Submission of comments on Concept paper on the revision of the Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies

Fields marked with * are mandatory.

* Name of organisation or individual

European Association of Nuclear Medicine

* Country of organisation or individual

Austria

* Email

euaffairs@eanm.org

If you respond on behalf of an organization, please allocate yourself a name abbreviation to be used as "Stakeholder name" in the comment tables below. If you comment as an individual, please ignore this field and use your full name as your "Stakeholder name".

EANM

Please click here to be redirected to the guideline text. The public consultation is launched on 21 July 2023 until 31 October 2023.

Those participating in the public consultation are asked to please submit comments via the EU Survey tool, by using the specific table for each section. Please note that login is not required to fill in the survey.

Before submission, a draft of the comments can be saved in the EU Survey tool. Once submitted, comments can be edited (by 31 October 2023) by clicking on "Edit contribution" in the link https://ec.europa.eu/eusurvey/ and entering your ID contribution that can be found on the pdf copy of your submission sent via email.

You are invited to provide your organisation or name, country and email address below for the purpose of this public consultation (for further information, please see EMA's Data Protection Statement below).

EMA Privacy Statement

All personal data provided within this survey questionnaire will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.

This data protection statement provides details on how the Agency, in its capacity as data controller, will process the information that you have given in your questionnaire.

Internally, an 'Internal Controller' has been appointed to ensure the lawful conduct of this processing operation. The contact details of the Internal Controller are the following: Datacontroller. HumanMedicines@ema.europa.eu

Collection of data

EMA will collect all the personal data in this questionnaire, such as your name, organisation, your view on the topics subject to the survey, country of residence and your contact details. Please do not reveal any other personal data in the free text fields. EMA does not directly intend to collect personal data but to use the aggregated data for the purpose of this survey.

For the collection of data in this survey, EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home/privacystatement

The EU Survey external system uses:

- Session "cookies" to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated.
- Local storage to save copies of the inputs of a participant to a survey to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.
- The local storage contains the IDs of the questions and the draft answers.
- IP of every connection is saved for security reasons for every server request.
- Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage.

Your consent to the processing of your data

When you submit this questionnaire, you consent that EMA will process your personal data provided in the questionnaire as explained in this data protection statement. You may also withdraw your consent later at any time. However, this will not affect the lawfulness of any data processing carried out before your consent is withdrawn.

Start of data processing

EMA will start processing your personal data as soon as the questionnaire response is received.

Purpose of data processing

The purpose of the present data processing activity is to collect the views of stakeholders and/or concerned individuals in relation to the subject-matter of the survey. Your personal data may be used to contact you in relation to the feedback you have provided in response to the survey. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

Location of data storage

All data is stored within a secure data centre at the EMA premises which is password protected and only available to EMA staff members.

Publication of data

The following data collected in this questionnaire will be published on the EMA website at the time of issuing the final guideline subject to this survey:

- organisation name (the entity on behalf you respond to this survey)
- or your name (only if you do not respond to the survey on behalf of an organisation)
- your view/comments on the topics concerned

Country information and your email address will not be published.

Retention period

If you complete and submit this survey, your personal data will be kept until the results have been completely analysed and utilised. Your personal data will be deleted by EMA at the latest 5 years after the questionnaire response was submitted. The file of the data as published will remain stored for archiving purposes beyond the maximum 5 years-retention time of the submitted questionnaire responses.

Your rights

You have the right to access and receive a copy of your personal data processed, as well as to request rectification or completion of these data. You may also request erasure of the data or restriction of the processing in accordance with the provisions of Regulation (EU) 2018/1725. You can exercise your rights by sending an e-mail to Datacontroller.HumanMedicines@ema.europa.eu.

Complaints

If you have any complaints or concerns about the processing of your personal data, you can contact EMA's Data Protection Officer at dataprotection@ema.europa.eu.

You may also lodge a complaint with the European Data Protection Supervisor: edps@edps.europa.eu.

* Please confirm that you have read and understood the Data Protection Statement above and that you consent to the processing of your personal data.

- (●) Yes
- ( ) No

* Please confirm that you consent to possibly be contacted by EMA in relation to your survey responses to support the finalisation of the document subject this EU Survey.

- (●) Yes
- ( ) No

* Please confirm that you consent to the publication of your organisation name, your name (only if you do not respond to the EU Survey on behalf of an organisation) and your survey responses on the EMA website at the time of issuing the final guideline subject to this survey.

- (●) Yes
- ( ) No

Should you not want to give consent to publish, please send your objections to Datacontroller. HumanMedicines@ema.europa.eu.

Please be aware that the sender of the comments is responsible to not disclose any personal data of third parties in the comments.

When you have filled in the EU Survey, please use the submission button at the end of the form to submit the comments to the European Medicines Agency.

For additional information, please consult EMA's privacy statement.

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1. General comments on the Concept paper on the revision of the Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies

	Stakeholder name *(to be repeated in all rows)*	General comment
1	EANM	With all the recent developments in radiopharmaceuticals, the EANM believes that the guideline on Radiopharmaceuticals Based on Monoclonal Antibodies is not needed anymore. Instead, we would suggest to merge the two guidelines into a single one. Therefore, for more detailed feedback, please consult the EANM reply to the revision of the EMA guideline on radiopharmaceuticals. Non clinical aspects of this guideline should be aligned with /transferred to the "Guideline on the non-clinical requirements for radiopharmaceuticals" EMA/CHMP/SWP/686140/2018 A few specific points are addressed below.
2	EANM	The scope of the guideline should be explicitly pointed out (as is the case for the Guideline on radiopharmaceuticals: is it applicable to marketing authorization applicants, clinical trials, in-house preparation?
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2. Specific comments on text

2.1. Introduction

	Line number(s) of the relevant text *(e.g. 20-23)*	Stakeholder name *(to be repeated in all rows)*	Comment and rationale	Proposed guidance text
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2.2 Problem statement

	Line number(s) of the relevant text *(e.g. 20-23)*	Stakeholder name *(to be repeated in all rows)*	Comment and rationale	Proposed guidance text
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2.3 Discussion (on the problem statement)

	Description of the element of the figure	Stakeholder name *(to be repeated in all rows)*	Comment and rationale	Proposed guidance text / element of the figure
1	45	EANM	The requirement for ASMF files should be clearly restricted to products aiming at marketing authorization and not for products in clinical research (where radiolabelled antibodies are used frequently as diagnostic products). An ASMF requirement would hamper research efforts and endanger Europe's leading role in this field).	
2	49	EANM	The specific activity might not be easy for the radiochemical to be determined. The supplier of the radiochemical should provide this information if possible, not the producer of the radiopharmaceutical.	
3	49	EANM	Radiochemical purity for the radionuclide should be omitted , since radiochemical purity typically applies to the radiopharmaceutical and not the radiochemical.	
4	51	EANM	For every isotope, this will differ and having general requirements is not easy to describe. It is therefore recommended to	

			exclude this item.	
5	56	EANM	Here the “Guideline on the non-clinical requirements for radiopharmaceuticals” EMA/CHMP/SWP/686140/2018 should be referred to and not separate recommendations being introduced. Also specific points are only applicable to therapeutic applications and diagnostic should be exempted (reproductive function, fetal toxicity, mutagenic potential, carcinogenic potential).	
6	56	EANM	Stability of conjugate in plasma: this is highly dependent on the concentration of tracer, concentration of mAb and in vitro is not representative of the in vivo situation typically. Therefore EANM recommends to remove this point.	
7	57	EANM	Free antibody: typically this is present and also needed. Therefore, EANM recommends to remove this point. The required dose of mAb is dependent on the target and free antibody is often added even.	
8	59	EANM	Guidance in relation to dose calculations should not be “stand alone” in this guideline as this is not restricted to monoclonal antibodies but	

			radiopharmaceuticals in general.	
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2.4 Recommendation

	Line number(s) of the relevant text *(e.g. 20-23)*	Stakeholder name *(to be repeated in all rows)*	Comment and rationale	Proposed guidance text
1	65	EANM	Looking at the items addressed above, this is going further than quality of the radiopharmaceuticals.	
2	68	EANM	Many items can be done with the mAb without the radioactivity. If preclinical studies with the radiolabeled mAb are needed, this will hamper translation of image-guided drug development significantly. Often preclinical testing is not of added value since the data is already obtained with the mAb. Important to determine is that the radiolabeled mAb is behaving the same as the native mAb. This is crucial and must be proven.	
3	73	EANM	See comment in section 3. Effective dose equivalent data do not necessarily need to be obtained in preclinical studies (often in case of mAbs this is not useful at all).	
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2.5 Proposed timetable

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2.6 Resource requirements for preparation

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2.7 Impact assessment (anticipated)

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2.8 Interested parties

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2.9 References to literature, guidelines, etc.

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Other comments

	Line number(s) of the relevant text (e.g. 20-23)	Stakeholder name (to be repeated in all rows)	Comment and rationale	Proposed guidance text
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Thank you for your contribution.

Contact

Contact Form