



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# New e-form for minor variations

## Prescription medicines

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# Minor variations to prescription medicines



New electronic form



How will it help you apply for minor variations



Next steps





# Reforms context

## Reducing regulatory burden

- Need for improvements to processes
- Acknowledged in the Review of Medical Devices (MMDR) -
- Staged implementation





# New electronic form

## First step for prescription medicines

- One-stop shop:  
Consolidating six paper forms into one
- Reduced time and effort in making applications
- More efficient processing of requests






# Benefit

## Easy to identify your ARTG entries



Add variation

Step 2a Search for goods  Step 2b Select goods > Step 2c Variation >

### Search for goods

All active ingredients need to be entered before the form will auto populate.

Search by active ingredient  Search by ARTG ID

 Remove Selected  Remove All



# Benefit

## Easy selection of types of minor variations

The screenshot displays the 'Variations' e-form interface. The main window is titled 'Variations' and contains the following sections:

- Add variation**: A green header bar.
- Step 2a**: A green bar with the text 'Search for goods'.
- Select therapeutic goods**: A blue header bar with the sub-label 'Nominate products for a subset of products'.
- Variation**: A blue header bar with the sub-label 'Select the variation category. Multiple'.
- Category Group**: A dropdown menu.
- Category**: A dropdown menu with 'CMBT: Container/closure system - changes to material used for bottles, jars and tubes of non-sterile dosage forms' selected.
- Type**: A dropdown menu with the text 'Select a Type based on selected Category'.
- Assurances**: A section for providing assurances.
- Legislation basis**: A section for providing the legislation basis.
- Comment**: A text area with the placeholder 'Provide a comment (optional - 2000 characters)'.

At the bottom of the form, there are three buttons: 'Previous step', 'Close', and 'Complete variation'. A list of variation types is visible in the background, including:

- ACCS: API container - changes to container/closure system of a non-sterile API
- ACEP: API Certificate of Suitability (CEP) - a revision for a non-sterile API that is not a synthetic polypeptide or prepared by fermentation
- AMBS: API and intermediate manufacture - change to batch size of a non-sterile API (existing site)
- AMCS: API site of manufacture - cessation
- AMIT: API and intermediate manufacture - addition, revision or deletion in-process control tests and limits
- AMMC: API and intermediate manufacture - minor manufacturing changes not involving sterilising steps (existing site)
- AMMF: API starting material/intermediate site of manufacture - change to/addition of (for APIs manufactured by multi-step syntheses or fermentation)
- AMTA: API site of manufacture - transfer of/addition to an existing manufacturer's site of a non-sterile API that is not prepared by fermentation
- ASAM: API starting material/intermediate specifications - changes to non-biological test methods for assay and/or residual solvents (including water)
- ASDR: API re-test period and storage conditions - decrease to re-test period and/or more restrictive storage conditions
- ASID: API starting material/intermediate specifications - changes to identification tests
- ASNL: API starting material/intermediate specifications - narrowing of limits
- ASNT: API starting material/intermediate specifications - addition of new test and limit
- ASPT: API specifications - amendments resulting from pharmacopoeial or TGO changes
- CCAD: Container/closure - change to components
- CCSS: Container/closure - change to size and shape for non-sterile dosage forms
- CCST: Container/closure - changes to specification and test methods
- CMBP: Container/closure material - changes to material used for blister packs, strip packs and sachets of non-sterile dosage forms
- CMBT: Container/closure system - changes to material used for bottles, jars and tubes of non-sterile dosage forms



# Benefit

## Summary of changes and associated fees before you submit

New Application > Prescription Medicine Minor Variation Application ID: PM-2017-MV-00134-1 | Status: Passed validation | [Print Preview](#) 

Step 1  
Applicant information 

Step 2  
Make variation(s) 

Step 3  
Declaration and submit 


### Fees




Variation Group	Legislative basis	Fee item	Fee	A new good with a new ARTG Id will be generated for the following goods based on the variation being made under this legislative basis:
Correct an ARTG entry Quality Information	9D(1) 9D(3)	2A(a)	\$1,625.00	
Product Information (PI)	9D(2)	2CA	\$5,270.00	



# Benefit

## Submission number generated at point of submission

New Application > Prescription Medicine Minor Variation Application ID: PM-2017-MV-00153-1 | Status: Passed validation | [Print Preview](#) 

Step 1 Applicant information 	Step 2 Make variation(s) 	Step 3 Declaration and submit 
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**Submission successful**

You have successfully completed the submission.

Please use reference number **PM-2017-00316-1**, **PM-2017-00317-1** to track the progress of the assessment.

[Continue to portal home](#)

Enables provision of data via email at time of application





# Next steps

e-form testing



External stakeholders involved

e-form launch



After successful testing

Guidance updated and  
published



Printable version and e-book

Ongoing improvements



New 'notifications' process –  
pending new legislation



# More information

## Prescription medicines reforms

<https://www.tga.gov.au/prescription-medicine-regulatory-reforms>



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