Australian Government
Department of Health

GUIDE TO COMPLETING THE **PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION** – INFORMATION FOR APPLICANTS

A completed **PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION** (the Application Form) must be completed with every submission to the Pharmaceutical Benefits Advisory Committee (PBAC) and forwarded to the PBAC Secretariat with the submission.

The Application Form constitutes an essential component of the Pharmaceutical Benefits Scheme (PBS) Cost Recovery process. If the Application Form is not completed, the PBS Cost Recovery invoicing procedures may not be triggered and evaluation of the submission may not proceed.

Compiling the submission to the PBAC:
Submissions to the PBAC must be compiled in accordance with the **Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee** (the Guidelines). The Guidelines are periodically updated. The most current Guidelines can be viewed at www.pbs.gov.au/info/industry/listing/elements/pbac-guidelines

It is recommended, although not mandatory, that an authorised representative of the applicant contact the PBAC Secretariat for a preliminary discussion about the intended submission. At these pre-submission meetings, the Secretariat can also provide advice on the application process and the submission category for the prospective application, and will provide guidance, where appropriate, on fee exemptions and fee waivers. Preliminary discussion may help prevent delays in evaluation of the submission.

Prior to completing the Application Form and nominating the fee payment category:
It is recommended that applicants familiarise themselves with the *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009* (the Regulations). These Regulations include important information about the PBS Cost Recovery framework and applicable fees for service.

The PBAC meets three times annually – in March, July and November. It is advised that the applicant review the cut-off dates for submissions of each category type. Applicable date can be viewed at www.pbs.gov.au/info/industry/useful-resources/pbs-calendar

Completing the Application Form:
The applicant is required to nominate the fee category for the applicant's submission. Note that this fee category assessment is not binding upon the fee assessment by authorised Departmental officers. However, should an applicant disagree with the Departmental assessment, fee assessment review rights are available. Details of the review process can be obtained at www.pbs.gov.au If intending to apply for a fee exemption or a fee waiver, the applicant is required to nominate the fee category that would apply in the absence of the exemption or waiver.

Circumstances in which fee exemptions or fee waivers may apply are described in the Regulations. Information can also be found in the **Questions and Answers for Industry Information Fact Sheet** available at www.pbs.gov.au

An applicant may withdraw the submission at any time. If it is withdrawn in the first 14 calendar days following advice of fee payable, the applicant is entitled to a full refund of any fees paid. If the submission is withdrawn after 14 calendar days have passed, the fee remains payable and will be subject to Commonwealth Government debt recovery processes should it remain unpaid after the due date.

PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION

This submission is for PBAC consideration at the PBAC meeting of (Applicant to nominate):
March / July / November 20__ __

ITEM DESCRIPTOR:

Drug / Vaccine:
Generic Name: .....Tioropium.....
Brand Name(s): .....Braltus.....
Your Drug / Vaccine reference number, if applicable (this will be quoted in any correspondence with you regarding fees): .....

PURPOSE OF APPLICATION (Applicant to nominate):

New Listing ☑ Pricing matter ☐ Change to Existing Listing ☐ Other ☐
If 'Other' please explain: .....
.....

Brief Summary of Request (for example, Conditions / Indications that are the basis for this submission):
...Request to list a generic brand of tiotropium capsule containing powder for oral inhalation 13 micrograms (as bromide). For use with a Zonda inhaler, provided with each pack.

The reference product is: Tiotropium capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler)

Product Dose Form(s) and Strength(s):
Form: capsule containing powder for oral inhalation Strength(s): 13 microgram (as bromide).
Form: ..... Strength(s): .....
Form: ..... Strength(s): .....
(If additional forms and strengths please attach details on a separate page)

PBS Restriction Sought (Applicant to nominate):
Section 100 ☐ Authority required ☐ Authority required (streamlined) ☐
Restricted benefit ☑ Unrestricted benefit ☐

Is this a re-submission? Yes ☐ No ☑ If Yes, complete the 're-submission details' section.

Have you undertaken any pre-submission meetings with the PBAC Secretariat staff in preparing this submission? Yes ☑ No ☐
If Yes, please provide date/s of the meeting/s (if known) 9/8/2018 Pathway advice only via email

RE-SUBMISSION DETAILS:

If the application is a re-submission please provide the following information:

Number of times previously considered by the PBAC ..... N/A

Date of most recent PBAC consideration .....

APPLICANT FEE CATEGORY NOMINATION (Nominate one category only):
Major submission ☐ Minor submission ☒ Committee Secretariat Listing ☐

FEE EXEMPTION / FEE WAIVER REQUEST
☐ Fee Exemption requested ☐ Supporting documents attached (*Exemptions may only be approved for items specified in Regulation 5.1.*)

PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION

☐ Fee Waiver requested ☐ Approval or supporting documentary evidence attached (*Waivers may only be approved in the circumstances specified in Regulation 5.2.*)

APPLICANT DETAILS:

Name of Company or supplier of the Drug / Vaccine:

Teva Pharma Australia Pty Ltd.

ABN: 41 169 715 664

Responsible Person: Teva Pharma Australia Pty Ltd

Authorised Representative [redacted]
Authorised Representative

[redacted]

Telephone: [redacted] **Facsimile:** N/A

Address:
Level 1, 37 Epping Rd. Macquarie Park NSW 2113

Postal address (if different from above):

If you or your organisation are not the company directly responsible for the manufacture or importation of the drug / vaccine, a letter supporting this application and signed by a Director of the relevant manufacturing or importing company must be attached with this application.

ADDITIONAL INFORMATION:

If there is any further information you wish to advise the Department about concerning this application, please provide details:

DECLARATION:
By signing this form I declare that:

- The submission has been prepared in accordance with the most recent version of the **Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC);**
- This Application Form has been completed having regard to the *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009*; and

PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION

- I understand that the submission may not be progressed to the PBAC until the applicable fee* has been paid or, where relevant, a fee exemption or fee waiver has been approved.

[redacted]

Date ..... 14/Dec/2018 .....

Signature of Responsible Person ... [redacted] .....

Print Name ..... [redacted] .....

Date ..... 14 Dec 2018 .....

*The applicable fee amount and payment options will be outlined in the request for Payment notification and the invoice, including terms of trade advice, you will receive following submission of the application.