Public consultation for MSAC Draft Framework for the Assessment of Radiopharmaceuticals

Overview

The Medical Services Advisory Committee (MSAC) has developed a Draft Framework for the MSAC assessment of radiopharmaceuticals**.**

The purpose of this Framework is to identify the supplementary information requirements to those set out in the [**Guidelines for preparing assessments for the Medical**](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/%24File/MSAC%20Guidelines-complete-16-FINAL%2818May21%29.pdf)[**Services Advisory Committee**](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/%24File/MSAC%20Guidelines-complete-16-FINAL%2818May21%29.pdf)

[*<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/%24File/MSAC%20Guidelines-complete-16-*](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/%24File/MSAC%20Guidelines-complete-16-FINAL%2818May21%29.pdf)[*FINAL(18May21).pdf>*](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/E0D4E4EDDE91EAC8CA2586E0007AFC75/%24File/MSAC%20Guidelines-complete-16-FINAL%2818May21%29.pdf)(“MSAC Guidelines”) to ensure that radiopharmaceuticals to be used within the scope of a proposed MBS item descriptor in an application for a new or amended MBS item are adequately characterised and produced according to accepted standards, in order to be evaluated for clinical (diagnostic or therapeutic) noninferiority against a comparator product or products.

The question of noninferiority of radiopharmaceuticals has arisen in the context of several MSAC applications. For example, there may be a scarcity or lack of evidence to inform the safety and efficacy of a radiopharmaceutical product or products for which a new or amended MBS item descriptor(s) is being proposed, and the applicant may cite evidence for the comparator(s) as the best available evidence on which to base a claim of clinical noninferiority between the two products.

**This Draft Framework and MSAC assessment applies for the purpose of MBS listing only.** Applicants must satisfy themselves in relation to the requirements of the *Therapeutic Goods Act 1989* and other applicable legislation.

## How to participate

The Draft Framework can be downloaded for reading by clicking on the link at the end of this webpage.

When you are ready to provide your feedback, click on the link to the consultation survey and input your responses directly into the survey.

Alternatively if you prefer to provide your feedback through an attachment there are two ways you can do this. You can send your attachment

to **MSAC.SECRETARIAT@health.gov.au**with the email subject heading "Consultation feedback on Draft Framework for Radiopharmaceuticals" OR proceed to the consultation survey where you can click on the option to upload an attachment after you fill in some details about yourself. If you wish you can also download a Word version of the consultation questions from the links at the bottom of the page to be used as the basis for your attachment.

Public consultation must be received by no later than **21 November 2023** for it to be considered by the *MSAC Working Group*.

## How your submission and information will be used

Details you provide including identifying information about you or your organisation will be made available in full to a Working Group of MSAC and may be summarised and analysed for review by the Working Group. However your feedback will not be published.

Your feedback will be taken into account by MSAC in finalising the Draft Framework.

If you have any questions about this review and its processes, please contact the MSAC Secretariat at **MSAC.SECRETARIAT@health.gov.au**

## Privacy notice

Your personal information is protected by law, including the Privacy Act 1988 (Privacy Act) and the Australian Privacy Principles (APPs), and is being collected by the Department, via Citizen Space, for the purposes of conducting a consultation process in relation to the Draft Framework. You can access more information about the way in which the Department will manage your personal information, including our privacy policy at [www.health.gov.au/resources/publications/privacy-policy](http://www.health.gov.au/resources/publications/privacy-policy) .

Privacy and consent

# **1** Privacy Information

Your personal information is protected by law, including the *Privacy Act 1988* (Privacy Act) and the Australian Privacy Principles (APPs), and is being collected by the Department, via Citizen Space, for the purposes of conducting a consultation process in relation to an application submitted to the Office of Health Technology Assessment. The Department will collect your personal information at the time that you provide a submission.

To protect privacy, do not include identifying personal or sensitive information about another individual (third party).

**More information about privacy**

You can access more information about the way in which the Department will manage your personal information, including our privacy policy,

at [**https://www.health.gov.au/resources/publications/privacy-policy**](https://www.health.gov.au/resources/publications/privacy-policy)[*<https://www.health.gov.au/resources/publications/privacy-policy>*](https://www.health.gov.au/resources/publications/privacy-policy). You can obtain a copy of the Department’s privacy policy by contacting the Department using the contact details set out below. The Department’s privacy policy contains information about:

how you may access the personal information the Department holds about you and how you can seek correction of it; and how you may complain about a breach of

the APPs; or

a registered APP code that binds the Department; and how the Department will deal with such a complaint.

You can contact the Department by telephone on (02) 6289 1555 or free call 1800 020 103 or by using the online enquiries form at [**http://www.health.gov.au**](http://www.health.gov.au/)

[*<http://www.health.gov.au/>*](http://www.health.gov.au/).

# **2** How your input will be used

Details you provide including identifying information about you or your organisation will be made available in full to a Working Group of MSAC and may be summarised and analysed for review by the Working Group. However your feedback will not be published.

Your feedback will be taken into account by MSAC in finalising the Draft Framework.

Please indicate your consent below

**3** Consent

 I have read the above text on how public consultation input will be used and consent to the input being used as described above *(Required)*

Your details

# **1** Please provide your name and email address.

Name

Email

# **2** Is your feedback being provided on an individual basis or on behalf of an organisation?

*(Required)*

*Please select only one item*

Individual Collective

What is the name of your employer (if your feedback is being provided on an individual basis) or the organisation you represent (if it is on behalf of an organisation)

# **3** How would you best identify yourself?

*(Required)*

*Please select only one item*

General practitioner Specialist Researcher Consumer

Other

If specialist, please specify what kind of specialist

If other please specify

Upload a file

# **1** If you would prefer to respond to the consultation questions by uploading a file, please do so below.

## Please attach a copy of any documents you wish to include to this printout.

The preferred file types are PDF or Microsoft Word. Should you have any difficulties submitting a file, please contact MSAC.SECRETARIAT@health.gov.au

Consultation Questions

# **1** Do the questions in the Draft Framework indicate clearly what applicants must provide to satisfy MSAC’s additional information requirements?

*(Required)*

*Please select only one item*

Yes No

If your answer is no, you can provide more detail here on why not

# **2** Are the additional information requirements for radiopharmaceuticals not registered on the ARTG as set out in Attachment A of the Draft Framework:

*(Required)*

*Please select only one item*

too onerous insufficiently rigorous proportionate

If your view is that the requirements are either too onerous or insufficiently rigorous, please explain why and, if possible, suggest any areas for improvement

**3** Are there any existing processes which could achieve the same intended result as the Draft Framework or a component of it? If so, please provide details

**4** Do you have any additional comments on the Draft Framework?