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You can now submit your New brand or New oral form submission online via the Health Products Portal (HPP). For instructions on how to get started, please visit the [HPP website.](https://www.pbs.gov.au/info/industry/hpp/health-products-portal)

# **Application Form for Submission Services Part C**

**This form must be completed for all applications to list a new brand or new oral form of an existing pharmaceutical item where consideration by the Pharmaceutical Benefits Advisory Committee (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 New Brand or New Oral Form of Existing Pharmaceutical Item and nominating the fee payment category:**

It is recommended that applicants familiarise themselves with the *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2022* (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.

| **PART C: APPLICATION FOR NEW BRAND OR NEW ORAL FORM OF EXISTING PHARMACEUTICAL ITEM (APPLICATION)** This form – APPLICATION FOR NEW BRAND OR NEW ORAL FORM OF EXISTING PHARMACEUTICAL ITEM (application1) must be provided for every New Brand or New Oral Form of existing pharmaceutical item and submitted to [PBS Information Management](mailto:pbslisting@health.gov.au) by the submission due day. Please refer to the [PBS website](https://www.pbs.gov.au/info/industry/listing/procedure-guidance/5-lodging-submissions/5-8-new-brand-of-existing-pharmactcl-item-sub) for further information on preparing New Brand or New Oral Form of an existing pharmaceutical item submissions.  This form – APPLICATION FOR NEW BRAND OR NEW ORAL FORM OF EXISTING PHARMACEUTICAL ITEM must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.  This form – APPLICATION FOR NEW BRAND OR NEW ORAL FORM 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.** |
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### **Before completing the Application Form (application) to list a New Brand or New Oral Form of an existing pharmaceutical item:**

**Within 15 business 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 10 business 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** **10 business 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 10 business 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 C: Application for New Brand or New Oral Form of Existing Pharmaceutical Item** |
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**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)**

| PBS Code(s) (if known): | Form: | Strength | Pack Size |
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(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 section 67 of the Regulations. **Waivers** may only be approved in the circumstances specified in section 68 of the Regulations. Guidance on how to submit a waiver application is included in the Cost Recovery Administrative Guidelines. | |

Your application to list a New Brand or New Oral Form 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 8.3).](https://www.pbs.gov.au/info/industry/listing/procedure-guidance/8-procedures-positive-recommendation-list/8-3-pricing-offer-package) |

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**

**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 2022*, 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:** | Click or tap here to enter text. |
| --- | --- |
| Authorised for electronic signature. | Click or tap to enter a date. |

A complete APPLICATION FOR NEW BRAND OR NEW ORAL FORM OF EXISTING PHARMACEUTICAL ITEM must be submitted electrically 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 15 business days of submission of a complete Part C – Application for New Brand or New Oral Form of an existing pharmaceutical item.