Australian Government
Department of Health
Therapeutic Goods Administration

# Changing sponsor details in Product Information (PI) and labels of prescription medicines

Version 1.0, October 2020

TGA Health Safety Regulation

# Contents

# About this guidance

This guidance describes how to change sponsor details in the Product Information (PI) and labels for prescription medicines.

Sponsor details may include:

- name
- address
- phone number
- email
- website of the sponsor and/or the distributor

Changes to sponsor details in PIs and labels may be required when:

- there is a change in sponsor
- the sponsor changes their name or address.

## New sponsors

Prescription medicines must be registered in the Australian Register of Therapeutic Goods (ARTG). Making a change to an ARTG entry requires that you apply to the TGA for a variation.

If you are the new sponsor of a registered prescription medicine you must notify us of the change in sponsorship.

The ARTG must reflect the new sponsor details before any application can be made to vary the PI and/or labels.

An approved PI is required to register prescription medicines in the ARTG under Section 25AA of the *Therapeutic Goods Act 1989*.

Any changes to the approved PI for a registered prescription medicine must also be approved by the TGA.

# Timeframe

You must apply to change the sponsor details:

- in the **PI immediately** after a change has occurred
- on the **label** within **12 months** after a change has occurred.

# Supplying products with former sponsor details

You may continue to supply medicines with the existing sponsor details for up to 12 months while you are waiting for TGA approval. Your product must comply with Therapeutic Goods Order No. 91 (TGO 91) - Standard for labels of prescription and related medicines.

## Products complying with TGO 69

The Therapeutic Goods Order No. 69 (TGO 69) - General requirements for labels for medicines ceased to be in effect from 1 September 2020. Products released to the market from 1 September 2020 must comply with the requirements of TGO 91.

If your product complies with TGO 69, you must apply for consent to supply the goods with the former sponsor details on the label.

For information on how to update your labels to TGO 91, refer to Variations to prescription medicines - excluding variations requiring the evaluation of clinical or bioequivalence data.

# Applying for a variation to change sponsor details

To change the sponsor details in the PI and label of a registered prescription medicine, you must:

- ensure that the sponsor details have been updated in the ARTG
- apply for a **variation** under Section 9D(3) of the Therapeutic Goods Act.

## Applying for the PI and label variation at the same time

We encourage you to apply to change the details in the PI and the label in the **same application**.

As these are related requests, if you apply at the same time:

- you will only need to pay a **single fee** related to the SAR
- you will **not** need to pay for the notification request.

## Complete a self-assessable request (SAR)

If you are only planning on updating the sponsor details in the PI and labels, then you need to go to TGA Business Services (TBS) and complete a **self-assessable request (SAR)**. Choose the code **PIPS**: PI- changing the name, address or other details of the product's sponsor or distributor.

Refer to the Application process for details on how to complete your request.

### Data requirements for the PI

In your application include:

- a copy of the currently approved PI for the relevant registered medicine, with changes clearly marked
- a clean copy (not marked-up) of the currently approved PI for the relevant registered medicine containing the proposed changes

Ensure that:

- any included technical information is accurate and obtained from recognised reference sources
- all names and terminology used in the PI are Australian approved names or entered in the TGA Business Services code tables

Submit the PI in the form for providing product information.

### Submit the PI in the new PI format

If the PI was approved before 1 January 2018 it may be in an old format. You should reformat your PI at the same time as the variation request if your PI is still in the old format. Please include the request to reformat the PI in the comments section of the e-form. Otherwise you will have to apply separately to reformat the PI.

The PIs for all marketed products will need to be in the new format by **31 December 2020.**

### Data requirements for the label

In your application include:

- final copies or mock-ups of the amended labels (for each strength, where applicable)
- final copies or mock-ups must:
  - include any logos, design work or graphics
  - be to scale
  - verify the size/dimensions of the labels
  - indicate the colours to be used
- where there are multiple pack sizes available, one representative label can be provided for each strength, as long as the only difference between the labels is the pack size

Ensure that:

- there are no other changes to the label made under this request
- the new label follows labelling best practice
- the new name and address are the same as the one in the ARTG and PI

## Applying for the label variation separately

If you apply separately to change the sponsor details on the label, **you will have to pay an additional fee**.

To change only the label, complete a **notification request** on TBS and select the code **LPCS**: Label - addition or deletion of, or change to, the name or address of the Australian sponsor or supplier of the product.

# Fees

To view the current fee for this variation go to Requests with a single fee on the Fees and Charges summary page.

For the **SAR fee**, refer to 'Self-assessable request with no evaluation of data'.

For the **notification request fee**, refer to 'notification request' (if applying for the notification request separately).

# Application process

The application process must be completed online through the TBS portal.

## Logging in to TBS

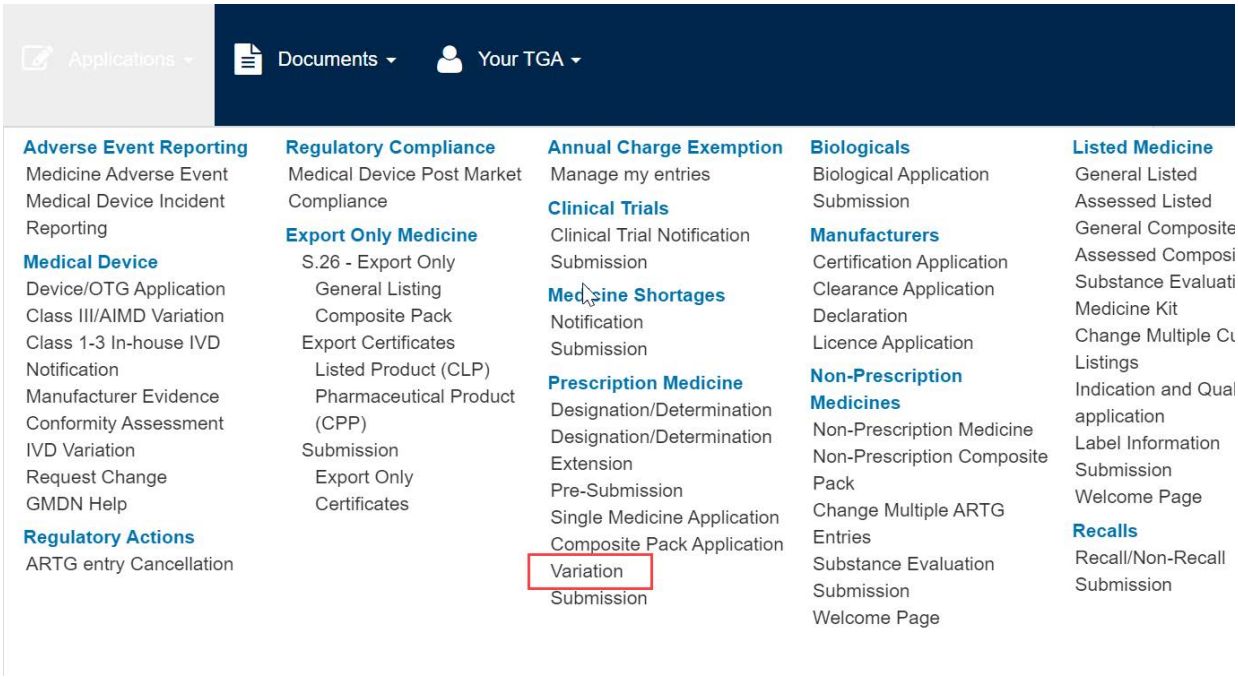
To apply for a variation, you will need:

- a TGA client identification number
- access to the TBS portal

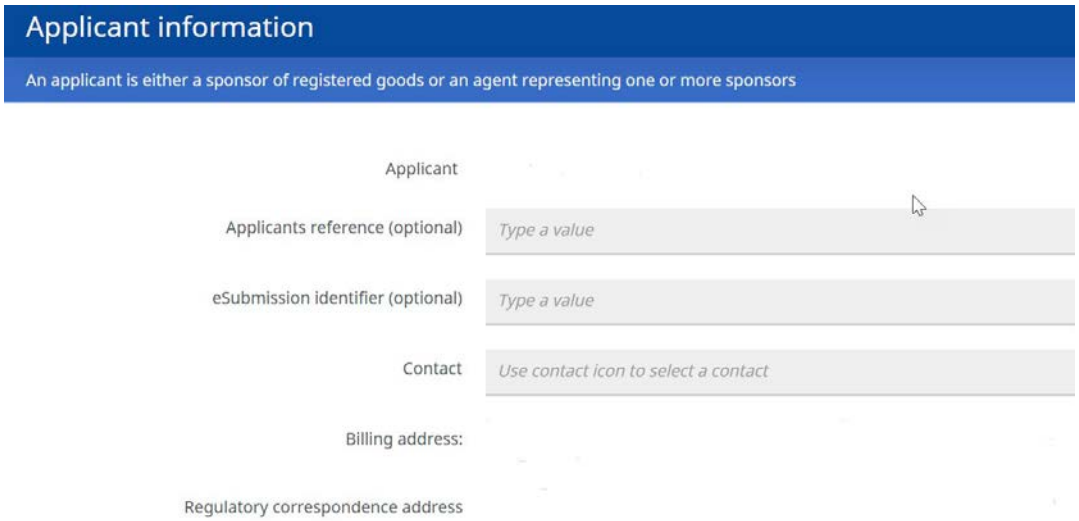
TGA Business Services: getting started with the TGA provides information about TGA business services.

## Steps to complete your application

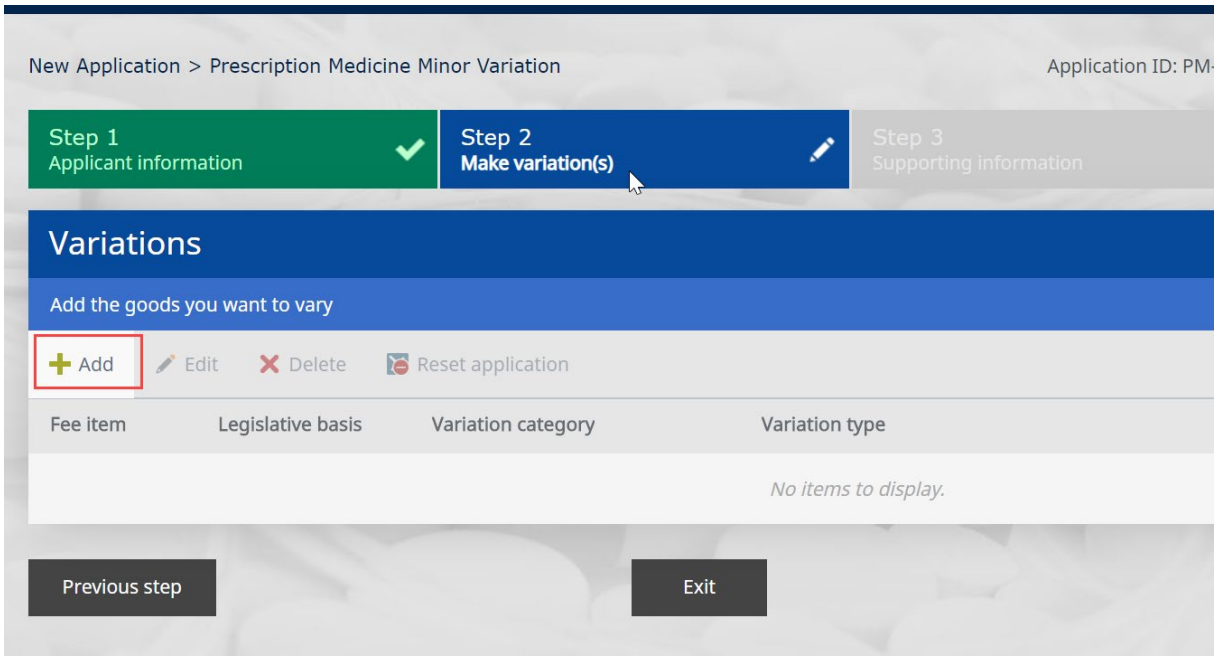
1. Log in to TBS and on the Applications tab, select Variation to access the variation e-form on the TBS portal.



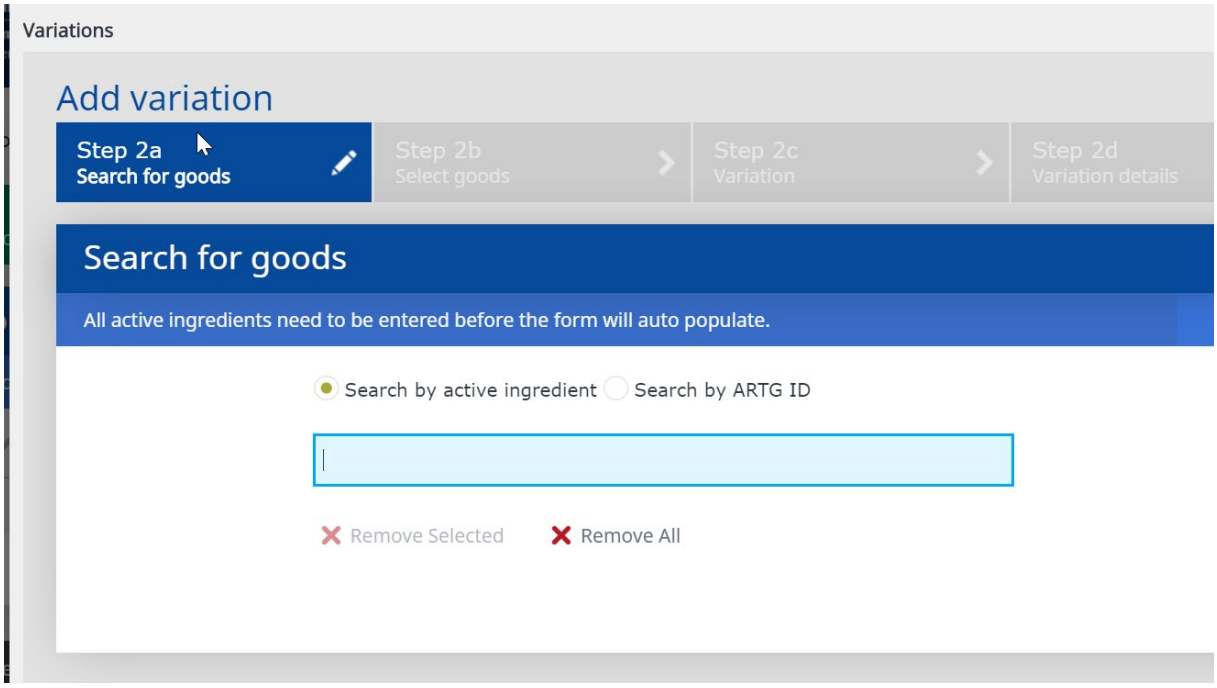
2. Fill in your details.



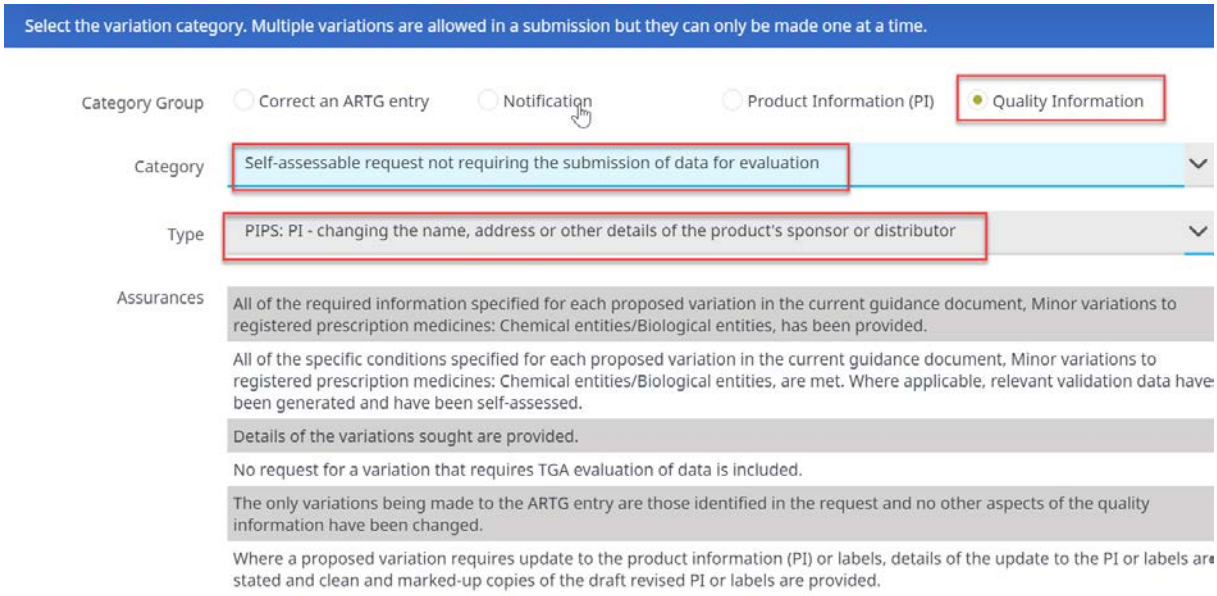

3. Add the product that you want to vary. A single PI often refers to multiple ARTG entries for prescription medicines. If you are applying to change the sponsor details for **multiple ARTG entries** select all AUST-R entries included in the PI. If you don't include all of the ARTG entries in your application, you will have to make another variation request in future.



4. You will be able to search for the product by typing the first letter of the active ingredient, or by its ARTG ID.

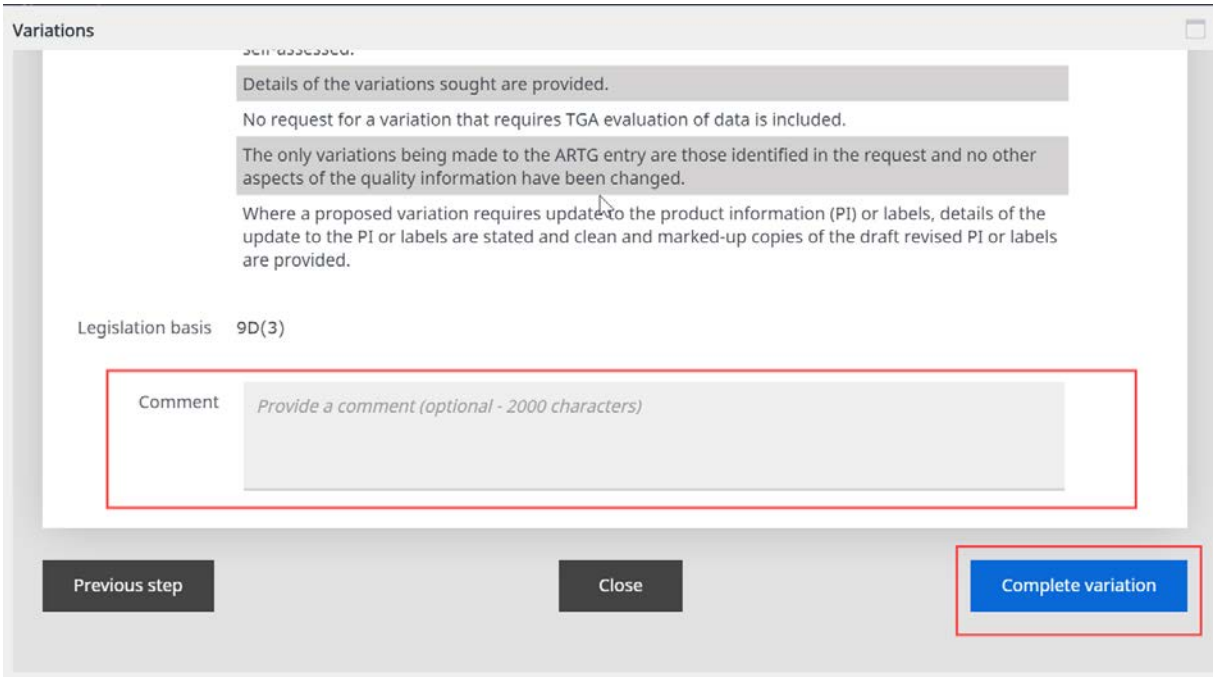



5. In Category Group select Quality Information. In Category select Self-assessable request not requiring the submission of data for evaluation. In Type select PIPS (PI - changing the name, address or other details of the product's sponsor or distributor).

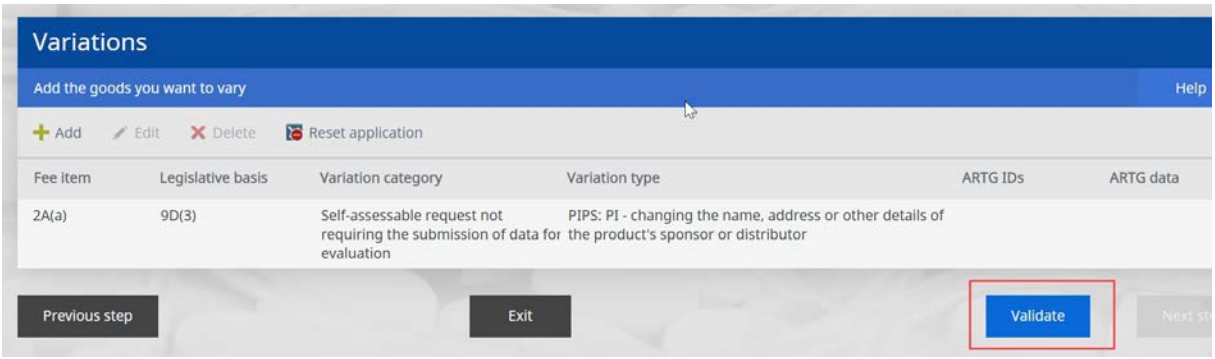



If you are applying for the label variation at the same time, you **do not need to select a separate variation type for the label variation**. Instead, include this information in the cover letter of your application.

6. Include a summary of the changes in the comments field in the variation e-form and complete your variation request.




7. Validate your variation request. You will then be able to attach your supporting documentation.




8. You will receive a **single invoice** via the variation e-form if all your changes are for the same fee item.

## Prescription medicines with more than one registered trade name

If you are applying to change the sponsor details for prescription medicines that have multiple registered trade names, you may include the following in your application:

- one representative marked-up copy of the complete PI
- one clean copy of the PI for each registered trade name
- an assurance that all PI documents for all trade names will be changed in the same way, and at the same time, once we have approved the changes.

## Timeframes for approval

Changes to the PI and label will be approved within **45 working days** if requested as a **SAR**.

Changes to the **label** will be approved within **48 hours** if submitted as a **separate notification**.

# When PI changes are approved

If we approve your PI with the updated sponsor details, you will receive an **approval letter** informing you of the **date of effect** of the variation.

## After receiving your approval letter

After you receive this letter, you must submit the approved PI on TBS within **2 weeks** of the date of approval. Agents cannot upload an approved PI on behalf of a sponsor via the agents TBS portal.

If the Consumer Medicine Information (CMI) document needs to be changed as a consequence of the change to the approved PI, it must be lodged with the TGA within 2 weeks of the date of the changed PI.

The change in sponsorship is processed independently of the changes to the PI and/or labels. Sponsorship transfer must first occur in order for you to make changes to the PI and labels. For more information on changing sponsors refer to Changing the sponsor of therapeutic goods.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Regulatory Guidance Team | September 2020 |

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