Australian Government
Department of Health
Therapeutic Goods Administration

[redacted]
Email: [redacted]
Ref: MB19/0137040

Notice of decision to grant an approval
under paragraph 19(1)(a) of the *Therapeutic Goods Act 1989*
(Special Access Scheme – Category B)

I refer to the application made on 14 Jun 2019 seeking approval by the Secretary of the Department of Health to a health practitioner for the importation into, the exportation from, or the supply in Australia of specified therapeutic goods (namely, a specified medicine) that are not registered goods, listed goods or exempt goods for use in the treatment of another person in accordance with paragraph 19(1)(a) of the *Therapeutic Goods Act 1989* (**the Act**).

This is a notice of decision given to you in accordance with subsection 19(4) of the Act.

Decision

I am a delegate of the Secretary of the Department of Health for the purposes of section 19(1) of the Act. I have decided to grant approval to [redacted] (the **approval holder**) identified in column 1 of Schedule 1 to this notice to import into, export from, or supply in Australia the specified medicine identified in column 2 of Schedule 1 for use in the treatment of the patient identified in column 3.

Reasons for decision

I have decided to grant this approval having considered the application made on 14 Jun 2019 and the information provided with that application.

In making this decision, I am satisfied that:

(a) the specified medicine is not included in the Australian Register of Therapeutic Goods (**Register**) or otherwise exempt from the requirement to include the specified medicine in the Register;

(b) the importation into, the exportation from, or the supply in Australia of the specified medicine is for use in the treatment of another person; and

(c) the approval holder is a health practitioner within the meaning of the Act.

Conditions

This approval is granted subject to the following conditions imposed by me in accordance with subsection 19(1) of the Act:

1. the approval holder must only import into, export from, or supply in Australia the specified medicine for use in the treatment of the patient in the manner described in the application;

2. the approval holder, and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the specified medicine;

3. the approval holder must obtain informed consent in writing from the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the specified medicine;

4. the approval holder must report adverse events or defects associated with the use of the specified medicine to the TGA within 15 calendar days after the approval holder become aware of the adverse event. The preferred reporting route is via the online portal https://aems.tga.gov.au;

Please note that it is the responsibility of the approval holder to arrange for the importation into, exportation from, or the supply in Australia of the specified medicine and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from, or the supply in Australia is arranged.

Period of approval

This approval has effect for a period of 12 Month(s) commencing on the date of this notice, unless the Secretary (or her delegate) decides to revoke the approval.

Dated 17 Jun 2019

[redacted]
Delegate of the Secretary
Therapeutic Goods Administration

Schedule 1

Reference: MB19/0137040

Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
[redacted] [redacted]	*Medicine:* Fesoterodine *Product description:* Tablet	*Patient initials:* [redacted] *Patient gender:* [redacted] *Patient DOB:* [redacted]	*Purpose:* Detrusor function *Dosage:* 8mg daily PO