[insert only for CHMP/CAT adopted doc & add EMA header and footer]

Amsterdam, <insert full date>

<insert Doc.Ref.>

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

<Rapporteur <and Co-Rapporteur> <Joint><CHMP><CAT><Assessment report <List of questions> on the claim of new active substance (NAS) status of <active substance> contained in <Product name>

International non-proprietary name or common name: <…>

Procedure no.: EMEA/H/C/<XXX>

Applicant:

| <CHMP><CAT> Rapporteur: |  |
| --- | --- |
| <CHMP><CAT> Co-rapporteur: |  |
| <CHMP coordinator(s)> *to be included only for CAT procedures* |  |
| EMA PL: |  |
| Start of the procedure: |  |
| Date of this report: |  |
| Deadline for comments: |  |

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 on the use of this template**

The CHMP/CAT (Co)Rapporteurs are responsible for the circulation of this assessment report together with the other ARs in line with the evaluation TT. Further to receipt of comments from committee members, the Rapporteur should update the AR; the circulation of a Joint Rapp-Corapp AR should be made at the time of the circulation of the draft D120 LOQ. If so, the Overall conclusion should be updated in order to integrate the comments/potential clarifications received and reflect the final position of the (co)Rapporteurs. The AR will then be adopted by the relevant committee(s)at procedural milestones (D120 LOQ).

If a LOQ is proposed, the relevant sections in the AR should be used for the LOQ and the detailed assessment of responses to it and circulated with D150 JAR. These sections could either be repeated if a list of outstanding issues is adopted on the NAS claim. If necessary, an updated discussion and conclusion sub-section can be introduced at the end of the assessment of responses to the LOQ or LoOI; alternatively, the body of the AR could be updated. In all cases of an updated AR, the Overall conclusion should be amended, as appropriate.

General guidance related to the Co-Rapporteur assessment at Day 95:

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 this NAS 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.

The consolidated List of Questions will be prepared after the peer review teleconference between both Rapporteurs and EMA. The Rapporteur will review the Co-Rapporteur’s evaluation and MS comments when preparing the consolidated draft Day 120 LoQ.

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.

Table of contents

[Administrative information 4](#_Toc73025074)

[Declarations 4](#_Toc73025075)

[1. Executive summary 5](#_Toc73025076)

[1.1. Problem statement 5](#_Toc73025077)

[2. Scientific evaluation 5](#_Toc73025078)

[2.1. <Quality aspects> 5](#_Toc73025079)

[2.1.1. Discussion on quality aspects 5](#_Toc73025080)

[2.1.2. Conclusions on quality aspects 5](#_Toc73025081)

[2.2. <Non-clinical aspects> 5](#_Toc73025082)

[2.2.1. Discussion on non-clinical aspects 5](#_Toc73025083)

[2.2.2. Conclusions on non-clinical aspects 5](#_Toc73025084)

[2.3. <Clinical aspects> 5](#_Toc73025085)

[2.3.1. Discussion on clinical aspects 5](#_Toc73025086)

[2.3.2. Conclusions on clinical aspects 5](#_Toc73025087)

[3. Overall conclusions 6](#_Toc73025088)

[4. List of questions 7](#_Toc73025089)

[4.1. <Quality aspects> 7](#_Toc73025090)

[4.2. <Non-clinical aspects> 7](#_Toc73025091)

[4.3. <Clinical aspects> 7](#_Toc73025092)

[5. <Assessment on the responses to the list of questions> 7](#_Toc73025093)

[5.1. <Quality aspects> 7](#_Toc73025094)

[5.2. <Non-clinical aspects> 7](#_Toc73025095)

[5.3. <Clinical aspects> 7](#_Toc73025096)

[6. <Final conclusion> 7](#_Toc73025097)

Administrative information

| **Name of the medicinal product:** |  |
| --- | --- |
| **Applicant:** |  |
| **Active substance:** |  |
| **International Non-proprietary Name/Common Name:** |  |
| **Pharmaco-therapeutic group**  **(ATC Code):** |  |
| **Therapeutic indication(s):** |  |
| **<CHMP><CAT>Rapporteur’s contact person:**  **<CHMP> <CAT> Co-Rapporteur’s contact person:**  **EMA Product Lead:** | **Name:**  Tel:  Email:  **Name:**  Tel:  Email:  **Name:**  Tel:  Email: |
| **Names of the <CHMP>CAT>(Co)Rapporteur assessors (internal and external):** | **Name(s):**  Tel:  e-mail: |

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 (e.g. 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 (including the Product Information document) here:

1. Executive summary
   1. Problem statement

This application was submitted in accordance with Article 8(3) of Directive 2001/83/EC and it contained discussion and/or data as to why the active substance <active substance> should be regarded as new.

<The applicant requested the active substance {*active substance*} contained in the above medicinal product to be considered as a new active substance, as the applicant claims that it is not a constituent of a medicinal product previously authorised within the European Union.>

[or]

<The applicant requested the active substance {active substance} contained in the above medicinal product to be considered as a new active substance in comparison to {active substance} previously authorised in the European Union as {*name of the medicinal product authorised*}, as the applicant claimed that {*active substance*} differs significantly in properties with regard to safety and/or efficacy from the already authorised active substance.>

[or]

<The applicant requested the radiopharmaceutical substance *<active substance >* to be considered as a new active substance as <it is a constituent radionucleide or a ligand- not previously authorised in a medicinal product in the European Union> <the coupling mechanism to link *<active substance>* and <the radionuclide> has not been authorised previously in the European Union>.>

1. Scientific evaluation

In this section, for the Co-Rapporteur assessment separate boxes have been introduced in relevant sub-sections (discussions and conclusions) below. For factual data, Co-Rapporteur only to add if additional data are of relevance. In this case, please insert relevant boxes for co-Rapporteur assessment as applicable.

* 1. <Quality aspects>
     1. Discussion on quality aspects

Co-Rapporteur assessment:

Co-Rapporteur discussion should be inserted here.

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

* + 1. Conclusions on quality aspects

Co-Rapporteur assessment:

Co-Rapporteur conclusion should be inserted here.

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

* 1. <Non-clinical aspects>
     1. Discussion on non-clinical aspects

Co-Rapporteur assessment:

Co-Rapporteur discussion should be inserted here.

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

* + 1. Conclusions on non-clinical aspects

Co-Rapporteur assessment:

Co-Rapporteur conclusion should be inserted here

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

* 1. <Clinical aspects>
     1. Discussion on clinical aspects

Co-Rapporteur assessment:

Co-Rapporteur discussion should be inserted here.

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

* + 1. Conclusions on clinical aspects

Co-Rapporteur assessment:

Co-Rapporteur conclusion should be inserted here.

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

1. Overall conclusions

For Co-rapporteur assessment, please use a dedicated box to insert the relevant conclusion from the proposals listed below.

1. For opinions where the applicant claimed that the compound is a new active substance in itself and where no further information should be provided to conclude on the applicant’s claim

<Based on the review of available data on the active substance, the <Rapporteur> <CHMP><CAT> considers that <active substance> is <not> to be qualified as a new active substance in itself as it is <not> a constituent of a medicinal product previously authorised within the European Union.

In case NAS in itself is denied, the following should be added:

<{Active substance} is contained in the marketing authorisation {invented name} which was authorised in the European Union on {date of authorisation}.>

This is without prejudice to the possibility for the applicant to provide as part of the responses to the LoQ/LoOI evidence to demonstrate that this active substance differs significantly in properties with regard to safety and efficacy from the previously authorised substance.

*2. For opinions where the applicant claimed that the compound is a new active substance in comparison to a known isomer/mixture of isomers/complex /derivative/salt of a chemical substance or biological previously authorised as a medicinal product in the European Union and where no further information should be provided to conclude on the applicant’s claim*

<Based on the review of data on the quality, non-clinical and clinical properties of the active substance, the <Rapporteur> <CHMP><CAT> considers that <*[for chemicals]* <isomer/mixture of isomers/complex /derivative/salt of> {INN (+salt) applicant} in comparison to the known <isomer/mixture of isomers/complex /derivative/salt of> {INN (salt) approved}><*[**for biologicals]* {active substance (biological of the applicant)} in comparison to {active substance} (biological approved)> previously authorised as a medicinal product in the European Union is <not> to be qualified as a new active substance as <it differs><insufficient evidence has been provided to demonstrate that it differs> significantly in properties with regard to safety and/or efficacy from the previously authorised substance.>

*3. For opinions where further information should be provided by the applicant in order to conclude on the applicant’s claim*

< Based on the review of available data on the active substance, the <Rapporteur> <CHMP><CAT> considers that further evidence should be provided by the applicant to substantiate the claim that <active substance> is to be qualified as a new active substance <in itself> < in comparison to the known <*[for chemicals]*<isomer/mixture of isomers/complex /derivative/salt of> {INN (salt) approved} > <*[for biologicals]* {active substance} (biological approved)>previously authorised as a medicinal product in the European Union >. Satisfactory answers must be given to the concerns as detailed in the List of Questions.>

***[For radiopharmaceutical products]***

<Based on the review of available data, it is considered that this radiopharmaceutical substance which is <a radionuclide> <a ligand> is <not> a new active substance as <it is a constituent of a medicinal product previously authorised within the European Union> <the coupling mechanism to link {*active substance*}and <the radionuclide> has not been authorised previously in the European Union>.>

In case NAS in itself is denied, the following should be added:

This is without prejudice to the possibility for the applicant to provide as part of the responses to the LoQ/LoOI evidence to demonstrate that this radiopharmaceutical substance differs significantly in properties with regard to safety and efficacy from the previously authorised substance.

*[or for cases where the same active substance is already authorised in a medicinal product or authorised in the meantime.]*

<Based on the review of available data, it is considered that {*active substance*} is not a new active substance, as it is a constituent of a medicinal product previously authorised within the European Union. {*Active substance*} is contained in the marketing authorisation {*invented name*} which was authorised in the Union on {*date of authorisation*}.>

Co-Rapporteur assessment:

Co-Rapporteur overall conclusion should be inserted here.

Please always insert the Co-Rapporteur conclusion 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. <Quality aspects>
  2. <Non-clinical aspects>
  3. <Clinical aspects>

<Not applicable>

1. <Assessment on the responses to the list of questions>
   1. <Quality aspects>
   2. <Non-clinical aspects>
   3. <Clinical aspects>
2. <Final conclusion>

For co-rapporteur assessment, please use a dedicated box to insert the relevant conclusion from the proposals listed below.

1. For opinions where the applicant claimed that the compound is a new active substance in itself and where no further information should be provided to conclude on the applicant’s claim

<Based on the review of available data on the active substance, the <Rapporteur> <CHMP><CAT> considers that <active substance> is <not> to be qualified as a new active substance in itself as it is <not> a constituent of a medicinal product previously authorised within the European Union.

In case NAS in itself is denied, the following should be added:

<{Active substance} is contained in the marketing authorisation {invented name} which was authorised in the European Union on {date of authorisation}.>

This is without prejudice to the possibility for the applicant to provide as part of the responses to the LoQ/LoOI evidence to demonstrate that this active substance differs significantly in properties with regard to safety and efficacy from the previously authorised substance.

*2. For opinions where the applicant claimed that the compound is a new active substance in comparison to a known isomer/mixture of isomers/complex /derivative/salt of a chemical substance or biological previously authorised as a medicinal product in the European Union and where no further information should be provided to conclude on the applicant’s claim*

<Based on the review of data on the quality, non-clinical and clinical properties of the active substance, the <Rapporteur> <CHMP><CAT> considers that <*[for chemicals]* <isomer/mixture of isomers/complex /derivative/salt of> {INN (+salt) applicant} in comparison to the known <isomer/mixture of isomers/complex /derivative/salt of> {INN (salt) approved}><*[for biologicals]* {active substance (biological of the applicant)} in comparison to {active substance} (biological approved)> previously authorised as a medicinal product in the European Union is <not> to be qualified as a new active substance as <it differs><insufficient evidence has been provided to demonstrate that it differs> significantly in properties with regard to safety and/or efficacy from the previously authorised substance.>

*3. For opinions where further information should be provided by the applicant in order to conclude on the applicant’s claim*

< Based on the review of available data on the the active substance, the <Rapporteur> <CHMP><CAT> considers that further evidence should be provided by the applicant to substantiate the claim that <active substance> is to be qualified as a new active substance <in itself> < in comparison to the known <*[for chemicals]*<isomer/mixture of isomers/complex /derivative/salt of> {INN (salt) approved} > <*[for biologicals]* {active substance} (biological approved)>previously authorised as a medicinal product in the European Union >. Satisfactory answers must be given to the concerns as detailed in the List of Questions.>

***[For radiopharmaceutical products]***

<Based on the review of available data, it is considered that this radiopharmaceutical substance which is <a radionuclide> <a ligand> is <not> a new active substance as <it is a constituent of a medicinal product previously authorised within the European Union> <the coupling mechanism to link {*active substance*}and <the radionuclide> has not been authorised previously in the European Union>.>

In case NAS in itself is denied, the following should be added:

This is without prejudice to the possibility for the applicant to provide as part of the responses to the LoQ/LoOI evidence to demonstrate that this radiopharmaceutical substance differs significantly in properties with regard to safety and efficacy from the previously authorised substance.

*[or for cases where the same active substance is already authorised in a medicinal product or authorised in the meantime.]*

<Based on the review of available data, it is considered that {active substance} is not a new active substance, as it is a constituent of a medicinal product previously authorised within the European Union. {Active substance} is contained in the marketing authorisation {invented name} which was authorised in the Union on {date of authorisation}.>

[Sections 4, 5, and 6 should be repeated in case of multiple rounds of evaluation]

Co-Rapporteur assessment:

Co-Rapporteur final conclusion should be inserted here.

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