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Amsterdam, <insert full date>

<insert Doc.Ref.>

<Committee for Medicinal Products for Human Use (CHMP)><Committee for Advanced Therapies (CAT)>

<Updated><Rapporteur <and Co-Rapporteur> ><<CHMP><CAT> <Assessment Report><List of Questions> for <Product> on derogations applicable to similar orphan products

International Nonproprietary Name: <INN>
Procedure No. EMEA/H/C/XXX

|  |  |
| --- | --- |
| **Rapporteur:**  |  |
| **Co-Rapporteur:** |  |
| <**CHMP coordinator**(s)> ***to be included only for CAT pro****cedure****s*** |  |

*Note to the (Co)*[*Rapporteurs*](https://www.ema.europa.eu/en/glossary/rapporteur)*: Assessment reports and comments should be circulated* ***VIA EUDRALINK****.* *Product Shared Mailbox: product.name-xxxx@ema.europa.eu and product initial MAA dedicated mailbox: MAAxxxx@ema.europa.eu (xxxx refers to the product number EMA/H/C/xxxx) should always be copied.*

General guidance related to the Co-Rapporteur assessment at Day 95 (note: this does not apply to the assessment of ATMPs and Covid-19 vaccines/therapeutics dossiers for which a full Co-Rapporteur Assessment report is expected at D80. For such products the guidance referring to the D95 Co-Rapporteur Assessment report should not be taken into consideration.)

The Co-Rapporteur assessment is incorporated within the Rapporteur Overview assessment report, Product Information and when applicable into the Similarity, New Active Substance Status and Data exclusivity/Marketing Protection ARs. The Co-Rapporteur may introduce their assessment into the Quality, Non-Clinical and Clinical ARs but this is optional.

For factual data prepared by the Rapporteur in the D80 AR, the Co-Rapporteur only adds information if additional data are of relevance. In this case, the Co-Rapporteur should insert boxes for its assessment into the relevant section.

The Co-Rapporteur should incorporate its evaluation into the Rapporteur assessment report. Co-Rapporteur statements such as ‘we agree’ or ‘we do not agree’ are not necessary. The Co-Rapporteur’s evaluation is not intended as a peer review of the Rapporteur’s evaluation. The Co-Rapporteur should not adapt its evaluation based on the Rapporteur’s evaluation.

The Co-Rapporteur’s assessment is inserted in dedicated pre-inserted boxes. Please use a blue colour to fill-in these boxes to ease reading. Tracked changes or strikethrough of Rapporteur’s evaluation must not be used.

Guidance text for Co Rapporteur is in blue italics. You may print a copy of this template with the drafting note, then delete them all in one go:

Click on Ctrl-Alt-Shift-S to view the “styles” window. Select “Drafting notes (Agency) blue” and click on the icon on the right, chose “Select all XXX instances”, press the “Delete” key on the keyboard.

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Administrative information

|  |  |
| --- | --- |
| **Name of the medicinal product:** |  |
| **INN/Common name:**  |  |
| **Applicant:** |  |
| **Applied therapeutic indication(s):** |  |
| **Pharmaco-therapeutic group(ATC Code):** |  |
| **Pharmaceutical form(s) and strength(s):** |  |
| **<CHMP ><CAT> Rapporteur’s contact person:****<CHMP><CAT> Co-Rapporteur’s contact person:**For CAT procedures:**<CHMP Coordinator(s)>****EMA Product Lead:** | **Name:**Tel: Email:**Name:**Tel: Email:**Name:**Tel: Email:**Name:**Tel: Email: |
| **Names of the <CHMP><CAT> Rapporteur´s assessors:****Names of the <CHMP><CAT> Co-Rapporteur´s assessors:** | **Name:**Tel: Email:**Name:**Tel: Email: |

Declarations

**Rapporteur**

[ ]  The assessor confirms that this assessment does **not** include non-public information, including commercially confidential information (eg. ASMF, information shared by other competent authorities or organisations, reference to on-going assessments or development plans etc), irrespective from which entity was received\*.

*\*If the entity from which non-public information originates has consented to its further disclosure, the box should be ticked and there* would *be no need to add details below.*

Whenever the above box is un-ticked please indicate section and page where confidential information is located here:

**Co-Rapporteur**

[ ]  The assessor confirms that this assessment does not include non-public information, including commercially confidential information (eg. ASMF, information shared by other competent authorities or organisations, reference to on-going assessments or development plans etc), irrespective from which entity was received\*.

*\*If the entity from which non-public information originates has consented to its further disclosure, the box should be ticked and there* would *be no need to add details below.*

Whenever the above box is un-ticked please indicate section and page where confidential information is located here:

1. Introduction

On <date> the <rapporteurs><CHMP> <CAT> concluded that the medicinal products <name of product> (INN of the product) and <name of the authorised orphan product> (INN of authorised product) are similar as defined in Article 3 of Commission Regulation (EC) No 847/2000 (attachment 1). Furthermore, Regulation (EC) No 141/2000 states:

* Article 8(1)

"Where a marketing authorisation in respect of an orphan medicinal product is granted […], the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product..." unless one of the three derogations laid down in Article 8(3) applies.

* Article 8(3):

By way of derogation from paragraph 1, and without prejudice to intellectual property law or any other provision of Community law, a marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if:

1. the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the second applicant, or
2. the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or
3. the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.

<A marketing authorisation>< An extension of the marketing authorisation><An authorisation>for <name of product> can therefore not be granted with the currently proposed indication, unless one of the above derogations are fulfilled.

In line with the above-mentioned legislation, the applicant provided a derogation report:

<The <applicant> <MAH> provided a report justifying that their <initial marketing application of> <extension application of> <extension of indication of> <name of product> is clinically superior to the authorised orphan medicinal product,<name of the authorised orphan product>.>

<The <applicant> <MAH> provided a report that the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product.>

This report reflects the <rapporteurs><CHMP> <CAT> assessment of the report on the claimed derogations.

1. <Clinical superiority assessment>

Consideration should be given to the applicant’s arguments for claiming superiority; i.e. if these are based on theoretical assumptions, or are head-to-head (non-)clinical comparisons. The design, conduct, reproducibility and results of such comparative studies or tests are to be evaluated. If no comparison data showing superiority, or justification for the lack of such data are presented, the applicant should be asked to address this in a response to the List of Questions.

For the Co-Rapporteur assessment:

The Co-Rapporteur should reflect its independent assessment into the Rapporteur AR.

It is not a “peer review” of the Rapporteur’s evaluation i.e. statements such as ‘we agree’ or ‘we do not agree’ are not needed.

In this section, for the Co-Rapporteur assessment separate boxes have been introduced in relevant sub-sections (discussion and conclusion) below.

The Co-Rapporteur may add further information in the factual section prepared by the Rapporteur. In this case, the Co-Rapporteur should insert information in a dedicated box for the specific section.

If the Co-Rapporteur assessment leads to new questions, removal or modification of questions proposed by the Rapporteur, including change of categorisation (MO, OC), the Co-Rapporteur should insert its assessment in the dedicated box for the relevant section but should not use strikethrough or track-changes mode in the questions from the Rapporteur.

* 1. Efficacy

**Applicant’s position**

**<Rapporteur><CHMP> <CAT> position**

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

* 1. Safety

**Applicant’s position**

**<Rapporteur><CHMP> <CAT> position**

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

* 1. Major contribution to diagnosis or patient care

**Applicant’s position**

**<Rapporteur><CHMP> <CAT> position**

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

1. <Assessment on the inability of <applicant/MAH> to supply sufficient quantities of the <name of the authorised orphan product>>
	1. Outline of supply shortage of the <name of the authorised orphan product>

**Applicant’s position**

**<Rapporteur><CHMP> <CAT> position**

[This will be a question to be addressed by the applicant/MAH of the authorised orphan product.

Points to consider:

supply and availability of the product to the patients in the EU, local/national situations, declaration of the real causes of supply problem, nature and extent of the problem, consequences for the applicant/MAH, manufacturing or other changes/rectifications conducted or planned, regulatory actions, revocation and suspension of MA, etc…]

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

* 1. Demand and supply of the <name of the authorised orphan> in the EEA

**Applicant’s position**

**<Rapporteur><CHMP> <CAT> position**

[This will be a question to be addressed to the applicant/MAH of the authorised orphan product.

Points to consider: response to the current demand for the orphan product in the EEA, sales, orders and supply numbers, compassionate use, on-going clinical trials, planned batch releases and supply strategy in the EEA countries, duration of shortage, etc., in case of shortage, its duration, extent and cause.]

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

* 1. Current treatment situation for the orphan condition

**Applicant’s position**

**<Rapporteur><CHMP> <CAT> position**

[These questions are to be addressed to patients’ and physicians’ organisations; depending on the disease, they might also be addressed to the member states (e.g. for questions related to registries).]

- How many patients within your remit do not receive < orphan medicinal product> as prescribed.

- If patients are not treated/sub-treated, is this due to an inability of < MAH> to supply <orphan product>

Points to consider: Numbers of patients currently treated with the orphan product with a full dose, with an adjusted dose or frequency of dosing, availability of the orphan product under different system (compassionate use), previous experience with orphan product shortage in this or similar indication, experience with “switching” patients to other treatment, etc…]

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

1. Conclusion
	1. <Conclusion on clinical superiority>

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

* 1. <Conclusion on the inability of <applicant/MAH> to supply sufficient quantities of the <name of the authorised orphan product>>

Co-Rapporteur assessment

Please always insert the Co-Rapporteur assessment even if there is agreement with the Rapporteur.

1. <List of questions>

For the Co-Rapporteur assessment:

When there is a proposal to have new questions, remove questions from the Rapporteur or amend them, such proposal must always be introduced in a separate box ideally within each relevant section. Track-changes and strikethrough must not be used. These amendments should always be justified in the relevant sections of the report with a cross reference to the LoQ.

1. <Assessment on the responses to the list of questions>
2. <Final conclusion>
3. Attachments
	1. <CHMP> <CAT> assessment report for <name of the product> on similarity with <name of the authorised orphan product>.