



Ensuring your voice is heard on access to medicines

Guide to submitting
Online Consumer Comments to
the Pharmaceutical Benefits
Advisory Committee (**PBAC**)
for listing medicines on the
Pharmaceutical Benefits
Scheme (**PBS**)

YOUR VOICE CAN BE HEARD: HOW TO SUBMIT AN ONLINE CONSUMER COMMENT FOR MEDICINES BEING CONSIDERED FOR LISTING ON THE PBS

What is the Pharmaceutical Benefits Scheme (PBS)?

The PBS subsidises the cost of new medicines needed by the Australian public. A PBS listing makes medicines more affordable for the people who need them. Under the PBS, the Australian Government covers most of the cost of a medicine.

Who decides which medications are listed on the PBS?

The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent body that considers whether to add new medicines to the PBS, thereby making them affordable for Australians. The PBAC meets three times a year (March, July, November) to review new medicines for listing on the PBS. It also regularly holds 'Intracycle' Meetings (May, December) to consider other issues, or to review medicines that have been 'deferred' at a previous meeting.

Following its review, the PBAC makes recommendations to the Government about whether a medicine should (or shouldn't) be listed on the PBS. The PBAC's recommendations influence the Government's decision-making on which medicines to add to the PBS.

Who should submit a Consumer Comment for a PBS submission?

Anyone with an interest in a particular medicine or treatment can submit a Consumer Comment to the PBAC, including people living with the condition, as well as anyone else impacted by it (i.e. family, friends and community members). The PBAC also welcomes comments from members of the public, carers, healthcare professionals, and patient or consumer groups. All comments received will be considered by the PBAC when it reviews a new medicine for listing on the PBS.

The PBAC is interested in the personal experience (or on behalf of a group) of the potential benefits a new medicine will bring for patients, families and carers. For example, the impact on quality of life, or other benefits that may come as a result of having access to a medicine through the PBS.

How to submit a Consumer Comment on a PBS submission

All medicines being considered by the PBAC for listing on the PBS are included on the '**PBAC Meeting Agenda**', which is published on its website 14 weeks before each meeting, at the following link: <https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda>. The Meeting Agenda is then updated 9 weeks before each meeting to reflect any changes that may have occurred (e.g. medicines added to, or removed from, the Agenda).

In order to submit a Consumer Comment for a particular medicine (or medicines), the medicine/s must be included on the current PBAC Meeting Agenda.

Consumer Comments for the July 2022 PBAC meeting can be submitted from:

Wednesday 30 March - 5.00pm, Wednesday 25 May. Submissions received after 5:00pm on Wednesday 25 May will have missed the cut-off and will not be considered by the PBAC.

Currently, members of the public are only able to provide their views about medicines included on each PBAC Agenda through an online/web interface, available through the **Office of Health Technology Assessment (OHTA) Consultation Hub** at: <https://ohta-consultations.health.gov.au/>

This is under review, and improvements to gather consumer input in ways that will promote meaningful and useful contributions to the PBAC's consideration of medicines are under development. All enquiries relating to the PBAC Consumer Comments process can be directed via email to: CommentsPBAC@health.gov.au.

The following document provides a step-by-step guide to take you through the Online Consumer Comments process in detail.

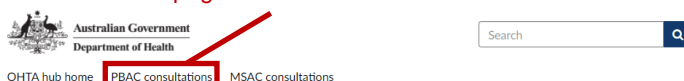
A STEP-BY-STEP GUIDE FOR SUBMITTING ONLINE CONSUMER COMMENTS FOR MEDICINES BEING CONSIDERED FOR LISTING ON THE PBS



STEP 1: Visit the Office of Health Technology Assessment (OHTA) consultation hub, at the URL/link provided below

<https://ohta-consultations.health.gov.au>

Click on the '**PBAC consultations**' tab on the homepage to be taken to STEP 2



Welcome to the Office of Health Technology Assessment (OHTA) consultation hub

Use this site to find, share and participate in health technology assessment (HTA) consultations. Input is welcome from consumers, health practitioners and any other interested groups or organisations.

- Click on the Pharmaceutical Benefits Advisory Committee (PBAC) [link](#) above to provide input about a medicine or vaccine being considered by the PBAC;
- Click on the Medical Services Advisory Committee (MSAC) [link](#) above to provide input about a health service, medical test or device being considered by the MSAC;
- Or look at the 'Open Consultations' list below.

Consumers and consumer groups and organisations can contact the Consumer Evidence and Engagement Unit for questions on upcoming or current consultations via email: HTAconsumerengagement@health.gov.au

[Information on consultation process for medicines and vaccines \(PBAC\)](#)

[Information on consultation process for medical tests, devices, services and programs \(MSAC\)](#)

STEP 2: Select the correct PBAC meeting (i.e. July 2022) to submit a Consumer Comment for a medicine that is included on the relevant PBAC Meeting Agenda

<https://ohta-consultations.health.gov.au/pbac/>

The screenshot shows the Australian Government Department of Health website. At the top, there is a search bar and navigation links for OHTA hub home, PBAC consultations, and MSAC consultations. The main content area features a banner with two call-to-action boxes: 'Medicine Status Website' and 'PBAC meeting agenda and consultation dates'. Below this, there is a section titled 'Open PBAC consultations for feedback' with two entries. The first entry is for a 'Public consultation on items to be considered by the PBAC (May 2022 Intracycle Meeting)' which closes on 8 April 2022. The second entry, highlighted with a red box, is for a 'Public consultation on items to be considered by the PBAC (July 2022)' which closes on 25 May 2022.

Click on the July PBAC meeting to submit a Consumer Comment for one or both of the PKU treatments

STEP 3: Once Consumer Comments are open for the relevant PBAC meeting, you will be taken to an 'Overview' page, with guidance for input from the public

Public consultation on items to be considered by the PBAC (July 2022)

Ensure the details of the correct PBAC meeting (i.e. July 2022) are displayed at the top of the page

Overview

Consultation is now open for items listed on the July 2022 PBAC agenda.

The PBAC welcomes input from patients, carers, health professionals, consumer groups or organisations and members of the public on medicines submitted for PBAC consideration.

The PBAC considers these public consultation inputs when considering the clinical and economic evidence presented by the applicant.

- Input can be submitted via the **online survey**. A copy of the questions asked in the survey can be downloaded below under 'Related' to assist your preparation.
- **There is the option to upload a file with your submission.** The preferred file types are PDF or Microsoft Word, however other file types will be accepted, provided they are no larger than 25mb. If your file is too large, or you wish to upload more than one file, please contact commentsPBAC@health.gov.au.
- You can save and come back at any time to your response before the consultation close date.
- Once you have submitted, a copy of your submission will be emailed to the contact email address provided.

Should you wish to provide input on another medicine, you will need to start a new survey.

Please note that we may be updating this survey in the coming months to provide additional guidance and welcome suggestions on ways to further improve this process.

Closes 25 May 2022
Opened 30 Mar 2022

Contact
CommentsPBAC@health.gov.au

The opening and closing dates for Consumer Comments will be provided for the relevant PBAC meeting – along with contact details for the PBAC Secretariat

When you're ready to share your comments, click 'Provide your input' to be taken to STEP 4

PBAC consultation open

[Provide your input >](#)

July 2022



STEP 4: The first step of the Consumer Comments submission –
Privacy and consent

Page 1 of 6

Closes 25 May 2022

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Ensure you have cookies enabled on your internet/web browser before you proceed.

Privacy and consent

Privacy Information

Your personal information is protected by law, including the *Privacy Act 1988* (Privacy Act) and the Australian Privacy Principles (APPs), and is being collected by the Department, via Citizen Space, for the purposes of conducting a consultation process in relation to an application submitted to the Office of HTA. The Department will collect your personal information at the time that you provide a submission.

To protect privacy, do not include identifying personal or sensitive information about another individual (third party).

▼ [More information about privacy](#)

You can obtain a copy of the Department's [privacy policy](#) by contacting the Department using the contact details set out below. The Department's privacy policy contains information about:

- how you may access the personal information the Department holds about you and how you can seek correction of it; and
- how you may complain about a breach of
 - the APPs; or
 - a registered APP code that binds the Department; and
- how the Department has dealt with such a complaint.

You can contact the Department by telephone on (02) 6289 1555 or free call 1800 020 103 or by using the online enquiries form at www.health.gov.au.

How your input will be used

- All input from individuals will be made available in **summary** form to the sponsor of the application and the PBAC.
- No identifying information about individuals or third parties will be included in the summary. This type of information will be removed by the Department.
- All input from groups or organisations will be provided in full to both the PBAC and its subcommittees and the sponsor of the medicine. Any identifying information relating to third parties detected will be removed prior to distribution.
- In addition all input received will be noted in the relevant Public Summary Document. Public Summary Documents are available approximately four (4) months after the PBAC meeting and outline the PBAC discussion and advice. See the [PBAC calendar](#) for publication dates.

Please indicate your consent below

Consent

- I have read the above text on how public consultation input will be used and consent to the input being used as described above (Required)

Save and come back later...

Continue >

After reviewing the information on this page and checking the consent box, click the 'Continue' button to proceed to the next page

Once you have reviewed the privacy information on this page, check the box to give your consent and proceed with your submission

At any time, you can click the 'Save and come back later' button to save your work as you go, so you can return to the same point in the process when you are ready

STEP 5a:

The second step of the Consumer Comments submission – providing your **Contact Details**

Page 2 of 6

Closes 25 May 2022

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Contact details

Below is a section to provide your contact details. These details are not made public or shared with the PBAC. We ask for these individual details only to ensure submissions are recorded accurately and can be confirmed, if required.

Enter your name and email address at Questions 1 & 2

1. What is your name?

Name (Required)

2. What is your email address?

If you enter your email address then you will automatically receive an acknowledgement email when you submit your response.

Email (Required)

At Question 3, select the most appropriate description that reflects the capacity in which you are submitting a Consumer Comment

3. Please choose a category that best describes the primary reason for your input.

(Required)

- Individual who would like to access the medicine to treat own health condition
- Individual who has used this medicine for own health condition
- Parent or partner of an individual from above two groups
- Consumer group/organisation
- Health professional working in the area
- Medical/other organisation
- Other interested individual (including family members, friends, or members of the public)

For noting:

- Input from individuals will be deidentified, collated and summarised before provision to Applicants and the PBAC
- Input made by organisations (consumer, medical or other) will be shared in full with applicants and the PBAC.
- If you are a health professional with experience treating the condition or using the medication and are providing input that represents your own views, select 'Health professional'. If you are a health professional providing input on behalf of a group of clinicians or an organisation, please select 'Medical/other organisation'.

STEP 5b:

Providing your **Contact Details** (continued) & **Selecting the medicine** you would like to submit a Consumer Comment for

Unless you are submitting a Consumer Comment on behalf of a patient advocacy or support organisation, leave Question 4 blank and proceed to Question 5

4. If you selected consumer group/organisation, or medical/other organisation above, please provide the name of the group/organisation.

Organisation

Enter your phone number at Question 5

5. What is your phone number?

Phone number (Required)

6. What is your state?

Please select your state

-- Please Select --

Select the Australian state or territory in which you live, from the drop down menu at Question 6

Scroll through the drop-down menu until you find: **'PEGVALIASE – Palynziq®: Phenylketonuria'**

7. Select the medicine you would like to provide input on

To provide input for more than one medicine you will need to fill out another survey.

Select a medicine (Required)

MIDAZOLAM - Zyamis®: Epilepsy
NATALIZUMAB - Tysabri®: Multiple sclerosis
NIVOLUMAB - Opdivo®: Urothelial carcinoma
NIVOLUMAB - Opdivo®: Oesophageal carcinoma or gastroesophageal junction carcinoma
OLAPARIB - Lynparza®: Ovarian cancer
PEGVALIASE - Palynziq®: Phenylketonuria
PEMBROLIZUMAB - Keytruda®: See below for full list of conditions
POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL - Optix®: See below for full list of conditions
PROGESTERONE - Cyclogest®: Infertility
RELATLIMAB WITH NIVOLUMAB - Opdualag®: Melanoma
RISANKIZUMAB - Skyrizi®: Crohn disease
ROMOSOZUMAB - Evenity®: Osteoporosis
RUXOLITINIB - Jakavi®: Graft versus host disease
SAPROPTERIN - Puvan®: Phenylketonuria
TEZEPELUMAB - Tezspire®: Asthma
TRASTUZUMAB DERUXTECAN - Enhertu®: Breast cancer
UPADACITINIB - Rinvoq®: Ulcerative colitis

At Question 7, all medicines listed on the Agenda for the July 2022 PBAC Meeting will be included in the drop-down menu

Medicines are listed with their **generic name first, brand name second, followed by the condition** the PBAC is reviewing the medicine for

Click on **'PEGVALIASE –Palynziq®: Phenylketonuria'** to select it and proceed to Question 8

Remember: If you would like to provide input into both PKU treatments being considered by the PBAC, you must complete another/new Online Consumer Comments form for the second treatment separately

STEP 5c: Selecting the other medicine you would like to submit a Consumer Comment for

If you would like to submit a Consumer Comment for the other PKU treatment first (or instead) please see below instructions

Scroll through the drop-down menu until you find: **'SAPROPTERIN – Kuvan®: Phenylketonuria'**

7. Select the medicine you would like to provide input on

To provide input for more than one medicine you will need to fill out another survey.

Select a medicine (Required)

-- Please Select --

- MIDAZOLAM - Zyamis®: Epilepsy
- NATALIZUMAB - Tysabri®: Multiple sclerosis
- NIVOLUMAB - Opdivo®: Urothelial carcinoma
- NIVOLUMAB - Opdivo®: Oesophageal carcinoma or gastroesophageal junction carcinoma
- OLAPARIB - Lynparza®: Ovarian cancer
- PEGVALIASE - Palynziq®: Phenylketonuria
- PEMBROLIZUMAB - Keytruda®: See below for full list of conditions
- POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL - Optix®: See below for full list of conditions
- PROGESTERONE - Cyclogest®: Infertility
- RELATLIMAB WITH NIVOLUMAB - Opdualag®: Melanoma
- RISANKIZUMAB - Skyrizi®: Crohn disease
- ROMOSOZUMAB - Evenity®: Osteoporosis
- RUXOLITINIB - Jakavi®: Graft versus host disease
- SAPROPTERIN - Kuvan® : Phenylketonuria**
- TEZEPELUMAB - Tezspire®: Asthma
- TRASTUZUMAB DERUXTECAN - Enhertu®: Breast cancer
- UPADACITINIB - Rinvoq®: Ulcerative colitis
- USTEKINUMAB - Stelara®: Severe Crohn disease; Severe chronic plaque psoriasis
- USTEKINUMAB - Stelara®: Ulcerative colitis
- VOSORITIDE - Voxzogo®: Achondroplasia

Click on **'SAPROPTERIN – Kuvan®: Phenylketonuria'** to select it and proceed to Question 8 (STEP 5d below)

Remember: If you would like to provide input into both PKU treatments being considered by the PBAC, **you must complete another/new Online Consumer Comments form for the second treatment separately**

STEP 5d: How you found out about this PBAC Consumer Comments opportunity

At Question 8, state how you found out about this 'consultation' (i.e. submitting a Consumer Comment for this PBAC meeting) – such as your doctor, a family member, patient organisation, etc.

8. How did you find out about this consultation?

(Required)

< Back << First Save and come back later... Continue >

You can use these buttons at any time to go **'Back'** to previous pages in your submission, go back to the **'First'** page in the submission, or **'Save and come back later'**

After completing all questions (except Question 4, unless you are making a submission on behalf of an organisation), click **'Continue'** to proceed to the next page of the submission

STEP 6a: The third step of the Consumer Comments submission – providing your input on the chosen medicine through the **PBAC public consultation survey**

Please consult the Department of Health's '[Tip Sheet for Submitting Consumer Comments to the PBAC](#)' on page 16 & 17 of this document, before you begin your submission

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Closes 25 May 2022

This service needs [cookies enabled](#).

Refer to the '**Points for consumers to consider**' drop-down section under each question, before you provide your response

These points have been provided by OHTA to assist members of the public to make a Consumer Comment to the PBAC, by asking them to consider a number of questions

An open text box is included below each of the 5 Questions on Page 3, where you can provide your comments about the medicine you have selected

PBAC public consultation survey

The PBAC welcomes input from anyone with an interest in the medicine proposed to be listed on the Pharmaceutical Benefits Scheme (PBS).

- You can submit input by answering the five (5) questions below and/or by uploading a file.
- You can choose to answer as many of the questions as you like but providing as much detail as you can will be most helpful for the PBAC.
- Your input will be saved so you can come back at any time to your response before the consultation close date.

1. Please outline your experience with the medical/health condition

▼ [Points for consumers to consider](#)

- How does this condition/disease impact your life? Try to be as specific as possible including impacts on your everyday activities, work, family, friends, mental and emotional health.

Please provide your comments

2. How is the medical/health condition currently treated?

▼ [Points for consumers to consider](#)

- What symptoms can not be controlled with the current treatment?
- Do you experience any particular difficulties accessing current treatment (for example due to eligibility requirements, or where or how the treatment is given)?

Please provide your comments

STEP 6b: The third step of the Consumer Comments submission – providing your input on the chosen medicine through the **PBAC public consultation survey**

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Closes 25 May 2022

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Refer to the '**Points for consumers to consider**' drop-down section under each question, before you provide your response

These points have been provided by OHTA to assist members of the public to make a Consumer Comment to the PBAC, by asking them to consider a number of questions

An open text box is included below each of the 5 Questions on Page 3, where you can provide your comments about the medicine you have selected

3. What do you see as the advantages of this proposed medicine, in particular for those with the medical condition and/or family and carers?

▼ [Points for consumers to consider](#)

- What specific **health benefits or changes to quality of life** are you expecting from this treatment?
- If you have used this medicine what was your experience?
- Are there benefits such as the way the medicine is delivered (for example, tablets rather than injection) or where the medicine is given (at home or in hospital)

Please provide your comments

4. What do you see as the main disadvantages of this proposed medicine?

▼ [Points for consumers to consider](#)

- Have you heard of any side effects from this medicine? Do you consider these to be manageable?
- What side effects would stop you from taking this medicine?
- If you have used this medicine, did you experience any side effects?

Please provide your comments

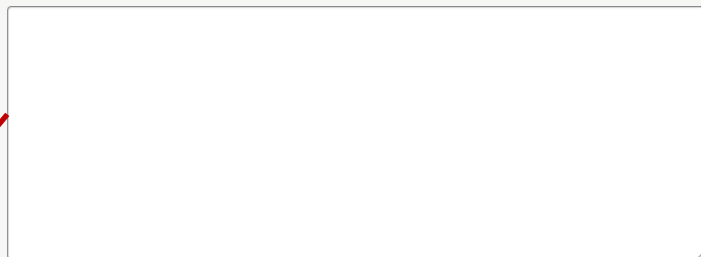
STEP 6c: The third step of the Consumer Comments submission – providing your input on the chosen medicine through the **PBAC public consultation survey**

Page 3 of 6

Closes 25 May 2022

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5. Please provide any additional comments you would like the PBAC to consider.



At Question 5, use the open text box to provide any comments you weren't able to include in your responses to Questions 1-4

As per the OHTA's guidance, you should never 'copy and paste' a template submission or attach a petition.

It's **important that your submission is personal** to you and **reflects your own experiences or views of the medicine** being considered by the PBAC

OHTA is currently reviewing improvements to gathering consumer input for PBAC consideration.

If you have any feedback or suggestions on how this process could be easier for members of the public in future, based on your experiences, include this in the open text box at Question 6

If you would prefer to upload a file for this medicine please do so below.

Please note we do not accept petitions, duplicate submissions from the same author, form letters (multiple copies of the same statements of support for access), or any material that is inappropriate in language or tone.

Please ensure file is in PDF or word format and under 25mb in size.

Please make sure your file is under 25MB

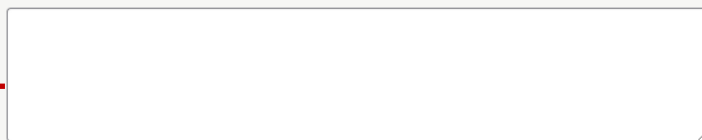
No file chosen

Should you have any difficulties submitting this form please contact commentsPBAC@health.gov.au

If you'd prefer not to have to complete the OHTA's online survey, you have the option of uploading a document file of your submission

You may also wish to upload documents or materials (in Word or PDF formats only) you feel will add value to, or support, your submission

6. We are considering revising the consultation survey for future PBAC consultation rounds, along with providing additional guidance. Are there any suggestions you would like us to consider as part of this process?



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Save and come back later...

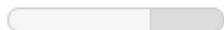
Continue >

You can use these buttons at any time to go 'Back' to previous pages in your submission, go back to the 'First' page in the submission, or 'Save and come back later'

Once you are happy with your responses to the questions on Page 3 of the online submission, click 'Continue' to proceed to the next page of the submission

STEP 7a: The fourth step of the Consumer Comments submission – Declaration of interests

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Closes 25 May 2022

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[cookies enabled](#).

Carefully review all of the information provided on Page 4 of the online survey to determine if you may have a conflict of interest in providing a Consumer Comment for a particular medicine being considered by the PBAC

Declaration of interests

Declaration of Interest Statement

The purpose of this declaration is to discover any financial, professional or personal interest on the part of a person, or on the part of their immediate family, who is providing consumer input to the PBAC.

▼ [Information on declaration of interests](#)

For example, a patient has an interest in a particular medicine, because they are currently using it, and wish to see it listed on the PBS. A doctor may be providing comments, and has also been involved in clinical trials investigating this medicine. A family member may want to provide comments on a particular medicine that another relative is using, and separately may also have shares in the company which manufactures a number of pharmaceutical drugs, including this specific item.

Such interests may affect or have the appearance of affecting a person's view on the merits of a drug, vaccine or medicinal preparation being considered by the PBAC. The existence of such interests may be a 'conflict of interest'.

A conflict of interest is declared so that information provided can be assessed fairly and in a transparent manner. The declarations are confidential to the PBAC, and do not prevent anyone from providing their comments.

A conflict of interest can be declared, but does not mean a person should not still provide their comments.

A **financial interest** may include, but is not limited to, any of the following involvement with companies or other organisations engaged in the development, manufacture, marketing or distribution of vaccines, drugs and medicinal preparations:

- a. current shareholdings;
- b. board memberships or other offices;
- c. paid employment or contracting work;
- d. grants
- e. hospitality (including conferences, travel).

A **professional interest** may include, but is not limited to, involvement in any of the following:

- a. development, manufacture or marketing and distribution of vaccines, drugs and medicinal preparations;
- b. making a public statement about that company or a drug or other product of that company.

A **personal interest** may include, but is not limited to, any of the following:

- a. where you are writing to support a drug being listed on the PBS, because you have a condition or illness for which that drug may be being considered by the PBAC;
- b. an immediate family is aware that a relative close to them suffers from a condition for which a drug before the PBAC may be being considered by the PBAC;
- c. where you or your immediate family has strong personal or religious beliefs about a drug or treatment under consideration by the PBAC.

STEP 7b: The fourth step of the Consumer Comments submission – Declaration of interests

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Closes 25 May 2022

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Please include any declarations you wish to make regarding the PBAC submission upon which you are commenting.

(Required)

- No conflicts
- Financial conflicts (describe below)
- Professional conflicts (describe below)
- Personal conflicts (describe below)

If you have no conflicts of interest after reviewing the information provided, check the **'No conflicts'** box

If you feel you do have conflicts that you would like to declare, select one of the other available check boxes and provide the details of this conflict in the open text box provided

< Back « First Save and come back later...

You can use these buttons to go **'Back'** to previous pages in your submission, go back to the **'First'** page in the submission, or **'Save and come back later'**

Continue >

Once you have declared any potential, or lack of, conflicts of interest, click **'Continue'** to proceed to the next page of the submission

STEP 8: The fifth step of the Consumer Comments submission – preparing to submit

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Closes 25 May 2022

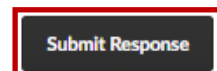
Almost done...

You are about to submit your response. By clicking 'Submit Response' you give us permission to analyse and include your response in our results. After you click Submit, you will no longer be able to go back and change any of your answers.

When you submit your response, you will be sent a receipt and a link to a PDF copy of your response.



If you would like to review your submission again, use these buttons to go '**Back**' to previous pages in your submission, or go back to the '**First**' page in the submission



Once you have completed all the required questions and are happy with your responses, click '**Submit Response**' to submit your Consumer Comments to the PBAC for consideration

After clicking the '**Submit Response**' button, you will be taken to the final page of the OHTA online consultation survey (Page 6).

You will then be sent an email confirming receipt of your submission, along with a PDF copy of your Consumer Comments, for your records

WHAT HAPPENS AFTER YOU'VE SUBMITTED AN ONLINE CONSUMER COMMENT TO THE PBAC?



What happens with Consumer Comments provided to the PBAC?

Comments from individuals and healthcare professionals will be made available in summary form to the sponsor of the application (this is typically the pharmaceutical company that manufactures the medicine in Australia), and the PBAC. The names of individuals will be removed. All comments from groups or organisations will be provided in a complete form to both the PBAC and the sponsor of the medicine.

How does the PBAC make its decision on whether to recommend a medicine for listing on the PBS?

The PBAC is an independent expert body appointed by the Australian Government. It is made up of healthcare professionals, health economists, two consumer advocates, and one industry nominee.

In evaluating applications for listing medicines on the PBS, the PBAC is required to take into account the clinical effectiveness (it works as it was intended), safety and cost effectiveness (value for money) of the medicine being considered, compared to other available therapies for that particular condition. Medicines can only be listed on the PBS, if they have first been granted approval for use in Australia by the Therapeutic Goods Administration (TGA).

What happens once the PBAC has reviewed an application to list a medicine on the PBS?

Once the PBAC has reviewed an application for a medicine to be listed on the PBS, there can only be three possible outcomes: 1) **'Recommended'** – the PBAC agrees the medicine should be listed on the PBS; 2) **'Not recommended'** – the PBAC doesn't feel the medicine meets its criteria for listing on the PBS, based on the available information, meaning the sponsor (pharmaceutical company) must resubmit a new application to a future PBAC meeting; or 3) **'Deferred'** – the PBAC needs further information in order to make an informed decision.

When can people find out if a PBAC submission has been successful?

Regardless of whether the PBAC decides to recommend a new medicine for listing on the PBS or not, all outcomes (i.e. 'recommended', 'not recommended', or 'deferred') will be published on the PBAC website 6 weeks after each meeting, available at:

<https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes>

In addition, Public Summary Documents (PSDs) containing full details of the PBAC's review and advice are published on its website 16-18 weeks after the PBAC meeting, available at:

<https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd>

DEPARTMENT OF HEALTH TIP SHEET FOR SUBMITTING CONSUMER COMMENTS TO THE PBAC

health.gov.au/PBAC-Tip-Sheet-for-Consumer-Comments

Tip Sheet for submitting Consumer Comments to the PBAC

About this Tip Sheet

This tip sheet is intended to assist people to make Consumer Comments to the Pharmaceutical Benefits Advisory Committee (PBAC). Consumer comments are generally most informative to the PBAC when you (or someone you know):

1. Are currently being treated with the medicine
2. Have been treated in the past with the medicine
3. Could potentially use the medicine in the future*

**Always check with your doctor if the medicine being considered is suitable for you*

The only way the PBAC can understand what is important to patients is by hearing your story/personal experiences. Here are some tips to help you show how the medicine has helped you (or someone you know), and the impact it has had on daily activities and work.

How to submit your comments

1. Online using the submission form
2. Email the PBAC directly:
CommentsPBAC@health.gov.au
3. Send a letter: PBAC Secretariat, MDP 952, Department of Health and Ageing, GPO Box 9848, Canberra ACT 2601

FOR PATIENTS WHO ARE / WERE ON THE MEDICINE

What difference has this medicine made to your life?

If you were unwell before treatment, it is **really important** to describe the difference between how you felt then compared to now. Explain what those improvements have allowed you to do, see or feel and how it impacts your quality of life.

Use the tips below to show the difference the medicine has made to your symptoms, side effects, and quality of life compared to (a) before treatment with this medicine, and (b) other treatments you have tried.

Compare BEFORE & AFTER starting treatment:

- Use examples to describe the differences in how you felt **BEFORE treatment vs AFTER treatment**.
- Rate how different symptoms/categories were like **BEFORE treatment** by giving them each a number between 0 – 10, then rate how they felt **AFTER treatment**.

Example: Rate your pain levels (0/10 = no pain, 10/10 = extreme pain)
What were your pain levels **BEFORE vs AFTER** treatment? How has the pain changed? Are the levels constant, or does it come and go? Is the intensity different? Or more/longer times where you are pain free?

Example: Rate your fatigue (0/10 = no fatigue, 10/10 = extreme fatigue)
How long were your rest times **BEFORE vs AFTER** treatment? Do you need to rest less frequently now? Can you do daily tasks, or leave the house?

Example: Movement/exercise How much independent movement or exercise could you do before starting treatment compared to now? How far could you walk before needing rest/assistance compared to now? Compare the number of flights of stairs you could climb. Could you walk up hills?

Example: Episodes/relapses If your condition is episodic, has the frequency of episodes/relapses changed since beginning treatment? Have they been shorter? Or less severe? Are you having more good days & less bad days?

Example: Hospital visits Have you had less hospital visits since starting the treatment?

IMPORTANT What you don't need to include:

- a) **Research, statistics, test results.** The PBAC are provided with clinical trial results that demonstrate effectiveness.
- b) **Petitions to list the medicine because you or others need it.** The information you provide will inform the relevance of the clinical trial results presented to the PBAC. Patient relevance is one factor of many that the PBAC must consider before recommending a listing.

What does receiving this medicine mean to you?

Use examples from the list below, or add your own...

Level of Independence

- Allows me to move freely
- Wash & groom myself
- Go shopping
- Drive a car safely
- Don't have to rely on others to do things for me

Home & family life

- Play with my (grand)children
- Contribute to home life
- Mow the lawn, gardening
- Be a role model to my family
- Prepare and cook meals

Social life

- Engage in social activities
- Attend functions
- Enjoy holidays
- Take my dog to the park
- Take up an old/new hobby
- Able to leave my room/house

Work & community

- Able to work/return to work
- An active member of the local community
- Do volunteer work
- Participate in community events
- Be a listening ear to friends

Emotional & psychological

- More motivated and positive
- Less frustrated/emotional
- More confidence
- Less depression/anxiety
- Feel stronger within myself
- Achieve the goals I set

DEPARTMENT OF HEALTH TIP SHEET FOR SUBMITTING CONSUMER COMMENTS TO THE PBAC

health.gov.au/PBAC-Tip-Sheet-for-Consumer-Comments

Tip Sheet for submitting Consumer Comments to the PBAC

Explain the medicine's effect on your QUALITY OF LIFE:

- What have the changes or improvements meant to you?
- How this has changed everyday life for you?
- Use your LIVED EXPERIENCE to describe what difference this medicine has made to your life.
- What has this medicine allowed you to do, see or feel?

If you have responded to the medicine well, describe what this has meant to you? How this has changed everyday life for you? What can you do now that you couldn't do before? Do you have more independence, engage in social activities, still drive a car, mow the lawns, shop, or go to work? Or are you in bed most of the day because the medicine is making you feel unwell? Do you need care to help you shower, get dressed & feed?

Examples: Back doing things you love, back at work, going away on holidays, celebrate a special occasion, see the birth of a child, turn your dreams into a reality, your sports team winning a grand final, socialise with friends, or develop deeper connections with loved ones.

Compare your experience on DIFFERENT TREATMENTS:

- How did you feel on PAST treatments vs THIS treatment?
- How this treatment changed everyday life for you?

Example: Side effects Does this medicine have different side effects to other treatments you have used? If the side effects of past treatments (eg chemotherapy) were much worse than the ones you experience on this medicine, talk about what your quality of life was like at that time compared to this medicine?

Example: Medicine is taken in a different way Does this medicine have different form to other treatments you have used in the past (eg tablet instead of injection)? Do you need to take it less often (eg once a week instead of every day), or at a different time of day? Talk about the difference has this made to your life.

Examples: more convenient, fewer doctor's appointments, less time off work, gives you more time to spend with family, allows me more flexibility so can travel away from home for longer.

What are the FINANCIAL IMPLICATIONS (Money)?

What is the financial impact of this medicine on you and your family?

If you have had to pay for this medicine, is this something you can realistically continue to do? What strategies have you had to use for you to pay for this medicine?

Examples: Fundraising Websites? Community fundraisers?

IMPORTANT

If you have **bad side effects** on this medicine, it's important to be honest about this, but also **say whether you have been willing to tolerate the side effects and why?**

FOR PATIENTS WHO DIDN'T RESPOND TO THE MEDICINE

Even if you are a patient who did not respond to the treatment as expected, you can write in and explain if there were any aspects of your health that improved while taking the medicine, whether this has allowed you to do more things and what impact this has had on your quality of life.

FOR FAMILY, FRIENDS & EMPLOYERS

The PBAC likes to hear many different perspectives so it can better understand the value of these medicines on the human life. This includes asking family members, friends and employers to write a submission. You may also want to sit with them and help talk them through this process.

It is important for them to talk about:

- What has it meant to them personally for you to have access to this medicine?
Examples: Contributions to the workplace and productivity, celebrate special occasions such as birthdays, Christmas/other religious events, go away on holidays together, help nurture your children, or your role as a grandparent.
- What benefits has the medicine had on you through THEIR eyes?
Examples: Allowed you to work xx hours per week, watched you sleep most of the day compared to now being more active
- How do they think this medicine has allowed you to continue to contribute to society?
Examples: Through charity work, employment, helping out within the local school etc
- In their opinion how has this medicine affected your QUALITY OF LIFE?
Examples: Are you able to still drive, do the grocery shopping, shower and dress yourself, wash the clothes, attend social functions, exercise, work etc?