Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Radiopharmaceutical regulation in Australia: Information paper to support public consultation

Version 1.0, May 2026

Copyright

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Table of Contents

1.0 Consultation overview

This public consultation is open from **5 June 2026** to **31 July 2026**.

Purpose of the consultation

The Therapeutic Goods Administration (TGA) is seeking high-level stakeholder feedback on how current regulatory settings for radiopharmaceuticals operate in practice. This consultation is intended to support informed consideration of stakeholder experiences with existing regulatory pathways, exemptions and access mechanisms. Feedback received will be used to inform future targeted consultation and engagement activities.

How to make a submission

Submissions to this consultation are invited via the **TGA Consultation Hub**.

To make a submission, stakeholders should:

- access the consultation via the TGA Consultation Hub
- respond to the consultation questions provided
- upload supporting documents where relevant (if applicable).

Submissions must be lodged through Citizen Space by **11:59 pm (AEST)** on the closing date.

Publication of submissions

Unless marked as confidential, submissions will be published on the TGA website in accordance with the confidentiality statement at the beginning of this paper. Submitters are encouraged to clearly identify any confidential information and provide reasons for confidentiality claims in the submission form.

Enquiries

For further information about this consultation, please contact the TGA at:
radiopharma@health.gov.au

2.0 Purpose of this document

This paper provides information on the regulation of radiopharmaceuticals in Australia to support informed, high-level stakeholder feedback to the open public consultation questions. It describes, at a high level, how existing regulatory pathways operate in practice. The paper is not intended to constitute legal advice or regulatory guidance, alter the operation of the *Therapeutic Goods Act 1989* (the Act) or *Therapeutic Goods Regulations 1990* (the Regulations), or resolve matters of regulatory interpretation, and it may not capture all aspects of the relevant regulatory framework. Stakeholders should consider the information alongside applicable legislation, guidance and professional standards.

For the purposes of this document, terms such as ‘radiopharmaceuticals’ and ‘nuclear medicine’ are used as defined in section 6.

3.0 Recent engagement

The TGA conducted a targeted consultation from 1 July to 8 August 2025 on the proposed repeal of radiopharmaceutical items 22 and 23 of Schedule 7 to the Regulations. Submissions were received from a broad range of stakeholders, including hospitals, manufacturers, government bodies, industry associations and research organisations. Whilst views varied and feedback differed depending on the type of radiopharmaceutical, a greater number of respondents did not support repeal at that time and sought further consultation.

This broader consultation is not a reconsideration of that proposal but draws on earlier feedback to inform understanding of stakeholder experience with the current framework.

Feedback from the earlier consultation has informed the department's understanding of stakeholder experiences and sensitivities relating to radiopharmaceutical manufacture and supply and provides important context for this broader consultation.

In addition, the department has undertaken a range of engagement activities in recent years on regulation of radiopharmaceuticals in Australia. This included attendance, as observers, at a national industry roundtable held at Parliament House in November 2025, which brought together patients, clinicians, researchers, industry representatives and government to identify key system barriers and explore future directions for nuclear medicine and radiopharmaceutical practice.

Building on this engagement, Nuclear Medicines Australia (NMA) released its *National Action Plan – Shaping the Future for Nuclear Medicine in Australia*. The Action Plan outlines sector perspectives on radiopharmaceutical regulation and practice and identifies a series of recommendations aimed at improving patient access to innovative nuclear medicine technologies. The department also acknowledges that other stakeholders, including industry bodies such as Medicines Australia, are undertaking related work in this space. The department acknowledges the contribution of this, and other stakeholder input received to date.

4.0 Context and scope of this consultation

This consultation focuses on how current regulatory settings operate in practice. Radiopharmaceutical regulation spans Commonwealth therapeutic goods legislation as well as Commonwealth, state and territory radiation safety and licensing frameworks.

This consultation does not seek to propose decisions on funding, reimbursement, transport regulation or radiation safety, which largely sit outside the TGA's remit. However, stakeholders are invited to provide high level feedback on how these factors interact with regulatory pathways in practice.

Stakeholders have reported differing experiences in how regulatory pathways and exemptions are interpreted and applied across clinical, hospital and manufacturing settings, particularly as models of care and manufacturing have evolved. While substantial engagement has already occurred with parts of the radiopharmaceutical and nuclear medicine sector, this consultation provides an opportunity to build on that engagement by gathering high-level feedback from a broader range of stakeholders, including those who may have had limited prior engagement or who experience the regulatory framework differently.

5.0 How feedback from this consultation will be used

Feedback received through this consultation will be analysed at a high level and considered alongside existing operational experience and policy work within the department, as well as with relevant input from previous engagement and consultation activities, including the targeted consultation undertaken in 2025.

The feedback will help to:

- identify common themes regarding the clarity, consistency and usability of current regulatory pathways
- highlight areas where additional guidance, education material or engagement may assist stakeholders
- inform future planning, including whether more targeted stakeholder discussions or workshops would be beneficial.

Feedback from this consultation will not, of itself, result in immediate regulatory changes. A summary of responses may be published in aggregate form, subject to confidentiality requests.

6.0 What constitutes a radiopharmaceutical

Radiopharmaceuticals are medicines that:

- contain a radioactive component; or
- are intended to be combined with a radioactive component prior to administration.

This includes:

- ready-to-use diagnostic and therapeutic radiopharmaceuticals (including Positron Emission Topography [PET] radiopharmaceuticals)
- non-radioactive kits and chemical precursors used for radiolabelling
- radionuclide generators
- radionuclide precursors used prior to administration

Both diagnostic and therapeutic products, including theranostic products, fall within scope.

For the purpose of this document, nuclear medicine refers to the clinical discipline that uses radioactive substances for diagnostic imaging and therapeutic purposes, including the preparation, quality control and administration of radiopharmaceuticals within hospital and clinical settings.

7.0 Overview of radiopharmaceutical regulation in Australia

Radiopharmaceuticals are regulated in Australia as prescription medicines under the Act and associated Regulations, with oversight by the TGA. Radiopharmaceutical regulation sits at the intersection of 2 regulatory regimes:

- Medicinal product regulation (Commonwealth: TGA)
- Radiation protection and licensing (Commonwealth, state and territory frameworks).

Sponsors and manufacturers must comply with both, and these operate alongside other applicable state and territory clinical governance frameworks.

8.0 Market authorisation and supply pathways

In practice, radiopharmaceuticals may be supplied in Australia through a range of lawful pathways under the therapeutic goods framework, depending on factors such as whether the product is approved or a relevant exemption applies. These pathways are not mutually exclusive, and multiple regulatory provisions may apply concurrently to a particular product or activity.

Radiopharmaceuticals supplied in Australia may be either:

- **approved**, where they are included in the Australian Register of Therapeutic Goods (ARTG), or
- **unapproved**, where an exemption or another pathway for accessing unapproved therapeutic goods applies.

8.1 ARTG Inclusion

As prescription medicines, radiopharmaceuticals generally require inclusion in the ARTG unless an exemption, approval or authority applies.

TGA assessment of the suitability for inclusion in the ARTG considers several criteria, including:

- pharmaceutical quality (including radiochemical purity and stability)
- non-clinical and clinical evidence, proportionate to use

- radiation dosimetry and biodistribution
- proposed Product Information (PI).

In assessing radiopharmaceutical applications, the TGA may have regard to relevant international guidance and standards, including those developed by recognised international organisations, where these are appropriate to the Australian regulatory context. Such guidance is considered alongside Australian legislative requirements and does not displace the need to comply with applicable domestic regulatory, licensing, Good Manufacturing Practice (GMP) and professional obligations.

8.2 Exemptions from ARTG inclusion

The Regulations include several exemptions from the requirement for inclusion in the ARTG that may be relied on where the relevant criteria are met. These exemptions include general exemptions that are not product-specific, and one exemption that is specific to certain radiopharmaceutical cold kits. In practice, stakeholders have reported differing views on how the criteria for some of these exemptions are interpreted and applied across clinical, hospital and manufacturing settings.

Schedule 5 exemptions — Overview

Schedule 5 item	General subject of exemption	Practical relevance for radiopharmaceuticals
Item 6	Dispensed/extemporaneously compounded for therapeutic application to a particular patient, i.e. in response to an identified clinical need.	Enables patient-specific extemporaneous compounding of a radiopharmaceutical preparation performed in a pharmacy/radio pharmacy when otherwise not available.
Item 6A	Anticipatory compounding within hospitals under Drugs and Therapeutics Committee (DTC) oversight.	Enables radio pharmacy operations in acute hospital settings where clinical demand requires pre-compounding ahead of individual orders.

Item 9	Starting materials that are ingredients or components for use in the manufacture of therapeutic goods, excluding starting materials that are:
	• pre-packaged
	• formulated as a dosage form
	• nicotine in solution imported for use as an ingredient in a therapeutic good
	• where the starting materials are ingredients or components imported for use in the manufacture of:
	  ○ a therapeutic vaping substance
	  ○ a therapeutic vaping substance accessory.
		Enables radionuclides, precursors and other inputs used to prepare radiopharmaceuticals, where they are not supplied as finished dosage forms.

Item 13	Radiopharmaceutical cold kits used for extemporaneous compounding and patient use within the same State or Territory.	Enables on-site kit preparation for immediate radiolabelling and patient use.

Other exemptions that may apply in some circumstances include item 3 of Schedule 5A of the Regulations, which covers most clinical trials undertaken in Australia; and item 5 of Schedule 5A of the Regulations, which covers therapeutic goods that are manufactured by a person under a contract

between the person and a private hospital, public hospital or public institution, in certain circumstances.

There are also powers in the Act to exempt unapproved therapeutic goods in connection with an emergency or to prepare for possible future emergencies.

Unlike ARTG-included medicines, unapproved products supplied under an exemption have not been evaluated by the TGA for quality, safety and efficacy.

Important:

These exemptions relate to ARTG inclusion only and do not waive radiation safety or licensing obligations. They do not exempt goods from compliance with applicable standards, and do not operate in isolation.

The relevance of individual exemptions may vary depending on the clinical context, model of care and characteristics of the activity being undertaken, and not all exemptions will be applicable to all radiopharmaceutical practices or products.

Sponsors and healthcare institutions are responsible for ensuring that all applicable legislative, licensing, GMP and professional obligations are met, noting that reliance on one pathway or exemption does not negate responsibilities under others.

8.3 Manufacturing exemptions for certain hospital-made radiopharmaceuticals

Under the Act, if a person carries out a step in the manufacture of a therapeutic good (other than a medical device) in Australia the person must hold a manufacturing licence issued under the Act that authorises the step of manufacture, unless either the person or the relevant goods are covered by an exemption.

The *Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020* introduced 2 manufacturing-licence exemptions (items 22 and 23) to Schedule 7 of the Regulations for certain radiopharmaceuticals and radiopharmaceutical active ingredients prepared in hospitals or public institutions within Australia by qualified personnel.

As noted in Section 3, these manufacturing-licence exemptions were the subject of a targeted consultation in 2025; this section describes how the exemptions operate under the current regulatory framework.

The applicability of these exemptions depends on the nature of the activity and the conditions of the relevant provisions, rather than the setting alone.

These manufacturing-licence exemptions were designed to be a temporary measure to address supply risks, particularly where decentralised manufacture within hospitals or public institutions was necessary to support timely patient access.

While the exemptions have the effect that a manufacturing licence under Part 3-3 of the Act is not required, it is important for patient safety that radiopharmaceuticals supplied in Australia in reliance on either of the exemptions are still prepared in accordance with appropriate GMP, by appropriately qualified personnel, under documented procedures, and with appropriate oversight to ensure quality and safety.

Stakeholders are invited to provide feedback on how these exemptions operate in practice, including any impacts on patient access, service delivery, workforce capability and supply resilience.

Schedule 7 of the Regulations also includes an exemption relating to the manufacture and supply of therapeutic goods, including radiopharmaceuticals, for use in initial experimental studies in human volunteers (Item 1). These provisions support initial investigational use under established clinical trial frameworks and operate alongside other applicable regulatory, ethical and radiation safety requirements. It is important to note that this exemption is limited to goods prepared for initial experimental use in human volunteers and is not a blanket exemption for all investigational medicinal products used in clinical trials.

There are also exemptions from the requirement for a manufacturing licence to be in place that apply to specified persons – these are set out in Schedule 8 to the Regulations. In particular, these include exemptions for specified persons manufacturing therapeutic goods, including radiopharmaceuticals, in specified settings, including pharmacies, and in hospital settings for supply to specific persons or patients within the same state or territory. These provisions operate independently of Items 22 and 23 in Schedule 7 of the Regulations and would continue to apply irrespective of any changes to those items.

8.4 Access to unapproved radiopharmaceuticals

Separate to the exemptions, unapproved therapeutic goods may also be imported or supplied if approved or authorised under the provisions of the Act that underpin the TGA's Special Access Scheme and Authorised Prescriber scheme. These are principally designed for use when there are no therapeutic goods for the treatment of the relevant condition, or where there are therapeutic goods in the ARTG but they are not available or are not clinically suitable.

Special Access Scheme (SAS)
The SAS enables prescribers to access unapproved therapeutic goods for individual patients under defined circumstances:

- **Category A** operates as a notification pathway for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment. A notification must be sent to the TGA within 28 days of supply.
- **Category B** requires an application and approval prior to supply by a health practitioner. This pathway is typically used where the clinical circumstances do not meet Category A criteria but clinical justification for use is provided.
- **Category C** operates as a notification pathway for authorised health practitioners to supply specified unapproved products. This pathway is typically used for products that have been determined to have an established history of use and low-risk profile in defined circumstances. A notification must be sent to the TGA within 28 days of supply.

Authorised Prescriber (AP) Scheme
The AP scheme allows an authorised medical practitioner to supply a specified unapproved therapeutic good, such as a radiopharmaceutical, to a specified class of patients, such as patients with a particular medical condition. This pathway may be used where the prescriber wishes to supply the product to multiple patients with the same medical condition.

The SAS and AP scheme are subject to conditions and requirements that apply to sponsors and prescribers. These include reporting and pharmacovigilance obligations, as well as requirements relating to the lawful manufacture, importation and supply of products.

Unlike ARTG-included medicines, unapproved products supplied under the SAS or AP scheme have not been evaluated by the TGA for quality, safety and efficacy.

The suitability of these pathways may depend on factors such as frequency of use, scale of supply, and the clinical context in which the product is administered.

8.5 Access during shortages

In circumstances where an ARTG-included radiopharmaceutical is unavailable, in short supply or in some circumstances does not exist, temporary access may be facilitated under section 19A of the Act. This pathway allows for the import and supply of substitute radiopharmaceuticals where necessary in the interest of public health, and where overseas supplies exist. For radiopharmaceuticals, section 19A is an established contingency mechanism used to support continuity of diagnostic and therapeutic services during supply disruptions when the legislative criteria are met. Use of this pathway is intended in most instances to be temporary, and subject to approval conditions.

9.0 Manufacturing and Good Manufacturing Practice

Regardless of the pathway through which a radiopharmaceutical is manufactured or supplied—including where exemptions from ARTG inclusion or manufacturing licensing apply—appropriate GMP remains a fundamental requirement. GMP obligations operate alongside, and are not displaced by, regulatory exemptions, and are critical to ensuring the quality, safety and efficacy of radiopharmaceuticals across all settings.

9.1 GMP expectations

Radiopharmaceuticals are subject to GMP requirements, applied on a risk-based basis in accordance with relevant standards, including PIC/S guidance and applicable professional frameworks. These expectations operate alongside relevant professional frameworks and guidance applicable to personnel preparing radiopharmaceuticals, including guidance issued by professional regulators such as the Pharmacy Board of Australia.

Exemptions from manufacturing licensing requirements do not remove the obligation for radiopharmaceuticals to be prepared in accordance with appropriate GMP. Manufacturing activities undertaken under exemptions are expected to be undertaken by qualified personnel and supported by documented procedures, and suitable quality systems to ensure product quality, safety and efficacy.

GMP requirements may be applied in a manner proportionate to risk. Factors such as batch size, release timelines or location of manufacture do not, of themselves, constitute exemptions or concessions from GMP requirements. Australia's GMP framework for radiopharmaceuticals is informed by internationally harmonised principles, applied in a risk-based manner consistent with domestic regulatory requirements.

9.2 Release specifications and quality control

Release specifications for radiopharmaceuticals are defined by applicable standards, including requirements for tests that must be completed prior to administration and those that may be completed post-administration. Clear governance arrangements are critical to ensure that any post-administration testing is appropriately managed and does not compromise patient safety.

10.0 Clinical trials involving radiopharmaceuticals

For the purposes of this document, investigational use refers to the use of therapeutic goods within an approved clinical trial framework and is distinct from routine clinical use of unapproved goods under access pathways such as the SAS or AP scheme.

Clinical trials involving unapproved radiopharmaceuticals, or approved radiopharmaceuticals used outside their ARTG indications, are regulated under the Clinical Trial Notification and Clinical Trial Approval schemes in the therapeutic goods legislation, as described in the Australian clinical trial handbook.

It is important for product safety that investigational medicinal products are manufactured in accordance with GMP and relevant clinical trial standards, including ICH E6(R3) *Guideline for Good Clinical Practice*, irrespective of whether an exemption from ARTG inclusion or manufacturing licensing applies. A range of requirements also apply under the clinical trial schemes mentioned above, including for instance compliance with the National Statement on Ethical Conduct in Human Research and Good Clinical Practice guidelines.

The TGA retains post-market monitoring and enforcement powers in relation to radiopharmaceuticals used in clinical trials.

11.0 Product Information, labelling and dosing

Radiopharmaceuticals must have an approved PI document that clearly sets out:

- indications
- dosing and administration
- radiation dosimetry
- precautions and contraindications
- handling and disposal.

The PI and labelling must comply with applicable legislative requirements and relevant standards. Labelling must clearly state the radioactive content, calibration date and time, and expiry.

These requirements do not apply to investigational medicinal products used in approved clinical trials.

12.0 Post-market monitoring and compliance

Sponsors must report adverse events, notify quality defects and submit variations, where required, and undertake recalls in accordance with legislative requirements. The TGA applies a risk-based approach to post-market monitoring, inspections and compliance activities.

For the purpose of therapeutic goods legislation, goods supplied under exemptions from ARTG inclusion remain unapproved goods and are subject to applicable post-market monitoring, safety reporting and compliance requirements.

13.0. Interaction with reimbursement and health technology assessment

Public funding decisions (e.g. Medicare Benefits Schedule listing) are considered separately through the Medical Services Advisory Committee and are outside the remit of the TGA. These processes do not replace the need to comply with TGA-relevant regulatory requirements.

However, stakeholders may wish to comment at a high level on how reimbursement and health technology assessment processes interact with regulatory pathways in practice.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch (PMAB) Therapeutic Goods Administration (TGA)	May 2026

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au