****

# **Application Form for Submission Services**

**From 1 July 2019, applicants must complete an Application Form for Submission Services (Part A AND Part B; OR Part C) in order for submission services to be provided by the Commonwealth.**

**Part A and Part B of this form must be completed** for all applications to list a new drug or to amend or extend an existing listing that require consideration by the Pharmaceutical Benefits Advisory Committee (PBAC). **Part C of this form must be completed** for all applications to list a new brand of an existing pharmaceutical item where consideration by the PBAC is NOT required.

### **IMPORTANT INFORMATION**

### **Privacy and your personal information**

Your personal information is protected by law, including the *Privacy Act 1988* and the Australian Privacy Principles, and is being collected by the Australian Government Department of Health for the purposes of your organisation applying to list a medicine on the [Pharmaceutical Benefits Scheme](http://www.pbs.gov.au/info/industry/listing/listing-steps).

If you do not provide this information, your organisation will be unable to apply for these benefits.

You can get more information about the way in which the Department of Health will manage your personal information, including our privacy policy, at <http://www.pbs.gov.au/info/general/privacy-policy>.

**Before completing an Application Form for Submission Services 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) and the PBS Cost Recovery Administrative Guidelines.These Regulations and guidelines 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 [PBAC calendar](http://www.pbs.gov.au/info/industry/useful-resources/pbs-calendar) which provides submission due dates for each category type.

| **PART A: INTENT TO APPLY (PRIOR NOTICE)**  PART A of this form – INTENT TO APPLY (prior notice[[1]](#footnote-1)) provides the Department with formal notice of submissions coming forward for PBAC consideration and will assist the Department to plan for the upcoming PBAC meeting. The [Procedure Guidance](http://www.pbs.gov.au/info/industry/listing/listing-steps) provides further information on the Intent to Apply process.  An Application for Submission Services with PART A complete must be provided for every intended Major or Minor submission to the Pharmaceutical Benefits Advisory Committee (PBAC) and submitted to the [PBAC Secretariat](mailto:pbssubmissions@health.gov.au) at least **28 days before** the Major/Minor (or relevant co-dependent) submission due date. Prior notice does not need to be given for Committee Secretariat and New Brand of an existing pharmaceutical item evaluation categories or where Regulation 2.9 applies.  An Application form for Submission Services with PART A – INTENT TO APPLY complete must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.  PART A of this form – INTENT TO APPLY (prior notice) constitutes an essential component of the Pharmaceutical Benefits Scheme (PBS) Cost Recovery process. Submission services will not be provided in response to an applicant’s submission if this prior notice is not given[[2]](#footnote-2). |
| --- |

### **Before completing PART A – Intent to Apply (prior notice):**

The applicant is required to nominate the fee category for the applicant’s submission. **Within 14 days** after receipt of PART A of this form, the Department will provide written notification to the applicant (authorised representative) acknowledging receipt and the fee payable for submission services.

The fee category nomination in PART A of this form will be assessed following lodgement of your submission. Note that this fee category assessment may be subject to validation by the Secretary (or a delegate) at any time after the application is made. Should an applicant disagree with the validation decision about the applicable assessment category review rights are available. For further information on the review process please refer to Part 6 of the Regulations. 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.

An applicant may withdraw an Intent to Apply Form (prior notice) at any time. If withdrawn (in writing) **within** **14 days** after notification is given by the Department about the prior notice, the applicant is entitled to a full refund of any fees paid less the non-refundable deposit[[3]](#footnote-3). If this prior notice is withdrawn **after 14 days** have passed from the day notification is given about the prior notice, the full fee remains payable and will be subject to Commonwealth Government debt recovery processes should it remain unpaid after the due date.

| **PART B: APPLICATION TO ACCOMPANY PBAC SUBMISSION (APPLICATION)**  PART B of this form – APPLICATION TO ACCOMPANY PBAC SUBMISSION (application[[4]](#footnote-4)) must be completed for all submissions to list a new drug, to amend or extend an existing listing that require consideration by the Pharmaceutical Benefits Advisory Committee (PBAC) and submitted to the [PBAC Secretariat](mailto:pbssubmissions@health.gov.au) with your submission by the submission due date.  PART B of this form – APPLICATION TO ACCOMPANY PBAC SUBMISSION must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.  Where prior notice was not required or an applicant was granted a prior notice waiver2 applicants **must complete both PART A and PART B of this form** and provide to the [PBAC Secretariat](mailto:pbssubmissions@health.gov.au) with your submission by the submission due date. |
| --- |

### **Before completing PART B the Application Form to accompany PBAC Submission (application form):**

**Within 21 days** after receipt of a complete application, the Department will provide written notification to the applicant (authorised representative) acknowledging receipt, the fee exemption or waiver decision (if applicable) and if prior notice is not required[[5]](#footnote-5) the fee payable for submission services.

If applying for a fee exemption or a fee waiver supporting documentation must be provided with your submission. Circumstances in which fee exemptions or fee waivers may apply are described in the Regulations.

An applicant may withdraw an application (application for submission services) at any time. If withdrawn (in writing) **within** **14 days** after notification is given by the Department about the application (where prior notice is not required under regulation 2.15(1) or a notification is given under regulation 2.17(2) about the application) the applicant is entitled to a full refund of any fees paid. If this application is withdrawn **after 14 days** have passed from the day notification is given about the prior notice, the full fee remains payable and will be subject to Commonwealth Government debt recovery processes should it remain unpaid after the due date.

| **PART C: APPLICATION FOR NEW BRAND OF EXISTING PHARMACEUTICAL ITEM (APPLICATION)** PART C of this form – APPLICATION FOR NEW BRAND OF EXISTING PHARMACEUTICAL ITEM (application[[6]](#footnote-6)) must be provided for every New Brand of existing pharmaceutical item and submitted to [PBS Information Management](mailto:pbslisting@health.gov.au) by the submission due date. Please refer to the [PBS website](http://www.pbs.gov.au/info/industry/listing/procedure-guidance/5-lodging-submissions/5-7-new-brand-existing-pharmaceutical-item-submissions) for further information on preparing New Brand of an existing pharmaceutical item submissions.  PART C of this form – APPLICATION FOR NEW BRAND OF EXISTING PHARMACEUTICAL ITEM must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.  PART C of this form – APPLICATION FOR NEW BRAND OF EXISTING PHARMACEUTICAL ITEM (application) constitutes an essential component of the Pharmaceutical Benefits Scheme (PBS) Cost Recovery process and **must be completed when seeking a waiver of the submission services fee.** |
| --- |

### **Before completing PART C the Application Form (application) to list a New Brand of an existing pharmaceutical item:**

**Within 21 days** after receipt of a complete Application Form, the Department will provide written notification to the applicant (authorised representative) acknowledging receipt, the fee exemption or waiver decision (if applicable) and the fee payable for submission services.

The fee category nomination in this form will be assessed. Note that this fee category assessment may be subject to validation by the Secretary (or a delegate) and the applicant will be notified of any decision made about the category within 14 days of receiving the application. Should an applicant disagree with the validation decision about the applicable assessment category review rights are available. For further information on the review process please refer to Part 6 of the Regulations. If intending to apply for a fee exemption or a fee waiver, the applicant is required to provide supporting documentation with this application. Circumstances in which fee exemptions or fee waivers may apply are described in the Regulations.

An applicant may withdraw an application at any time. If withdrawn (in writing) **within** **14 days** after notification is given by the Department about the application, the applicant is entitled to a full refund of any fees paid. If this application is withdrawn **after 14 days** have passed from the day notification is given about the application, the full fee remains payable and will be subject to Commonwealth Government debt recovery processes should it remain unpaid after the due date.

| **PART A: Intent to Apply** |
| --- |

**Office of Health Technology Assessment Branch**

**Department of Health**

**GPO Box 9848, Canberra ACT 2601**

## **Submission details**

| Drug / Vaccine name: | Click or tap here to enter text. |
| --- | --- |
| Brand name(s): | Click or tap here to enter text. |
| Applicant Reference number: | Click or tap here to enter text. |

To be provided by the applicant (If applicable). This reference will be quoted in any correspondence with you regarding fees).

**Product Dose Form(s) and Strength(s)**

| Form: | Click or tap here to enter text. | Strength(s): | Click or tap here to enter text. |
| --- | --- | --- | --- |
| Form: | Click or tap here to enter text. | Strength(s): | Click or tap here to enter text. |
| Form: | Click or tap here to enter text. | Strength(s): | Click or tap here to enter text. |

(If additional forms and strengths please attach details on a separate page).

| **Application purpose:** | Please select | If ‘Other’ please specify: |
| --- | --- | --- |
|  | Click or tap here to enter text. |
| **Brief summary of request** | Click or tap here to enter text. | |

(for example, conditions / indications that are the basis for your submission).

| **Intended PBAC meeting date:** | Month | | Year | | |
| --- | --- | --- | --- | --- | --- |
| **Initial submission or Resubmission:** | Please select | | | | |
|  | If the application is a **resubmission** please provide the following information: | | | | |
|  | Number of times previously considered by the PBAC: | | | | Please select |
|  | Date of most recent PBAC consideration: | | | Month | Year |
| **Fee category nomination:** | Category: | Please select | | | |
|  | Rationale: | Click or tap here to enter text. | | | |
| **Will you be requesting a Fee Exemption or Fee Waiver?** | Please select | | | | |
| If requesting a Fee Exemption or Fee Waiver supporting documentation must be provided with your submission. **Please note: Exemptions** may only be approved for items specified in Regulation 5.1. **Waivers** may only be approved in the circumstances specified in Regulation 5.2. Guidance on how to submit a waiver application is included in the Cost Recovery Administrative Guidelines. | | | | | |

**Have you undertaken any pre-submission meetings with the PBAC Pre-submission team in preparing your submission?**

|  |  | Yes. | If yes, please provide the most recent meeting date  (if known): | | |
| --- | --- | --- | --- | --- | --- |
| Click or tap to enter a date. | | |
|  | No. | | | |
| **TGA Status: (including parallel process, priority or provisional approval, etc.)** | Click or tap here to enter text. | | | | |
| Please select | | | | |
| **Indication:** | TGA indication: | | Click or tap here to enter text. | | Please select |
| Proposed PBS indication: | | Click or tap here to enter text. | | |
|  |  | | |  | |
| **Proposed clinical claim:** | Please select | | | If ‘Other’ please specify: | |
| Click or tap here to enter text. | |
| **Proposed economic approach:** | Please select | | | | |
| **Proposed main comparator:** | Click or tap here to enter text. | | | | |
| **Will you be requesting a  Managed Entry Scheme?** | Please select | | | | |
| **Will the submission involve a co-dependent technology?** | Please select | | | | |

## **Applicant details**

| **Name of Company or supplier of the Drug/Vaccine:** | | Click or tap here to enter text. | |
| --- | --- | --- | --- |
| **ABN:** | | Click or tap here to enter text. | |
|  | |  | |
|  | **Authorised Representative** | | **Secondary contact** |
| **Contact person (for the submission phase):** | Click or tap here to enter text. | | Click or tap here to enter text. |
| **Position:** | Click or tap here to enter text. | | Click or tap here to enter text. |
| **Email address:** | Click or tap here to enter text. | | Click or tap here to enter text. |
| **Telephone number:** | Click or tap here to enter text. | | Click or tap here to enter text. |
| **Mobile number (optional):** | Click or tap here to enter text. | | Click or tap here to enter text. |
| **Address:** | Click or tap here to enter text. | | Click or tap here to enter text. |
| **Postal address (if different from above):** | Click or tap here to enter text. | | Click or tap here to enter text. |

## **Applicant declaration (Part A)**

**I declare that:**

|  | I am authorised to make this request on behalf of the applicant. |
| --- | --- |
|  | The information I have provided in this form contains all information I know to be relevant to the listing of the drug / vaccine and is correct to the best of my knowledge. |

**I understand that:**

|  | Giving false or misleading information is a serious offence. |
| --- | --- |
|  | Consistent with the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009*, a fee will ordinarily be payable for submission services provided by the Commonwealth. |
|  | 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. |

| **Printed name:** | Click or tap here to enter text. |
| --- | --- |
| Authorised for electronic signature. | Click or tap to enter a date. |

An Application form for Submission Services with PART A – INTENT TO APPLY complete must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.

\*The applicable fee amount and the payment options will be outlined in the request for payment notification and the invoice, including terms of trade advice, sent by the Department. The notice will be issued within 14 days of submission of a complete Part A – Intent to Apply (prior notice).

| **PART B: Application Form to accompany PBAC Submission** |
| --- |

**Office of Health Technology Assessment Branch**

**Department of Health**

**GPO Box 9848, Canberra ACT 2601**

Was Part A – Intent to Apply Form (prior notice) submitted at least 28 days prior to the Major/Minor submission due date?

|  | Yes. | |
| --- | --- | --- |
|  | No. **If no please select a reason and also complete Part A of this form (Intent to Apply):** | Please select |
| Supporting documentation attached: | Please select |

**Supporting documentation must be provided with your submis**sion for an urgent public health need exception under Regulation 2.15(3).

I confirm that the information provided in Part A – Intent to Apply Form (prior notice) remains unchanged.

|  | Yes. | |
| --- | --- | --- |
|  | No. |  |
| If no, please provide details: | Click or tap here to enter text. |

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

| Click or tap here to enter text. |
| --- |

| **Fee Exemption or Fee Waiver requested?** | Please select |
| --- | --- |
| **Supporting documentation attached?** | Please select |
| If requesting a Fee Exemption or Fee Waiver supporting documentation must be attached. **Please note: Exemptions** may only be approved for items specified in Regulation 5.1. **Waivers** may only be approved in the circumstances specified in Regulation 5.2. Guidance on how to submit a waiver application is included in the Cost Recovery Administrative Guidelines. | |
|  | |

## **Applicant declaration (Part B)**

**I declare that:**

|  | I am authorised to make this application on behalf of the applicant.  *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.* |
| --- | --- |
|  | 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).** |
|  | The information I have provided in this form contains all information I know to be relevant to the listing of the drug / vaccine and is correct to the best of my knowledge. |

**I understand that:**

|  | Giving false or misleading information is a serious offence. |
| --- | --- |
|  | Submission services may not be provided by the Commonwealth until the applicable fee (in accordance with the Payment notification and the invoice) has been paid or, where relevant, a fee exemption or fee waiver has been approved. |

| **Printed name:** | Click or tap here to enter text. |
| --- | --- |
| Authorised for electronic signature. | Click or tap to enter a date. |

PART B of this form – APPLICATION TO ACCOMPANY PBAC SUBMISSION must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.

| **PART C: Application for New brand of existing pharmaceutical item** |
| --- |

**Pricing and PBS Policy Branch**

**Department of Health**

**GPO Box 9848, Canberra ACT 2601**

## **Submission details**

| PBS Code (if known): | Click or tap here to enter text. |
| --- | --- |
| Requested listing date: | Click or tap to enter a date. |
| Trade / Brand name: | Click or tap here to enter text. |
| Manufacturer Code  (if applicable): | Click or tap here to enter text. |

**Form(s), Strength(s) and Pack Size(s)**

| Form: | Strength | Pack Size |
| --- | --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

(If additional forms and strengths please attach details on a separate page).

| **Fee category nomination and rationale:** | Category: | Please select |
| --- | --- | --- |
|  | Click or tap here to enter text. | |
| **Fee Exemption or Fee Waiver requested?** | Please select | |
| **Waiver supporting documentation attached?** | Please select | |
| If requesting a Fee Exemption or Fee Waiver supporting documentation must be attached. **Please note: Exemptions** may only be approved for items specified in Regulation 5.1. **Waivers** may only be approved in the circumstances specified in Regulation 5.2. Guidance on how to submit a waiver application is included in the Cost Recovery Administrative Guidelines. | | |

Your application to list a New Brand must also include (please attach):

|  | TGA approved Product Information |
| --- | --- |
|  | A TGA bioequivalence statement  (If not provided PBAC consideration will be required and PART A and PART B of this form will need to be completed) |
|  | completed and signed [Responsible Person form](http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms#Responsible), which includes the authorised representative(s) |
|  | a complete [PB11a form](http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms#_PB11a) should be provided by the final documentation deadline [(refer to Section 8.1)](http://www.pbs.gov.au/info/industry/listing/procedure-guidance/8-procedures-positive-recommendation-list/8-1-price-agreement). |

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

| Click or tap here to enter text. |
| --- |

## **Applicant details**

| **Name of Company or supplier of the Drug/Vaccine:** | Click or tap here to enter text. |
| --- | --- |
| **ABN:** | Click or tap here to enter text. |

## **Applicant declaration (Part C)**

**I declare that:**

|  | The information I have provided in this form contains all information I know to be relevant to the listing of the drug / vaccine and is correct to the best of my knowledge. |
| --- | --- |
|  | **Supply assurance:** Sufficient stock of the product to meet demand will be available to allow for delivery to PBS dispensers (e.g. pharmacies, hospitals or other dispensers) in time for the PBS listing day. |

**I understand that:**

|  |  |
| --- | --- |
|  | Giving false or misleading information is a serious offence. |
|  | Consistent with the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009*, a fee will ordinarily be payable for submission services provided by the Commonwealth. |
|  | The submission may not listed by the requested listing date until the applicable fee\* has been paid or, where relevant, a fee exemption or fee waiver has been approved. |

| **Full name of authorised contact person:** | Click or tap here to enter text. |
| --- | --- |
| Authorised for electronic signature. | Click or tap to enter a date. |

PART C of this form – APPLICATION FOR NEW BRAND OF EXISTING PHARMACEUTICAL ITEM must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.

\*The applicable fee amount and the payment options will be outlined in the request for payment notification and the invoice, including terms of trade advice, sent by the Department. The notice will be issued within 21 days of submission of a complete Part C – Application for New Brand of an existing pharmaceutical item.

1. Refer to Division 2.2, regulation 2.15(1) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery Regulations 2009.*  [↑](#footnote-ref-1)
2. Refer to regulation 2.15(4) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009.*An exception may apply for an urgent public health need - refer to regulation 2.15(2). [↑](#footnote-ref-2)
3. Refer to Division 2.1, regulation 2.2(2) and Division 2.2, regulation 2.18(2) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009.*  [↑](#footnote-ref-3)
4. Refer to Division 2.2, regulation 2.16(1) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery Regulations 2009.*  [↑](#footnote-ref-4)
5. Refer to Division 2.2, regulation 2.9, 2.13 or 2.14 of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009.* [↑](#footnote-ref-5)
6. Refer to Division 2.2, regulation 2.16(1) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery Regulations 2009.* [↑](#footnote-ref-6)