Provisional approval implementation arrangements

Version 1.0

TGA is implementing a Provisional approval pathway for the registration of prescription medicines as part of the Government response to the Medicines and Medical Devices Regulation Review (MMDR). The pathway applies to new medicines or new uses for registered medicines which offer treatment options for serious illnesses, where none are currently available. Unlike other registered medicines, provisionally registered medicines are approved on the basis of preliminary clinical data as to their efficacy and safety, and their registration will be time-limited and subject to enhanced monitoring by TGA.

Provisional approval eligibility criteria

As the applicant, you are required to seek provisional determination **before** lodging a submission for provisional registration.

You need to meet all of the eligibility criteria, which are outlined in Provisional determination: eligibility criteria and supporting documentation.

Provisional approval implementation timeframe

The Implementation plan below applies to the first 18 months after the Provisional approval pathway is implemented. It describes the key features and estimated implementation dates for the first provisional determination and registration applications that we may receive and assess.

Implementation of the new Provisional approval pathway will occur in **two stages,** initial implementation, and review of processes and criteria.

Key steps in the implementation phase are:

- lodgment of the provisional determination application
- submission for provisional registration

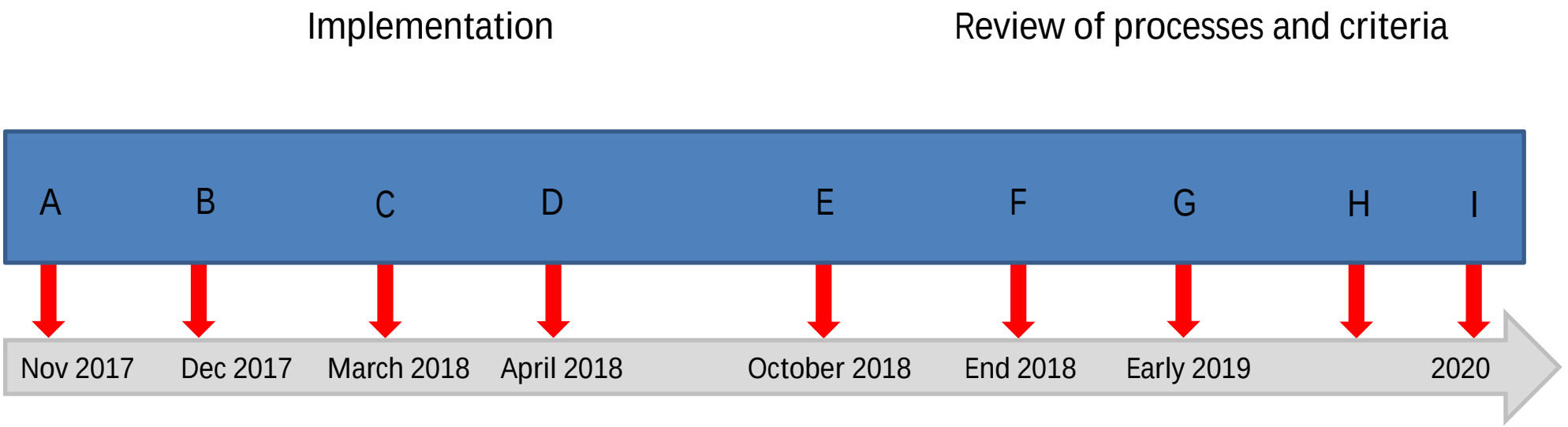
We will publish the following on our website:

- guidance to help you compile and submit provisional determination and registration applications
- details of medicines that have been successfully granted provisional determination

This implementation plan covers steps up to the first possible application for extension of provisional registration. Other steps will occur later on which are outside the scope of the current plan.

We will provide further information on the implementation of the Provisional approval pathway on our website as medicines progress through the pathway and we refine our processes.

Implementation plan



Implementation plan

Item	Description
A	TGA commences pre-submission meetings for sponsors who are interested in seeking Provisional approval determination
B	TGA commences accepting notices of sponsors' intention to lodge provisional determination applications
C	· TGA guidance on the Provisional approval pathway available · TGA provides an updated determination application e-form which will incorporate Provisional approval · TGA commences accepting provisional determination applications: – All four criteria must be met for the provisional determination application to be eligible – Applications are expected to be in the correct format and contain all relevant information as indicated in the guidance documents and must be lodged using the updated determination application form on TGA Business Services (TBS) – Target timeframe of 20 working days for determination decisions – Decision outcomes on eligible provisional determinations will be published on the TGA website – The validity of approved provisional determinations will lapse six months after the determination is granted. Sponsors may apply to the TGA for an extension of determination validity for a further six months

Item	Description
D	First determination decisions possible under the provisional determination process Earliest opportunity to lodge Pre-submission Planning Form (PPF) with valid provisional determination with TGA TGA starts to accept submissions for registration with valid provisional determination for evaluation under the provisional registration pathway. Submissions must be in eCTD format
E	Ongoing monitoring of the number of submitted determination applications, decision outcomes, and timeframes from determination application lodgement to decision
F	First possible provisional registration of a medicine with provisional determination
G	The impact of changes will be reviewed in the short term considering determination application numbers, determination outcomes and stakeholder feedback. The guidance material will be reviewed and updated if required
H	Medium-term review of the Provisional approval pathway (to assess the program once medicines have had sufficient time to complete the process of provisional registration)
I	First possible request for extension of provisional registration and/or acceptance of a submission to transition to full registration

Key features and estimated implementation dates for the first provisional determination and registration applications that we may receive and assess.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch	March 2018