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 8 July 2024 in relation to Sodium Chloride 0.9% solution for infusion bag 1000mL (Lavoisier, 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 package leaflets 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% solution for infusion bag 1000mL (Lavoisier, 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% solution for infusion bag 1000mL (Lavoisier, France).

7. The approval holder must provide the Secretary a report on the number of times Sodium Chloride 0.9% solution for infusion bag 1000mL (Lavoisier, 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

Zaheeda Patel
Co-Director (A/g)
Medicine shortages Section
Pharmacovigilance Branch
Health Products Regulation Group
Therapeutic Goods Administration
Department of Health and Aged Care

DELEGATE OF THE SECRETARY

23 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 VICTORIA 3000 ABN: 80 625 808 193	Sodium Chloride 0.9% solution for infusion bag 1000mL (Lavoisier, France)	Indicated 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 Numbers: 34009 300 042 8 9 34009 550 016 5 2 Manufacturers: Laboratorios Grifols S.A. Calle De Jose Roman Marti 4, Las Torres De Cotillas, 30565 Spain Laboratoires Chaix Et Du Marais Zone Industrielle Des Gailletrous, 2 Allee Henri Hugon, La Chaussee St Victor, 41260 France