AUSTRALASIAN ASSOCIATION of
Nuclear Medicine
Specialists (AANMS)

Radiopharmaceutical Substitution
Further information on the
TGA Special Access Scheme Category C

Dear Member

Further to our email of 17 September 2019 about the radiopharmaceutical substitution arrangements that apply during the current technetium shortage, this email sets out further information about the Special Access Scheme arrangements that apply. The substitute radiopharmaceuticals have been included on the relevant TGA list and part of the TGA's contribution to addressing the current technetium shortage has been to fast-track placing some radiopharmaceuticals on the TGA Special Access Scheme Category C list.

Special Access Scheme (SAS) Category C

The TGA's ***Special Access Scheme: Guidance for Health Practitioners and Sponsors Version 1.1 September 2017*** (available **here**) sets out the process for notifying the TGA of the use of a substitute radiopharmaceutical. The notification process, which appears on page 18 of this guidance document, is also set out at the foot of this email (see text in **BLUE**).

The Category C Codes referred to in the notification process are set out on pp 2-7 of the ***SAS Category C form.*** The relevant codes for the radiopharmaceutical substitution are on p 3 of the form (i.e. the specific code should be used rather than the boxes for medicine, biological or device). The SAS Category C form may be found **here** (*Word*) and **here** (*PDF*).

The following radiopharmaceuticals are currently on the Category C list of products:

F-18 NaF (sodium fluoride), injection, intravenous
F-18 myocardial perfusion trace (18F flurpiridaz), injection, intravenous (Note: this product is not yet available in Australia, but may be available later this year)
Gallium-68 (Ga-68) Galligas, Aerosol, Inhalation
Galliium-68 (Ga-68) MAA, injection, intravenous

The AANMS has also asked for **Ga-68 EDTA** to be added to the SAS Category C Codes as this unfortunately was omitted in the initial changes. We will advise when this occurs.

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The following is copied from the guidance notes for notification of the use of one of the substitute radiopharmaceuticals (page 18) under the current Radiopharmaceutical Substitution Arrangements (extract):

Notification process

The prescribing health practitioner or someone acting on their behalf (e.g. pharmacist) needs to complete and submit the SAS Category C form available on (the TGA's) website after the unapproved therapeutic good has been supplied through the SAS Category C pathway. The form does not need to be completed before the good is supplied or to effect the supply of the product.

Prior approval is not required before unapproved therapeutic goods used in accordance with the 'rules' of the legislative instruments can be accessed. However, a copy of the completed Category C form must be sent to the TGA within 28 days of the therapeutic goods being supplied. Failure to do so is an offence and carries a financial penalty.

A copy of the completed form should also be kept with the patient's medical record.

It is the notifying prescriber's responsibility to ensure they meet the legislative and regulatory requirements associated with the SAS Category C pathway.

Supplying unapproved therapeutic goods in a manner that is not in accordance with the 'rules' of the legislative instruments such as using a product on the instrument for an indication different to that on the instrument may constitute an offence and attract penalties.

Using the Category C form

· The form is completed by an appropriate health practitioner (the submitter) and submitted to TGA. The submission may be done on behalf of the treating health practitioner (e.g. a pharmacist may submit the form on behalf of a medical practitioner) or the treating health practitioner may complete and submit the form themselves (thus also acting as the submitter). In either case, only a single signature - from the person submitting the form (the submitter) - is required.

· To reduce administrative burden while also enhancing compliance, the paper form requests a code to be used in place of describing the good and the conditions of supply. The codes, which match the entries on the legislative instruments, are located on the back of the form.

· If the unapproved good, indication, and health practitioner do not all match an entry for a code on the back of the form, this pathway cannot be used. You may potentially still be able to access this good for the particular indication through one or more of the existing unapproved therapeutic goods schemes, including: SAS Category A, SAS Category B (application) or the Authorised Prescriber Scheme.

Document Links

TGA's Special Access Scheme: Guidance for Health Practitioners and Sponsors Version 1.1 September 2017

Special Access Scheme Category C form (Word)

Special Access Scheme Category C form (PDF)

Legislative Instrument and accompanying Explanatory Statement
(Note: these two documents have been circulated previously on 16 September 2019)

AANMS Secretariat