Australian Government
Department of Health
Therapeutic Goods Administration

New e-form for minor variations

Prescription medicines

Felicity Jameson, Klara Koelmeyer, Jola Samoc
Medicines Regulation Division
Therapeutic Goods Administration

TGA Health Safety Regulation

25 May 2017

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 Revie
  Medical Devices (MMDR) -
- Staged implementation

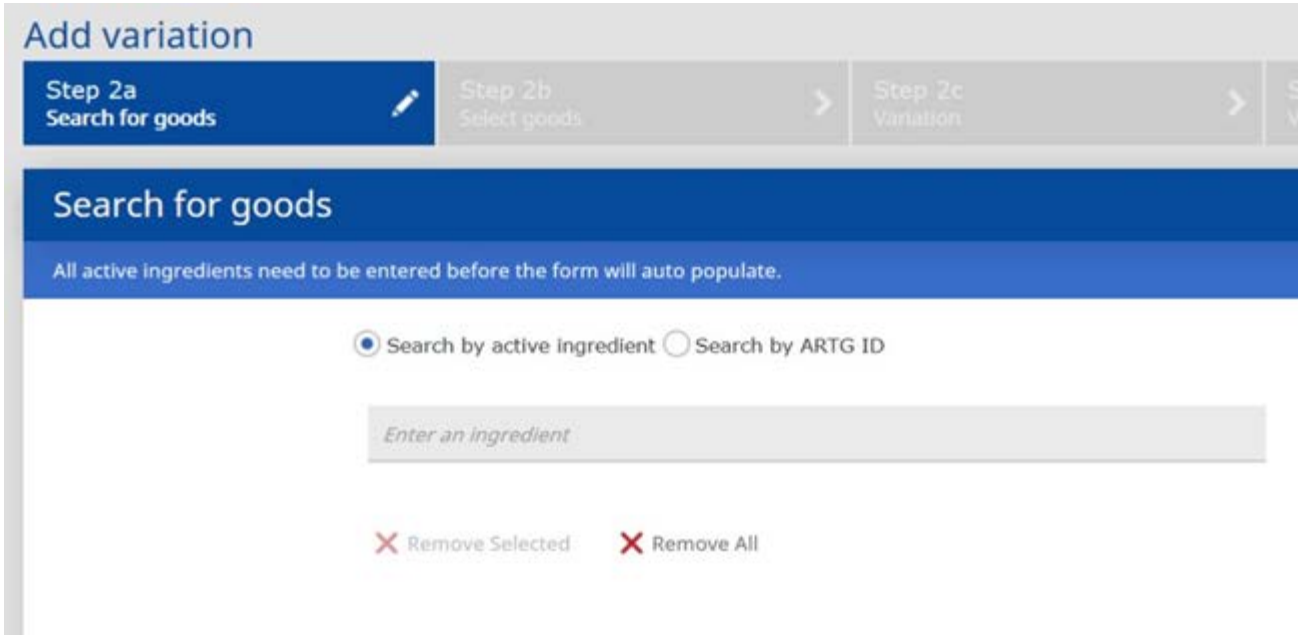
New electronic form

First step for prescription medicines

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

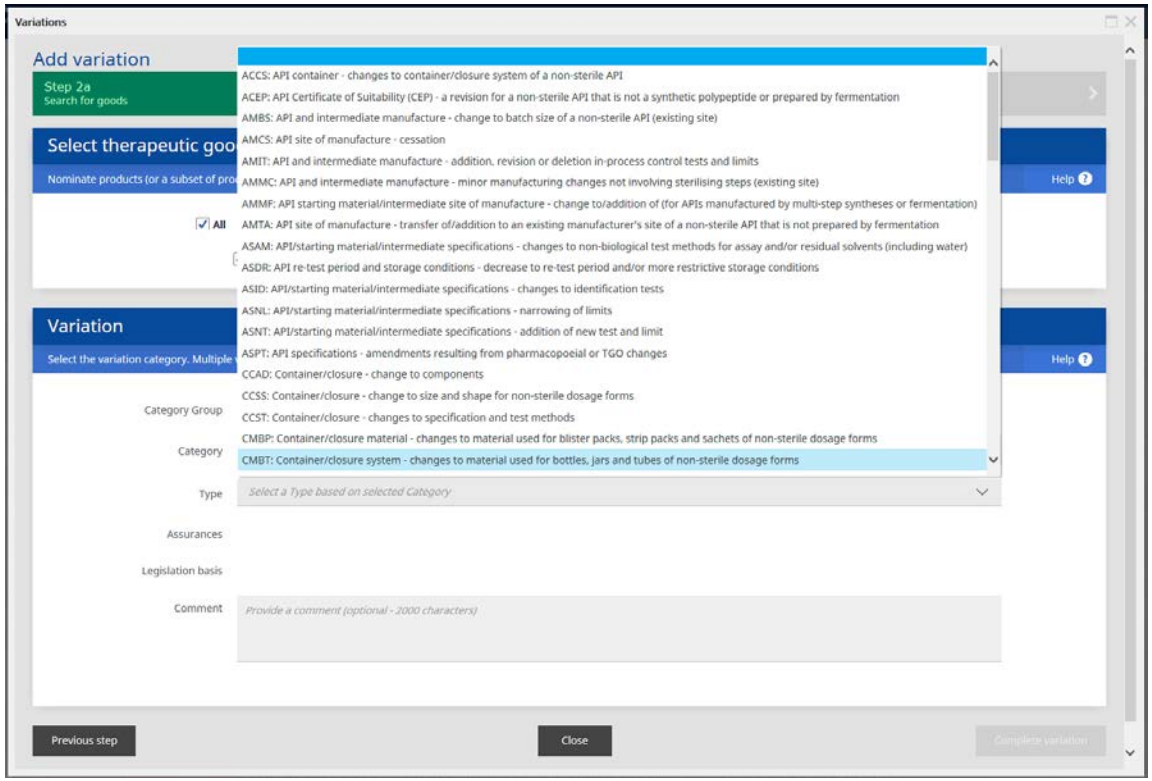
Benefit

Easy to identify your ARTG entries



Benefit

Easy selection of types of minor variations



New e-form for minor variations

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)

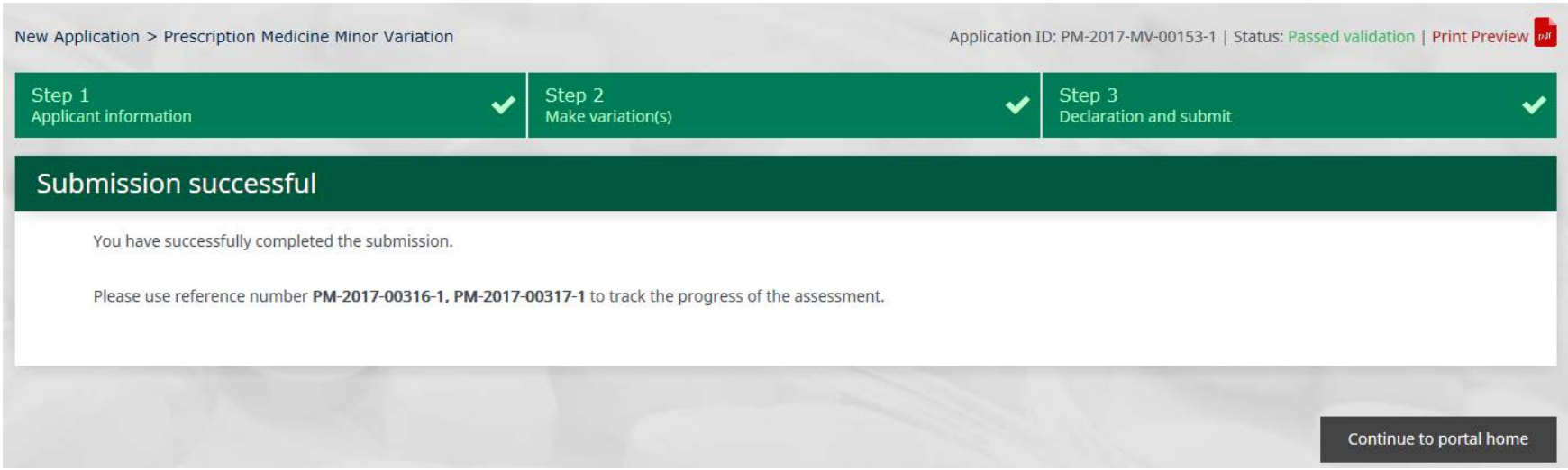
Step 3
Declaration and submit

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



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

Australian Government

Department of Health

Therapeutic Goods Administration