September 2022

CMDh/422/2020 Rev. 1

[The Applicant should use this template to prepare their report on potential similarity with authorized orphan medicinal product(s) under market exclusivity in the EU. The filled in template (PDF-version) should be added in the application in Module 1.7.1; the Word-version should be added in the “Working documents” folder of the application. The RMS will then use the document in the preparation of their Assessment Report on Similarity.
As Module 1.7.1 forms part of the legal submission, the applicant is obliged to ensure the information provided is accurate, notwithstanding that the RMS will validate certain sections (i.e. regulatory administrative and technical checking exercise), in the preparation of the AR.

If an update of Module 1.7.1 is necessary, the applicant is requested to include the new information of this update in the (initial) “RMS Assessment Report on Similarity” and clearly indicate which additions have been made. The PDF-version of this updated document should be added in Module 1.7.1 and the Word-version should be added in the “Working documents” folder.

Note: the applicant is not allowed to change the text in the (initial) “RMS Assessment Report on Similarity”, they should only add the new information and the corresponding tick box below should be ticked.]

**<Decentralised><Mutual Recognition><Repeat Use> <Variation> Procedure**

**Module 1.7.1 Similarity report**

[If this document is used for the AR, the RMS should change the title to “RMS Assessment Report on Similarity”]

**<Invented Name>**

**<(Active Substance)>**

**AB/H/{nnnn}/D/{nnn}**

**Applicant:**

|  |  |
| --- | --- |
| **Reference Member State** |       |
| **Start of the procedure:**[To be filled in by RMS] |       |
| **Date of this report:**[To be filled in by RMS] |       |

Tick boxes:

 [ ]  This is the initial Module 1.7.1 Similarity Report

 [ ]  This is an update of the (initial) Module 1.7.1 Similarity Report

☐ In case of an update: Confirmation that the (initial) RMS Assessment Report on Similarity is used as a base without any amendments.

 [ ]  Confirmation that word document and pdf document are identical

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1. Introduction

[The text below should be filled in by the applicant.

The RMS will validate the information before the AR on Similarity is circulated to CMS.]

The <applicant/MAH> has submitted an application for <an initial marketing authorisation> <an extension application> <an extension of an indication> of the medicinal product <name of product> using the <decentralised/mutual recognition/repeat use/variation> procedure for the following indication<s>:

* <list of indication(s) applied>

[The following table of currently authorised orphan medicinal products should be filled in by the applicant.

Similarity needs to be assessed against all authorised orphan products for an indication related to the therapeutic indication applied for.

If necessary, the applicant should create separate sections for each orphan indication (if more than one) and list all orphan medicines in the table for each indication. This could mean listing a product twice if it has two relevant Orphan Drug Designations (ODDs).

The RMS will validate the information before the AR on similarity is circulated to CMS.]

**Table 1: Designated Orphan medicinal product(s) that have been granted a marketing authorisation in the EU**

|  | **Currently authorised orphan medicinal products** |
| --- | --- |
| **Name of the authorised orphan product (active substance)**  | **MAH** | **MA/EU product number** | **Designated orphan indication** | **EU Orphan designation number** | **Date of EC decision** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Potential conflict with authorised orphan-designated medicinal products protected by market exclusivity in the EU**

According to Article 8(1) of Regulation (EC) No 141/2000, where a marketing authorisation in respect of an orphan medicinal product is granted, the Union and the Member States shall not, for a period of 10 years, without prejudice to intellectual property law or any other provision of European Union law, 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.

This Report will address the potential similarity between <name of product> (active substance) and the currently authorised orphan medicinal product(s) for the treatment of the orphan diseases/indications listed in Table 1 above, taking into account the Commission Regulation (EC) No 847/2000 and the Guideline on aspects of the application of Article 8(1) and 8(3) of Regulation (EC) No. 141/2000: Assessing similarity of medicinal products versus authorised orphan medicinal products benefiting from market exclusivity and applying derogations from that market exclusivity (2008/C 242/08).

1. Similarity assessment

[Table 2 should be filled in by the applicant.

For ease of handling the page formatting may be changed to landscape for this Table.

The RMS will validate the information before the AR on Similarity is circulated to CMS.]

**Table 2: Summary table of medicinal product under evaluation and authorised orphan medicinal product(s):**

|  |  |
| --- | --- |
| **Medicinal product under evaluation**  | **Authorised orphan medicinal product**  |
| **Name of product:** <Name of product>**Active substance:** <active substance>**Therapeutic indication:** <Therapeutic indication>**Mechanism of action:** <Mechanism of action>**Structure:** <Structure>**Other important quality information:** <Other important quality information:> [e.g molecular formula; relative molecular mass, functional groups; molecular formula; type of atoms; etc.]**Class of biological product:** <class of biological product>[particularly if mentioned in the legislation e.g. article 3.3(c)2 of Regulation 847/2000] | **Name of product:** <Name of product>**Active substance:** <active substance>**Therapeutic indication:** <Therapeutic indication>**Mechanism of action:** <Mechanism of action>**Structure:** <Structure>**Other important quality information:** <Other important quality information:> [e.g molecular formula; relative molecular mass, functional groups; molecular formula; type of atoms; etc. ]**Class of biological product:** <class of biological product>[particularly if mentioned in the legislation e.g. article 3.3(c)2 of Regulation 847/2000] |
| **Name of product:** <Name of product>**Active substance:** <active substance>**Therapeutic indication:** <Therapeutic indication>**Mechanism of action:** <Mechanism of action>**Structure:** <Structure>**Other important quality information:** <Other important quality information:> [e.g molecular formula; relative molecular mass, functional groups; molecular formula; type of atoms; etc. ]**Class of biological product:** <class of biological product>[particularly if mentioned in the legislation e.g. article 3.3(c)2 of Regulation 847/2000] |
| **Name of product:** <Name of product>**Active substance:** <active substance>**Therapeutic indication:** <Therapeutic indication>**Mechanism of action:** <Mechanism of action>**Structure:** <Structure>**Other important quality information:** <Other important quality information:> [e.g molecular formula; relative molecular mass, functional groups; molecular formula; type of atoms; etc. ]**Class of biological product:** <class of biological product>[particularly if mentioned in the legislation e.g. article 3.3(c)2 of Regulation 847/2000] |

* 1. Therapeutic Indication

Applicant´s position

[This section should be filled in by the applicant.
In case there are several indications, the applicant should address each indication separately.
If the applicant claims to cover a different therapeutic indication, which is a different subset of the designated orphan indication for the authorised orphan medicinal product, the applicant has to establish that the difference between the two subsets is clinically meaningful.

If there is an overlap of the target populations of two allegedly different therapeutic indications, the applicant has to provide an estimate of its extent.

In case multiple authorised orphan medicinal products are identified, the similarity of the indication should be discussed for each authorised orphan medicinal product.]

RMS position

[This section should be filled in by the RMS]

The RMS should shortly discuss the arguments provided by the Applicant in Module 1.7.1.

If there is an overlap of the target populations of two allegedly different therapeutic indications, the applicant would have to provide an estimate of its extent. The extent of the overlap will be a relevant factor for the RMS to establish whether the claim for two different therapeutic indications can be upheld.

For the purpose of similarity, RMS does not look at the orphan indication but at the therapeutic indication that comes within.

* 1. Mechanism of action

Applicant´s position

[This section should be filled in by the applicant.

In case multiple authorised orphan medicinal products are identified, the similarity of the mechanism of action should be discussed for each authorised orphan medicinal product.]

RMS position

[This section should be filled in by the RMS]

The RMS should shortly discuss the arguments provided by the Applicant in Module 1.7.1. Please note that two active substances may only be considered to have the same mechanism of action, provided that both share the same pharmacological target (receptor, enzyme, channel, carrier or an intracellular coupling process) and pharmacodynamics effect (primary pharmacodynamics effect of the active substance).

* 1. Molecular Structure

Applicant´s position

[This section should be filled in by the applicant.
In case multiple authorised orphan medicinal products are identified, the similarity of the molecular structure should be discussed for each authorised orphan medicinal product.]

RMS position

[This section should be filled in by the RMS]

The RMS should shortly describe the chemical, physico-chemical-biological structure of the active substance(s) under evaluation and of the active substance(s) of the orphan medicinal product(s) authorised. Furthermore, the RMS should highlight the main differences between the active substance(s) of the orphan medicinal product(s) already approved and the active substance under evaluation in terms of chemical, physico-chemical-biological features. In the final conclusion the RMS should reflect the reason why the two active substances are similar or not similar in the context of orphan medicinal product legislation i.e. they share or do not share the same principal molecular features (but not necessarily all of the same molecular features).

For biological active substances, examples of similar active biological substances in the context of orphan medicinal products is given in article 3.3(c)2 of Regulation 847/2000.

1. Conclusion of the RMS

[The columns “Medicinal product under evaluation” and “Authorised Orphan medicinal product” of Table 3 should be filled in by the applicant.

The RMS will validate the information before the AR on Similarity is circulated to CMS. The RMS will fill in the column “Final conclusion”.]

The position of the RMS on similarity with authorised products is summarised in the table below:

**Table 3: Similarity assessment [[1]](#footnote-1)**

| **Medicinal product under evaluation**  | **Authorised Orphan medicinal product**  | **Final conclusion**  |
| --- | --- | --- |
| <(Name of product> | <Name of product> | <SIMILAR><NOT SIMILAR> based on <therapeutic indication> <mechanism of action> <principal molecular structure> |
| <Name of product> | <SIMILAR><NOT SIMILAR> based on <therapeutic indication> <mechanism of action> <principal molecular structure> |
| <Name of product> | <SIMILAR><NOT SIMILAR> based on <therapeutic indication> <mechanism of action> <principal molecular structure> |

[The text below should be filled in by the RMS]

Having considered the arguments presented by the applicant and with reference to Article 8 of Regulation (EC) No 141/2000, <name of product> is considered<similar> <not similar> (as defined in Article 3 of Commission Regulation (EC) No. 847/2000) to the authorised orphan medicinal products listed in Table 1 above.

<Therefore, with reference to Article 8 of Regulation (EC) No. 141/2000, the existence of any market exclusivity for these product<s>, <prevents> <does not prevent> the granting of the marketing authorisation of <name of product>. This finding is without prejudice to the outcome of the scientific assessment of the marketing authorisation application.>

1. <List of questions>
2. <Assessment on the responses to the list of questions>
3. <Final conclusion>
1. All products stated in Table 2 should be included in this table on a separate line. [↑](#footnote-ref-1)