Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under subsection 19A(1)

Notice of approval for the importation and supply of specified therapeutic goods

This notice refers to the application made under section 19A of the *Therapeutic Goods Act 1989* (the Act) dated 20 June 2024 in relation to Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 1000ml (France).

I am a delegate of the Secretary of the Commonwealth Department of Health and Aged Care under section 19A of the Act. This notice constitutes my decision under subsection 19A(1) to grant approval to the person identified in column 1 of Schedule 1 to this notice, to import and supply in Australia the therapeutic goods specified in column 2 of Schedule 1 to this notice.

I have granted this approval on the basis of being satisfied that:

(a) registered goods that could act as a substitute for the specified therapeutic goods are unavailable or are in short supply; and

(b) the goods that are the subject of your application are registered or approved for general marketing in one or more foreign countries specified by the Secretary in a determination under subsection 19A(3); and

(c) the goods are of a kind included in Schedule 10 of the *Therapeutic Goods Regulations 1990*; and

(d) the approval is necessary in the interests of public health.

This approval has effect for the period commencing on the date of this notice until **30 April 2025**.

This approval lapses if either:

(a) the period specified above expires or a decision is made under subsection 25(3) of the Act in relation to the goods, whichever should occur first; or

(b) the Secretary is satisfied that paragraph 19A(1)(a), (b), (c) or (d) of the Act, as the case requires, no longer applies in relation to the goods, or that a condition of this approval has been contravened; and the Secretary has given to the person to whom this approval is granted a notice to the effect that the Secretary is so satisfied.

This approval is subject to each of the following conditions pursuant to subsection 19A(6) of the Act as specified below:

1. The approval holder identified in column 1 of Schedule 1 must only import and supply the therapeutic goods specified in column 2 of Schedule 1, for the indication(s) specified in column 3 of Schedule 1, being those goods which are registered or approved for general marketing in the foreign country specified in column 4 of Schedule 1.

2. The approval holder must report any adverse events relating to the specified therapeutic goods to the Therapeutic Goods Administration (TGA) where the usual adverse events reporting processes apply; i.e. serious reports sent to TGA within 15 days.

3. The approval holder must supply the specified therapeutic goods with labelling identifiable in English and prescribing information written in English; in this case, the labels and the summary of product characteristics as attached to this notice.

4. The approval holder must distribute the Dear Health Care Professional Letter which has been reviewed and agreed to by the TGA to health care professionals supplied with Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 1000ml (France). A copy of this letter has been attached to this notice.

5. The approval holder must over-sticker the specified therapeutic goods with a label that specifies the name and address of the Australian sponsor, as detailed in the attachment.

6. The approval holder must inform the TGA once aware of any supply issues associated with Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 1000ml (France).

7. The approval holder must provide the Secretary a report on the number of times Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 1000ml (France) was supplied and the quantities supplied:

    - during the first 6 months of the approval; and
    - during the period from six months after the approval to its expiration or lapsing (whichever is relevant).

The report is to be provided within 28 days after the end of the relevant reporting period.

Review rights

This decision is a reviewable initial decision for the purposes of the Act. If you are dissatisfied with my decision, you can find information about how to seek reconsideration of the decision in the Guidance for requesting reconsideration of an initial decision on the TGA website. More information is at Attachment 1 of this notice.

Copies of relevant legislation can be found on the Federal Register of Legislation at www.legislation.gov.au. The Act can be found at www.legislation.gov.au/Series/C2004A03952.

Signed electronically

Deborah Hay
A/g Co-Director
Medicine shortages Section
Pharmacovigilance Branch
Health Products Regulation Group
Therapeutic Goods Administration
Department of Health and Aged Care

DELEGATE OF THE SECRETARY

16 July 2024

Schedule 1

Specified therapeutic goods approved for importation and supply under subsection 19A(1) of the *Therapeutic Goods Act 1989*

Column 1	Column 2	Column 3	Column 4
Approval holder	Specified therapeutic goods	Indications	Foreign country and manufacturer
Aborns Pharmaceuticals Pty Ltd Level 42, 600 Bourke Street Melbourne VIC 3000 ABN: 80625808193	Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 1000ml (France)	For extracellular fluid replacement and in the management of metabolic alkalosis in the presence of fluid loss, and for restoring or maintaining the concentration of sodium and chloride ions.	Registered or approved for general marketing in: France Market Authorisation Number: 34009 326 874 3 5 Manufacture and Over-labelling: Laboratoire Bioluz Zone Industrielle De Jalday, Chemin De La Ferme, Bp 129, Saint Jean De Luz, 64500 France

Attachment 1

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website < https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision#:~:text=The%20only%20decisions%20that%20are,the%20Therapeutic%20Goods%20Regulations%20or> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**decision.review@health.gov.au**'

Subject: "**<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.