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**Application Form for Pricing Services**

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

## **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 Pricing 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.

| **PART A: NOTICE OF INTENT FOR PRICING** PART A of this form – NOTICE OF INTENT FOR PRICING (prior notice of a pricing application[[1]](#footnote-1)) provides the Department with formal notice of pricing applications coming forward for listing. The [Procedure Guidance](http://www.pbs.gov.au/info/industry/listing/listing-steps) provides further information on the Notice of Intent for Pricing process.  An Application Form for Pricing Services with PART A complete must be provided for every intended pricing application following a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC) and submitted to [PBS Pricing](mailto:pbspricing@health.gov.au) at least **5 business days before** the intended Pricing Offer Package (pricing application) submission date.  An Application Form for Pricing Services with PART A 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 – NOTICE OF INTENT FOR PRICING (prior notice) constitutes an essential component of the Pharmaceutical Benefits Scheme (PBS) Cost Recovery process. Pricing services in response to an applicant’s pricing application will be delayed if this prior notice is not given[[2]](#footnote-2). |
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**Before completing PART A of this form - Notice of Intent for Pricing (prior notice of a pricing application):**

The applicant is required to nominate the pricing pathway fee category of the applicant’s submission. Generally, the Department will provide written notification to the applicant (authorised representative) acknowledging receipt and the fee payable for pricing services **within 10 business days** after receipt of PART A of this form.

If applying for a fee exemption or a fee waiver supporting documentation must be provided with Part A of this form. The Department will provide written notification to the applicant (authorised representative) to acknowledge receipt and provide the fee waiver or exemption decision. The written notification from the Department will be provided within 15 business days after receipt of PART A of this form. Circumstances in which fee exemptions or fee waivers may apply are described in Part 5 of the Regulations.

The pricing pathway fee category nominated in PART A of this form will be assessed following submission of the Pricing Offer Package. Note that this fee category assessment may be subject to validation by the Secretary (or a delegate). However, should an applicant disagree with the Departmental assessment, fee assessment 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.

An applicant may withdraw a Notice of Intent for Pricing (prior notice) at any time. If withdrawn **within 10 business days** after notification of the fee payable is given, 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 10 business 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.

| **PART B: PRICING APPLICATION (APPLICATION)** PART B of this form – PRICING APPLICATION (pricing application[[4]](#footnote-4)) must be submitted to [PBS Pricing](mailto:pbspricing@health.gov.au) with your Pricing Offer Package.  PART B of this form – PRICING APPLICATION must be submitted electronically in word format. Please do not submit a scanned or pdf version of the form.  Where an applicant was granted a prior notice waiver2 applicants **must complete both PART A and PART B of this form** and provide to [PBS Pricing](mailto:pbspricing@health.gov.au) with your Pricing Offer Package. |
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**Before completing PART B of this form – Pricing Application (pricing application):**

**Within 15 business days** after receipt of a complete pricing 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 was waived the fee payable for pricing services.

An applicant may withdraw an application (application for pricing services) at any time. If withdrawn (in writing) **within** **10 business days** after notification is given by the Department about the application (where prior notice of a pricing application) is not required under regulation 3.10(1) 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 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 A: Notice of Intent for Pricing** |
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**Pricing and PBS Policy 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. | | |
| Department reference number (if applicable): | Click or tap here to enter text. | | |
| PBAC meeting and Item number: | Month | Year | PBAC Meeting – Agenda Item Number |

**PBS Indication/condition to be treated as recommended by the PBAC:**

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

**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).

## **Applicant intent**

Please select **one** of the three options below.

Do you intend to submit a pricing offer package (pricing application) to the Department?

|  | **Yes.** | Intended pricing offer package (pricing application) lodgement date:  Click or tap to enter a date. |
| --- | --- | --- |
|  |  |  |
|  | **No, we will submit to the PBAC for re-consideration.**  **Rationale:** Click or tap here to enter text. | |
|  |  | |
|  | **No, we do not intend to submit a pricing offer package at all.**  (This will be recorded as withdrawing from the listing process for reporting purposes). | |
|  |  | |

**If you answered ‘No’ above please only complete the Applicant details section below. If you answered ‘Yes’ above please complete the remainder of Part A below.**

| **Pricing Pathway fee category nomination** | |
| --- | --- |
| Did the PBAC recommend listing ‘Pathway A’ for this submission? | Please select |

Based on your listing requirements please select the relevant pricing pathway from the list below. Please refer to the Regulations\* and the [Procedure Guidance](http://www.pbs.gov.au/info/industry/listing/listing-steps) for further information on individual pathways.

|  | **Pricing Pathway A**  Note: This pathway may only be selected if the ratified minutes of PBAC confirm this pathway is appropriate for your proposed listing. Should you choose to proceed with this pathway, a case manager will be assigned by the Department following receipt of a complete PART A - Notice of Intent for Pricing (prior notice of a pricing application). The five-year rebate management fee applies to this pathway. |
| --- | --- |
|  |  |
|  | **Pricing Pathway B**  Generally, for submissions that require negotiation and finalisation of a deed of agreement (where the pricing terms in an existing deed are NOT substantially similar to those appropriate for the new drug) and a full assessment of proposed risk-sharing and/or pricing arrangements.  Note: The five-year rebate management fee applies to this pathway. |
|  |  |
|  | **Pricing Pathway C**  Generally, for submissions that negotiation and finalisation of a deed of agreement (where the pricing terms in an existing deed are substantially similar to those appropriate for the new drug). Note: The five-year rebate management fee applies to this pathway. |
|  |  |
|  | **Pricing Pathway D**  Not in Pathway A, B, or C (usually applicable where a new price is required to be agreed for a pharmaceutical item). |
|  |  |
|  | **Secretariat Pathway**  Generally, for changes to listings of existing medicines which do not require a new price to be agreed for a pharmaceutical item. |

\* See Division 3.2 of the Regulations for full details of Pathways. The selected pathway will be confirmed by the Department following acceptance of your Pricing Offer Package.

| **Fee category rationale:** | Click or tap here to enter text. |
| --- | --- |

| **Will you be requesting a Fee Exemption or Fee Waiver?** | Please select | |
| --- | --- | --- |
| **Supporting documentation attached?** | Please select | |
| If requesting a Fee Exemption or Fee Waiver supporting documentation will be required to be provided with your Pricing Offer Package. **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. | | |
| Is a Special Pricing Arrangement proposed? | | Please select | |

| Is a Risk Sharing Arrangement proposed? | Please select |
| --- | --- |
|  |  |
| Is a Managed Entry Scheme proposed? | 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 pricing services 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**

**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. |
|  | Pricing services may not be provided by the Commonwealth 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. |

An APPLICATION FORM FOR PRICING SERVICES with PART A 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.

| **PART B: Pricing Application** |
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**Pricing and PBS Policy Branch**

**Department of Health**

**GPO Box 9848, Canberra ACT 2601**

Was Part A – Notice of Intent for Pricing (prior notice of a pricing application) submitted at least 7 days prior to submission of your Pricing Offer Package?

|  | Yes. | |
| --- | --- | --- |
|  | No. **If no please select a reason and also complete Part A of this form (Notice of Intent for Pricing):** | 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 3.10(2)

I confirm that the information provided in Part A – Notice of Intent for Pricing (prior notice of a pricing application) remains unchanged

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

The Pricing Offer Package must include:

| Provided | Not Required | Documentation |
| --- | --- | --- |
|  |  | A complete [PB11 form](http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms#_PB11) (‘Application to list a drug or medicinal preparation as a Pharmaceutical Benefit’) |
|  |  | A complete [PB11a form](http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms#_PB11a) (‘Request for approved ex-manufacturer price’). |
|  |  | Pricing calculations or information to support price proposed in the PB11a form. |
|  |  | A special pricing arrangement (SPA) request addressing eligibility against the [SPA criteria](http://www.pbs.gov.au/industry/listing/elements/deeds-agreement/Special-Pricing-Arrangement-criteria.pdf). |
|  |  | Agreement in principle to any PBAC advice on deed arrangements. |
|  |  | Confirmation of PBAC recommended restriction wording. |
|  |  | TGA approval letter. |
|  |  | Updated Utilisation and Cost model workbook. |
|  |  | Completed and signed [Responsible Person form](http://www.pbs.gov.au/info/industry/useful-resources/pbs-forms#Responsible), which includes the authorised representative(s) |

Please refer to the PBS website for further information on [new listing requirements](http://www.pbs.gov.au/info/industry/listing/elements/listing-requirements-new-item).

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

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

| **Fee Exemption or Fee Waiver requested?** | Please select |
| --- | --- |
|  | |

## **Applicant declaration**

**I declare that:**

|  | **Supply assurance:** There is sufficient stock of the product to meet demand in time for the proposed PBS listing date. |
| --- | --- |
|  | 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. |
| --- | --- |
|  | Pricing 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. |

An APPLICATION FORM FOR PRICING SERVICES with PART B complete must be submitted electronically in word format. Please do not submit a scanned or PDF version of the form.

1. Refer to Division 3.3, regulation 3.10(1) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009*. [↑](#footnote-ref-1)
2. An exception may apply for an urgent public health need. Refer to Division 3.3, regulation 3.10(2) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009*. [↑](#footnote-ref-2)
3. Refer to Division 3.2, regulation 3.3(2) and Division 3.3, regulation 3.13(2) of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009.* [↑](#footnote-ref-3)
4. Refer to Division 3.3, regulation 3.11 of the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2009.* [↑](#footnote-ref-4)