of the generic medicinal product:	
INN (or common name) of the active substance(s):	
Applicant:	
Applied Indication(s):	
Pharmaco-therapeutic group (ATC Code):	
Pharmaceutical form(s) and strength(s):	
Rapporteur contact person: **<Co-Rapporteur contact person:>** **EMA Product Lead:** **Procedure Manager:**	**Name:** Tel: Fax: Email: **Name:** Tel: Fax: Email: **Name:** Tel: Fax: Email: **Name:** Tel: Fax: Email:
Names of the Rapporteur assessors (internal and external):	**Quality:** **Name(s)** Tel: Fax: Email: **Non-clinical:** **Name(s)** Tel: Fax: Email: **Clinical :** **Name(s)** Tel: Fax: Email:
<Names of the Co-Rapporteur assessors (internal and external):>	**Quality:** **Name(s)** Tel: Fax: Email: **Non-clinical:** **Name(s)** Tel: Fax: Email: **Clinical:** **Name(s)**

	Tel: Fax: Email:

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List of abbreviations

1. Recommendation

Based on the review of the data on quality, <safety> and <efficacy>, the Rapporteur considers that the generic application for <product name> in the treatment of <claimed indication>,

<is approvable. The Rapporteur considers some points could be resolved after the marketing authorisation (see section 5).>

<could be approvable provided that satisfactory answers are given to the "other concerns" as detailed in the List of Questions. Failure to resolve other concerns may render the application unapprovable>. <In addition, the Rapporteur recommends conditions for marketing authorisation and product information (see section 5).> <However, the answers to the "other concerns" may affect the final product information and/or other conditions for the marketing authorisation.>

<is not approvable since "major objections" have been identified, which preclude a recommendation for marketing authorisation at the present time. The details of these major objections are provided in the List of Questions (see section 4).>

<In addition, satisfactory answers must be given to the "other concerns" as detailed in the List of Questions.>

<The major objections precluding a recommendation of marketing authorisation, pertain to the following principal deficiencies :>

<Deficiencies arising from concerns over the confidential (ASM - Active Substance Manufacturer restricted) part of the DMF are mentioned in the appendix (this appendix is not supplied to the MAA). These concerns will be conveyed in confidence to the holder of the ASMF.>

Proposal for questions to be posed to additional experts

Proposal for inspection

GMP inspection(s)

[For routine GMP inspections]

<A request for GMP inspection has been adopted for the following site(s) in order to verify the GMP compliance status. The outcome of this/these inspection(s) is required for the Committee to complete its examination of the application and will be needed by Day 181.>

And/or

[For triggered GMP inspections]

<A request for GMP inspection has been adopted for the following site(s) in order to provide further product specific information. The outcome of this/these inspection(s) is required for the Committee during its examination of the application and will be needed by Day 121.>

GCP inspection(s)

[For routine GGP inspections]

<A request for GCP inspection has been adopted for the following clinical study(ies) <enter study number(s)>. The outcome of this inspection and the satisfactory responses to its findings are an integral part of this procedure and will be needed by Day 181.>

And/or

[For triggered GCP inspections]

<A request for GCP inspection has been adopted for the following clinical study(ies) <enter study number(s)>. The outcome of this inspection and the satisfactory responses to its findings are part of the responses to the LoQ and will be needed by Day 121.>

2. Executive summary

[GENERAL GUIDANCE

Give a one-page summary stating the main aspects of the Quality, Non-Clinical and Clinical aspects of the dossier and the assessors' conclusions and any important deficiencies in the dossier. If everything is standard and normal, just say so. Keep this executive summary focussed and simple.]

2.1. Problem statement

[Rationale for the product: epidemiology, main features of the disease and current therapy.]

2.2. About the product

2.3. The development programme/compliance with CHMP guidance/scientific advice

2.4. General comments on compliance with GMP, GLP, GCP

2.5. Type of application and other comments on the submitted dossier

- Legal basis

3. Scientific overview and discussion

3.1. Introduction

3.2. Quality aspects

3.2.1. Introduction

3.2.2. Active Substance

General Information

Manufacture, characterisation and process controls

Specification

Stability

Comparability exercise for Active Substance

3.2.3. Finished Medicinal Product

Description of the product and Pharmaceutical Development

Manufacture of the product and process controls

Product specification

Stability of the product

Comparability exercise for Finished Medicinal Drug Product

Adventitious agents

3.2.4. Discussion on chemical, pharmaceutical and biological aspects

3.2.5. Conclusions on the chemical, pharmaceutical and biological aspects

3.3. <Non clinical aspects>

3.3.1. Pharmacology

3.3.2. Pharmacokinetics

3.3.3. Toxicology

3.3.4. Ecotoxicity/environmental risk assessment

3.3.5. Discussion on non-clinical aspects

3.3.6. Conclusion on non-clinical aspects

3.4. Clinical aspects

3.4.1. Exemption

- ***Tabular overview of clinical studies***

3.4.2. Pharmacokinetics

Methods

Study design

Test and reference products

Population(s) studied

Analytical methods

Pharmacokinetic Variables

Statistical methods

Results

Safety data

3.4.3. Pharmacokinetic Conclusion

3.4.4. Pharmacodynamics

3.4.5. Additional data

3.4.6. Post marketing experience

3.4.7. Discussion on clinical aspects

3.4.8. Conclusions on clinical aspects

3.4.9. Pharmacovigilance system

<The Rapporteur considers that the pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.>

<The Rapporteur considers that the pharmacovigilance system as described by the applicant has the following deficiencies:<list the deficiencies>

<Provided that the deficiencies are rectified prior to the applicant placing the medicinal product on the market, the CHMP may consider that the pharmacovigilance system will fulfil the requirements. The

applicant must ensure that the system of pharmacovigilance is in place and functioning before the product is placed on the market>

3.4.10. <Risk management plan>

At Day 80 the CHMP rapporteur should have performed the first overall assessment of the application, together with identification of any major issues in the RMP. To assist the PRAC in the provision of their Advice it would be helpful for the CHMP rapporteurs to flag to the PRAC Rapporteur any particular issues and concerns that were identified during the assessment of the dossier that could impact the Risk Management Plan. This includes any particular nonclinical safety findings, gaps in the clinical pharmacology package, potential safety signals from the clinical trials, etc. At this stage it is particularly important that safety concerns are identified (important identified risks, important potential risks, important missing information). This is even more essential if these issues were not identified by the applicant in the dossier and are therefore unlikely to be reflected in the RMP.

The PRAC will provide the CHMP with its advice on the evaluation of the Risk Management Plan. This advice will in part be based on the assessments of the dossier by the (Co-)Rapporteur hence the Day 80 assessment reports will be an important source of information for the PRAC Rapporteur.

Once the PRAC Advice is received, this will be integrated into the draft D120 List of Questions for discussion by the CHMP. It is important to note that this PRAC Advice may also contain proposed questions on the Risk Management Plan to be added to the CHMP List of Questions. If the CHMP deviates from the PRAC advice then this will be discussed in the List of Questions (see guidance there).

Issues and/or concerns for consideration by the PRAC Rapporteur when assessing the RMP

Provide issues and concerns that were identified during the overall assessment of the application and that should be considered in the assessment of the Risk Management Plan by the PRAC.

4. Overall conclusion and benefit/risk assessment

The application contains adequate < quality > <non clinical> <and> <clinical> data <and> the bioequivalence has been shown. A benefit/risk ratio comparable to the reference product can therefore be concluded.

<The Rapporteur, having considered the data submitted in the application and available on the chosen reference medicinal product, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.>

OR

<The Rapporteur, having considered the data submitted in the application and available on the chosen reference medicinal product is of the opinion that the following risk minimisation activities are necessary for the safe and effective use of the medicinal product:>

[Then list activities and key elements/text as appropriate if educational material is a risk minimisation activity]

<The application contains inadequate < quality > <non clinical> <and> <clinical data> <and> the bioequivalence has not been shown. The aspects that are inadequately demonstrated are outlined in the List of Questions: >.

5. List of questions as proposed by <co->rapporteur

[Make cross-references from the actual question to what is stated in the scientific discussion. Try to limit the other concerns to what is needed to know!]

5.1. Quality aspects

Major objections

Active substance

Finished medicinal product

Other concerns

Active substance

Finished medicinal product

5.2. Non clinical aspects

Major objections

Pharmacology

Pharmacokinetics

Toxicology

Other concerns

Pharmacology

Pharmacokinetics

Toxicology

5.3. Clinical aspects

Major objections

Pharmacokinetics

Pharmacodynamics

Pharmacovigilance system

Risk management plan

Other concerns

Pharmacokinetics

Pharmacodynamics

Pharmacovigilance system

Risk management plan

6. Recommended conditions for marketing authorisation and product information

6.1. Proposed list of post-authorisation measures*

Post-authorisation measure(s)	Motivation
Proposed post-authorisation measure 1 with proposed classification:	Motivation/Background information on measure, including due date:
1.	

Post-authorisation measure(s)	Motivation
Proposed post-authorisation measure 2 with proposed classification:	Motivation/Background information on measure, including due date:
2.	
Proposed post-authorisation measure 3 with proposed classification:	Motivation/Background information on measure, including due date:
3.	
Proposed post-authorisation measure X with proposed classification:	Motivation/Background information on measure, including due date:
X.	

* Classification: Annex II (specific obligations; obligations), RMP

Proposed list of recommendations:

Description of post-authorisation measure(s)
1.
2.

6.2. Other conditions

6.3. Summary of product characteristics (SmPC)

[The rapporteur should only comment in sections specific to the generic/hybrid application(s)]

6.4. Labelling

6.5. Package leaflet (PL)

User consultation

7. QRD guidance and checklist for the review of user testing results

[Disclaimer: This guidance has been developed to provide practical information on how to evaluate user testing reports which are based on the readability testing method as described in the Annex to the EC Readability Guideline. This does not exclude the submission and evaluation of user testing reports based on other methods than the one outlined above, for which specific assessment guidance may be issued once experience has been gained.]

Useful links: More detailed practical guidance can be found in the following documents:

- *EC Readability Guideline http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/2009_01_12_readability_guideline_final.pdf*
- *"Operational procedure on Handling of "Consultation with target patient groups" on Package Leaflets (PL) for Centrally Authorised Products for Human Use http://www.emea.europa.eu/htms/human/qrd/qrdplt/27737805en.pdf*
- *"Consultation with Target Patient Groups-meeting the requirements of Article 59(3) without the need for a full test-Recommendations for Bridging" http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Consulation_PatientsGroups/CMDh_100_2007_Rev1_clean_April09.pdf*
- *"Position paper on user testing of package leaflets" http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Consulation_PatientsGroups/CMDh_234_2011.pdf*

PRODUCT INFORMATION

Name of the medicinal product:	
Name and address of the applicant:	
Name of company which has performed the user testing:	
Type of Marketing Authorisation Application:	
Active substance:	
Pharmaco-therapeutic group (ATC Code):	
Therapeutic indication(s):	
Orphan designation	☐ **yes** ☐ **no**
Rapporteur/CoRapporteur	

- Full user testing report provided ☐ yes ☐no

- Focus test report provided ☐ yes ☐no

- Bridging form provided[1] ☐ yes ☐no

[In case full user testing or focus test reports have been provided, please use the checklist for review of user testing results included in this document.]

- In case bridging form[1] has been provided, please perform the assessment in the bridging form and state the overall conclusion/recommendations below:

_____
_____
_____
_____
_____
_____
_____

[In case no user testing report or bridging form has been provided, a justification should be submitted by the applicant.]

- Is the justification for not submitting a report acceptable? ☐ yes ☐ no

[The following are examples of what are not considered valid justifications for not performing user testing:
- Administration in a hospital setting only,
- Orphan indication, therefore difficult to recruit participants from this population,

[1] QRD form for submission and assessment of user testing bridging proposals [EMA/355722/2014]

- Administration by a healthcare professional only,
- Compliance with the QRD templates,
- Long established use of the product.

Reasons *[assessor's views on acceptability or not of the justification for not submitting user testing report or bridging form]*

_____
_____
_____
_____
_____

1. Technical assessment

1.1 Recruitment

- Is the interviewed population acceptable? ☐ yes ☐ no ☐ no information

Comments/further details:

VIII.4.1 Guidance regarding Recruitment

The following points should be taken into consideration when assessing recruitment methods:

- *Is the recruitment method well defined? Is it clear that serious thought was given to the composition of the test group? (e.g. in terms of variables such as sex, age, education, previous job titles (in case of retirement, change of employment), job description and professional experience (e.g. vocational training, complete qualifications, use of information technology) in order to assess their level of education, experience with the medicinal product, existing knowledge of the complaint, access to information technologies, etc.). Is a detailed description of the subjects' profiles available?- How has the test group been recruited? Are they new users or patients, parents or carers?*
- *Is a listing of any respondents who volunteered previously in user testing and how often they have done so available?*
- *Is it clear how many people were involved in the test/test rounds?*
- *Is that number sufficient? (The PL should be tested in minimum 2 rounds of 10 participants each)*

1.2 Questionnaire

- Is the number of questions _____ sufficient? ☐ yes ☐ no ☐ no information
- Questions cover significant (safety) issues for the PL concerned? ☐ yes ☐ no ☐ no information

Comments/further details:

VIII.4.2 Guidance regarding Questionnaire

The following points should be taken into consideration when assessing the questionnaire:

- *Have the key messages for safe use been identified by the applicant? Is it clear how the questions were selected /drafted? The critical safety issues should be discussed prior to preparing the questionnaire.*
- *Do the questions cover the key messages and the following areas?*

=>General impressions of package leaflet;

=>"Diagnostic" part of PL (i.e. questions aiming to test whether the participants were able to find specific information quickly and easily in each section of the PL and to verify if they were able to understand this information correctly; the questionnaire should primarily concentrate on safety and correct use of the medicinal product and understanding of the participant to assure safe use –it must be ensured that key safety messages have been addressed);

=>Aspects such as design and layout of PL.

- *Is the number of questions sufficient? (too few or too many – e.g. 12- 15)*
- *Do the questions address "wording" aspects? Can respondents easily understand the text they are reading?*
- *Is the number of questions sufficient? (too few or too many – e.g. 12- 15)*
- *Do the questions address "wording" aspects? Can respondents easily understand the text they are reading?*
- *Do the questions provide open or pre-defined answers? Respondents should not be provided with ready-made answers which would increase the possibility of positive results. They should instead answer in their own words in order to check if they understand the information correctly. Questions should be open, should be ordered randomly to see how patients use the PL and should not be leading (however, it is good practice to start with an easy question to ease the participant). Questions that require self-assessment (example: in your opinion, is paragraph X clear?) should not be used. Questions that require a long list of answers to be given (example: "what are the adverse events of this medicinal product?") should also not be used.*

1.3 Time aspects

- Is the time given to answer acceptable? ☐ yes ☐ no ☐ no information
- Is the length of interview acceptable? ☐ yes ☐ no ☐ no information

Comments/further details:

Guidance regarding Time aspects

The following points should be taken into consideration when assessing the time aspects:

- *Is it clear how long the test lasted?*

- *Was the time given for respondents to read and answer the questions adequate? How long did the interview last? [The test should be designed in a way to last no more than 45 minutes, to avoid tiring participants]*
- *Is it clear at which point would a question be considered "not answered"? E.g. simply because the respondent took too much time to find and / or understand it? (It should not take more than 2 minutes to find the answer).*

1.4 Procedural aspects

- Rounds of testing including pilot _____ ☐ yes ☐ no ☐ no information

Comments/further details:

Guidance regarding Procedural aspects

The following points should be taken into consideration when assessing the procedural aspects:

- *Is the test based on different testing rounds? (a minimum of two test rounds, each involving 10 participants, is required: As this is an iterative process more rounds may be required in order to satisfy the success criteria; a pilot test (including 2 to 3 persons) could precede to assure the questionnaire is understood and major gaps are precluded. The PL after changes should then be tested on 20 participants in total. However, one single testing round may also be considered sufficient and acceptable on a case-by-case basis)*

A satisfactory test outcome for the method outlined above is when 90% of literate adults are able to find the information requested within the PL, of whom 90% can show they understand it, i.e. each and every question must be answered correctly by at least 81% of the participants.

In practice, it means to have 16 out of 20 participants able to find the information and answer each question correctly and act appropriately. However, it need not be the same 16 participants in each case. The success criteria will need to be achieved with each question. Results cannot be aggregated.

- *Does it makes use of modification phases in-between the testing rounds in order to maximise readability?*
- *Do interviewers use scenarios or live demonstrations (e.g. in order to increase the efficiency of the test, if appropriate.*

1.5 Interview aspects

- Was the interview conducted in well structured/organised manner? ☐ yes ☐ no ☐ no information

Comments/further details:

Guidance regarding Interview aspects

The following points should be taken into consideration when assessing the interview aspects:

- *Is the time given to the participants to read the leaflet before the interview starts clearly stated? (It should not be more than 15 minutes).*
- *Are there clear instructions for the test instructor(s)? (e.g. instructions on how to get more information from the consumers test, whether or not help should be given, etc.)*
- *Do interviewers let respondents show where information on the medicinal product can be found in the leaflet?*
- *Do they ask respondents to give their answer in their own words and not to rely on memory?*
- *Is there an internal Standard Operative Procedure (SOP) upon which the whole exercise was based?*

2. Evaluation of responses

2.1 Evaluation system

- Is the qualitative evaluation of responses acceptable? ☐ yes ☐ no ☐ no information

- Does the evaluation methodology satisfy the minimum prerequisites? ☐ yes ☐ no ☐ no information

Comments/further details:

Guidance regarding Evaluation system

The following points should be taken into consideration when assessing the evaluation system:

- *Is the assessment based on a check list covering the following 3 basic areas:*

  Whether the respondent was able:

  - *To find the information (e.g. can a respondent easily find the information on dosage?)*
  - *To understand the information (e.g. can a respondent say in his/her own words what the proper dosage and the instructions for use are?)*
  - *To use the information (e.g. "imagine you are in situation X and Y happens, what must you do?")*
- *Does the report identify difficulties (if any) in finding or understanding certain questions? If so, are these difficulties analysed? And, more importantly, are they addressed in the PL?*
- *If the company recorded the body language and behaviour of the participant, it should be described how it will influence the assessment/ results of the user testing.*

2.2 Question rating system

- Is the quantitative evaluation of responses acceptable? ☐ yes ☐ no ☐ no information

Comments/further details:

Guidance regarding Questions rating system

The following points should be taken into consideration when assessing the questions rating system:

- *How are answers evaluated? (e.g. 1= no answer, 2=wrong answer, 3=incomplete answer, 4=ambiguous answer, 5=complete and correct answer)*

3. Data processing

- Are data well recorded and documented? ☐ yes ☐ no ☐ no information

Comments/further details:

Guidance regarding Data processing

The following points should be taken into consideration when assessing the data processing:

- *Is it clear how the data are recorded? e.g. videotape, audiotape or in writing.*
- *Is it clear how long the data are kept for after the end of the study?*
- *Is the way in which they are recorded satisfactory?*
- *Have the data been processed satisfactorily? (e.g., is it clear how verbal assessments have been converted into graded answers?)*
- *Has the assessor been provided with the patient leaflets used during (different rounds of) testing?*
- *Are the revisions in the PL explained/justified? Is it also clear which comment from the participants were ignored and why?*

4. Quality aspects

4.1 Evaluation of diagnostic questions

- Does the methodology follow Readability guideline Annex? ☐ yes ☐ no ☐ no information
- Overall, each and every question meets criterion of 81% correct answers (e.g. 16 out of 20 participants) ☐ yes ☐ no ☐ no information

Comments/further details:

4.2 Evaluation of layout and design

- Follows general design principles of Readability guideline ☐ yes ☐ no

- Language includes patient friendly descriptions ☐ yes ☐ no
- Layout navigable ☐ yes ☐ no
- Use of diagrams acceptable ☐ yes ☐ no

Comments/further details:

Guidance regarding Quality aspects

The following points should be taken into consideration when assessing the quality aspects:

- *Is the report complete?*
- *Does the report clearly distinguish between quantitative and qualitative results?*
- *Is the medicinal product and the company concerned clearly indicated?*
- *Based on EC guidelines, are "diagnostic" questions (see 1.2) scoring satisfactorily?*
- *Do respondents find the layout and design of the package leaflet satisfactory?*

Special focus should be given to the following elements:

- *Writing style (simple language, short sentences, use of bullets)*
- *Type face (font size, italics/underlining, lower/upper case)*
- *Layout (spacing, white space, contrast, left justified, columns)*
- *Headings (consistent location, stand out)*
- *Use of colour (present, adequate contrast)*
- *Pictograms should be subject to user testing as it is well known that these can confuse patients.*
- *Do respondents encounter difficulties in locating and using correctly (if appropriate) the information provided in the PL?*
- *Is it clear whether general or specific comments on design and layout have been implemented? If not, has a justification been provided?*

5. Diagnostic quality/evaluation

- Have any weaknesses of the PL been identified? ☐ yes ☐ no
- Have these weaknesses been addressed in the appropriate way? ☐ yes ☐ no

Comments/further details:

Guidance regarding Diagnostic quality/evaluation

The following points should be taken into consideration when assessing diagnostic quality/evaluation:

- *Are the results (as far as possible) related to actual passages of text?*
- *Is an attempt made to explain that readers' problems arose because of certain characteristics of those passages (e.g. something was difficult to find because of a badly chosen heading; or a passage could not be understood because of a double negative; or specific information could not be applied properly because certain terms were unclear)?*
- *Was a second round revision carried out?*
- *Have weaknesses of the first round been clearly identified and addressed in the appropriate way? (e.g. questions that scored low led to modifications on the PL => introduction of stylistic changes to improve readability or removal of redundant and confusing information)*
- *Is it clear which passages have been revised and how and on the grounds of what observations in the first round?*
- *Is it also clear what observations were ignored in making the revision and why?*
- *Have modifications been tested and proved to improve readability?*
- *Is it clear what changes were made in between the different rounds (pilot, 1st and 2nd)? (e.g. summary of PL changes highlighted before and after? Has a new PL with track changes been included in the report reflecting changes between different rounds?)*
- *Have mock-ups used for each round been submitted? Is the final version the one which has been submitted with the application to be assessed?*

6. Conclusions

- Have the main objectives of the user testing been achieved? ☐ yes ☐ no
- Is the conclusion of applicant accurate? ☐ yes ☐ no
- Overall impression of methodology ☐ positive ☐ negative
- Overall impressions of leaflet structure ☐ positive ☐ negative

CONCLUSION/OVERVIEW

Guidance regarding Conclusions

A general view on the user testing performed and on the overall readability /quality of the PL should be provided here [to be used in the Day 80, Day 150 or Day 180 assessment report as appropriate and the CHMP assessment report – the complete evaluation report of the user testing results should only be included as an Annex of the Day 80 or Day 150 assessment report, as appropriate]

The following points should be taken into consideration when drafting the conclusions:

Objectives:

1. *To ensure the final PL reflects the results of testing with patients to make sure it meets their needs and can enable the patient to use the medicinal product safely and effectively. The overall quality of the PL should be the absolute focus rather than confirming a successful 81%+ for each and every question.*
2. *To assess the readability of the PL*
3. *To identify problems regarding comprehensibility and usefulness of information*
4. *To describe possible changes in the leaflet in order to improve the readability of the leaflet*
5. *To ensure that all comments, especially the ones related to design, lay-out, general impression (free text comments), have been taken into account.*

- *Does the report make it clear on what test results specific conclusions are based?*
- *Do the conclusions match the results or, given the actual results, is too favourable a picture painted?*
- *Are the conclusions clear, concise and well organised?*
- *Have the recommendations and conclusions also been incorporated in any revision of the text?*

8. Appendices

APPENDIX (As appropriate)

CHMP questions on the ASM (Active Substance Manufacturer) restricted part of the ASMF

NOTE that this annex should not be sent to the MA Applicant but only to the holder of the ASMF.

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