



Australian Government

Department of Health

Therapeutic Goods Administration



**Expert review of medicines and
medical devices regulation**

Prescription medicines
reforms



Australian Government
Department of Health
Therapeutic Goods Administration

Prescription Medicines MMDR Reforms

Expedited Pathways for Prescription Medicines

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Therapeutic Goods Administration
ARCS Webinar

13 December 2016

TGA Health Safety
Regulation

Review of Medicines and Medical Devices Regulation (MMDR review)

- The review was conducted by an expert panel and made 58 recommendations relating to the regulation of medicines, medical devices, post-market monitoring, complementary medicines and advertising of therapeutic goods.
- On 15 September 2016, the Australian Government released its response to the MMDR review.
- The Government accepted the majority of the review's recommendations in full or in-principle and announced a program of reform to facilitate their implementation.
- The Government response identified the need for consultation with stakeholders in progressing the reforms.

Seven bundles of work agreed and costed

- Increasing Flexibility for Registration and Post-Market Processes for **Prescription Medicines**
- Increasing Flexibility for Approval and Enhanced Post-Market Monitoring of **Medical Devices**
- Increasing Flexibility for Pre-Market Approval and Increased Evidence of Efficacy of **Complementary Medicines** for Consumers
- Simplified and More Effective Regulation of **Advertising**
- Streamlined Regulation of **Patient Access** to Therapeutic Products
- **Further Reviews**
- Rationalisation of **TGA Statutory Advisory Committees**

Indicative timeline

Next 12 months

- Prescription medicines – use of overseas approvals, Priority Review pathway
- Generics – work sharing pathway, use of overseas approvals and reform of pathways
- Risk-based approach to medicine variations
- Medical devices – overseas notified bodies list (develop approaches)
 - notified bodies in Australia (build framework)
- Patient-Specific Access – category B notifications
 - simplified authorised prescriber process
- Reviews of Scheduling Policy Framework and S3 advertising completed

Indicative timeline

By 18 months

- Prescription medicines – Provisional Approval pathway
 - Medical devices – Priority Review pathway
 - notified bodies in Australia (regulatory change)
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By 24 months

- Prescription medicines – work sharing pathway established
- Complementary medicines – permitted indications
- Medical devices – overseas notified bodies oversight in place
- Patient-Specific Access – online SAS system implemented
- New Scheduling Policy Framework and possible S3 medicine changes implemented
- Advertising – complaints process and enforcement powers in place
- Advertising – pre-approvals ceased

Interdependencies



- Implementation planning for the reforms is progressing
- First stakeholder consultations have commenced
- Delivery of many reforms is dependent on:
 - feedback from consultations
 - Inter-related reforms
 - passage of legislative amendments and regulatory changes

Legislative amendments

- First amendment Bill introduced to the lower house
- Amendments in this Bill will facilitate:
 - Regulation-making power to set out details of the Priority Review pathway
 - Notifications for low-risk variations
 - Easier access to certain unapproved goods
 - Conformity assessment of medical devices by Australian companies
 - Timeframes for decision making for listed complementary medicines
 - Review and appeal rights for sponsors seeking approval to use new ingredients for listed medicines
 - Consolidation of TGA advisory committees



MMDR Consultations

Public consultations recently closed

- Criteria for comparable overseas regulators for prescription medicines (12/12)
- Expedited pathways for prescription medicines (12/12)

Currently open public consultations (targeted already commenced):

- Regulatory framework for advertising therapeutic goods (complaints handling and sanctions and penalties)
- Designation of Australian conformity assessment bodies for medical devices
- Accelerated assessment of medical devices

From January 2017

- Complementary medicines reforms including
 - Introduction of a new class of assessed complementary medicines
 - List of permitted indications for complementary medicines



Consultation forecast

From February 2017

- Provisional approval for prescription medicines
 - Enhancements to post-market monitoring scheme for medicines
 - Medical devices overseas regulatory approvals and criteria for identifying comparable overseas designating authorities and regulators
 - Special Access Scheme Category B notification criteria
 - Streamlined process for Authorised Prescriber Scheme applications
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From March 2017

- Innovation incentives for complementary medicines
- Review of the Scheduling Policy Framework
- Review of low risk therapeutic products

See the
[**MMDR public consultation forecast**](#)
on the TGA website for further
information

Expedited pathways for prescription medicines

- The MMDR review recommended that we implement “expedited pathways for promising new medicines in certain circumstances”.
- Two new ‘expedited’ pathways are being developed:
 - **Priority Review** of a complete data dossier within a reduced timeframe in certain circumstances (target timeframe of 150 working days)
 - **Provisional Approval** on the basis of early data on safety and efficacy, where the immediate availability of the medicine outweighs the risk that additional data is still required.
- The key objective of the expedited pathways is to facilitate earlier access to medicines that address unmet clinical needs for Australian consumers, without compromising our standards for safety, efficacy and quality.

TGA's principles for expedited pathways

1. Health professional and consumer confidence in TGA regulation of the safety, efficacy and quality of therapeutic goods must be maintained
2. TGA will provide clear guidance to enable the applicant to adhere to the designation and registration processes
3. Applicants will be responsible for providing TGA with all information necessary to get and support continued designation
4. Both TGA and the applicant will commit to open and timely communication to support expediting the application in the interest of public health benefit
5. There will be transparency of the criteria, and of designation and registration decisions
6. The designation and registration processes will be cost recovered
7. Appeal rights regarding the designation decision will exist
8. The designation and registration processes should not result in an unreasonable diversion of TGA resources from business as usual activities

Proposed eligibility criteria for expedited pathways

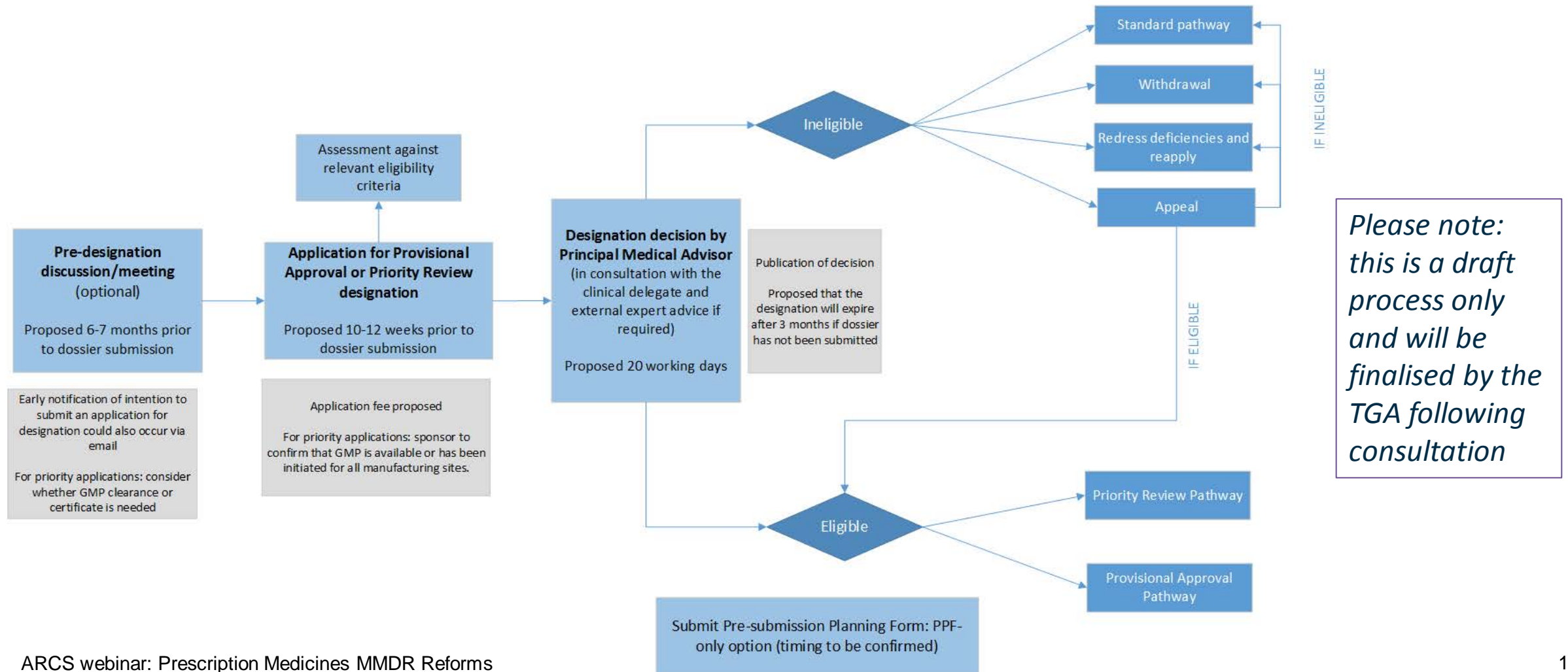
All three proposed criteria must be satisfied for entry into the expedited pathways

- **Serious condition** – the medicine is indicated for the treatment, prevention or diagnosis of a life threatening or seriously debilitating disease or condition; AND
- **Unmet clinical need** – the medicine addresses an unmet clinical need in Australian patients; AND
- **Major Therapeutic Advantage** –

For Priority Review: there is **substantial** evidence **demonstrating** that the medicine provides a major therapeutic advantage in efficacy and/or safety over existing treatments that are fully registered in Australia.

For Provisional Approval: there is **promising** evidence from **early data** indicating that the medicine is likely to provide a major therapeutic advantage in efficacy and/or safety over existing treatments that are fully registered in Australia.

Proposed designation process for expedited pathways



Proposed designation process: key details

Duration of designation

- Sponsors should know whether a medicine is eligible for designation 6-8 weeks prior to submission.
- It is proposed that designations for the expedited pathways will lapse if a full submission for registration is not provided within three months of a designation being granted.

Appeals

- Sponsors will be able to seek internal review of the designation decision.

Publication

- It is important that there is transparency of designation decisions for the expedited pathways.
- We have sought feedback on options for publication of designation decisions as part of the our recent public consultation.

Provisional Approval

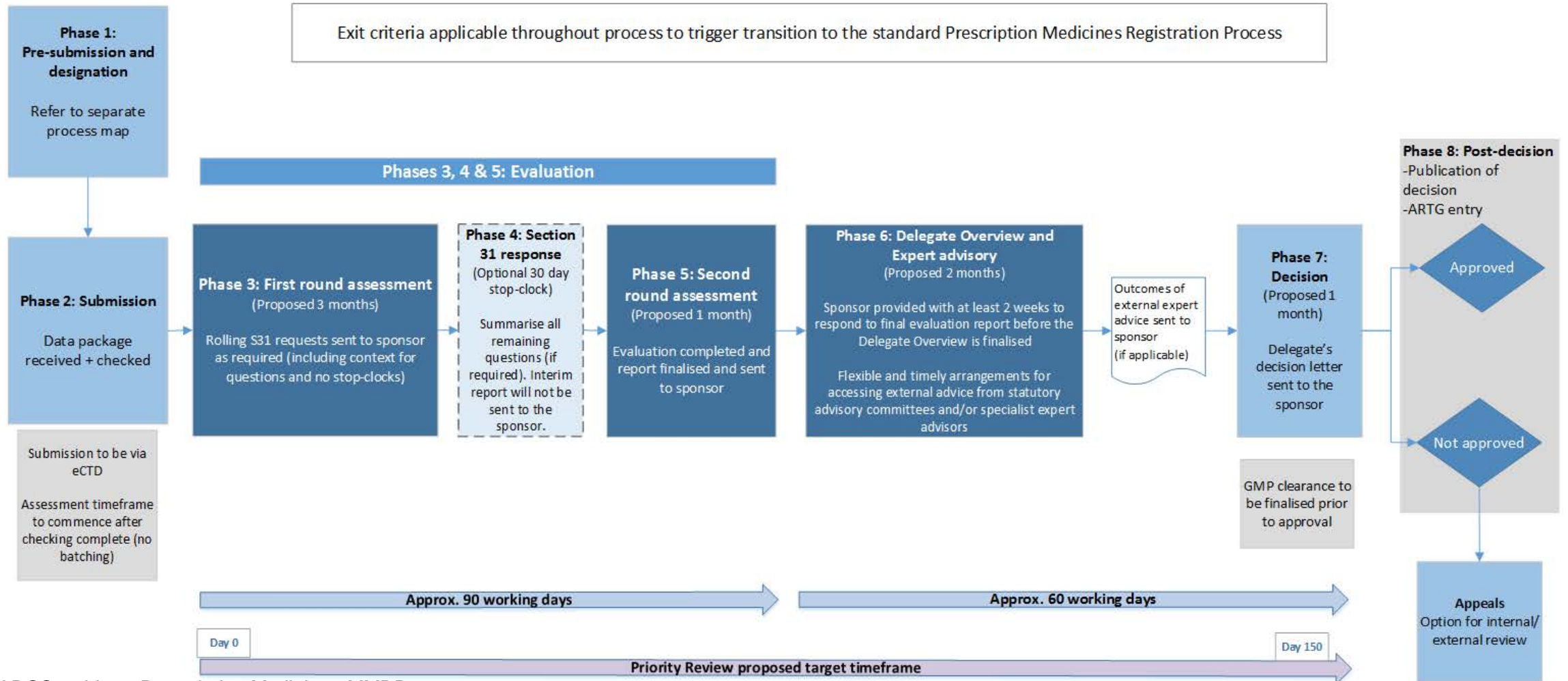
- Provisional Approval is currently scheduled to be implemented within the next 18 months, subject to consultation feedback, and will involve:
 - Allowing the TGA to provide provisional registration on the ARTG in the absence of clinical data on safety and efficacy
 - Provisional registration granted for a specified period of time (currently proposed 2-3 years)
 - Sponsors will be required to collect and submit post-market safety and efficacy data
 - Enhanced post-market monitoring and surveillance by both the medicine sponsor and TGA
 - Medicines may be able to obtain full registration when enough data is provided to confirm adequate safety and efficacy standards

The process for Provisional Approval and associated enhanced post-market surveillance is currently being developed. Public consultation on Provisional Approval will occur in 2017.

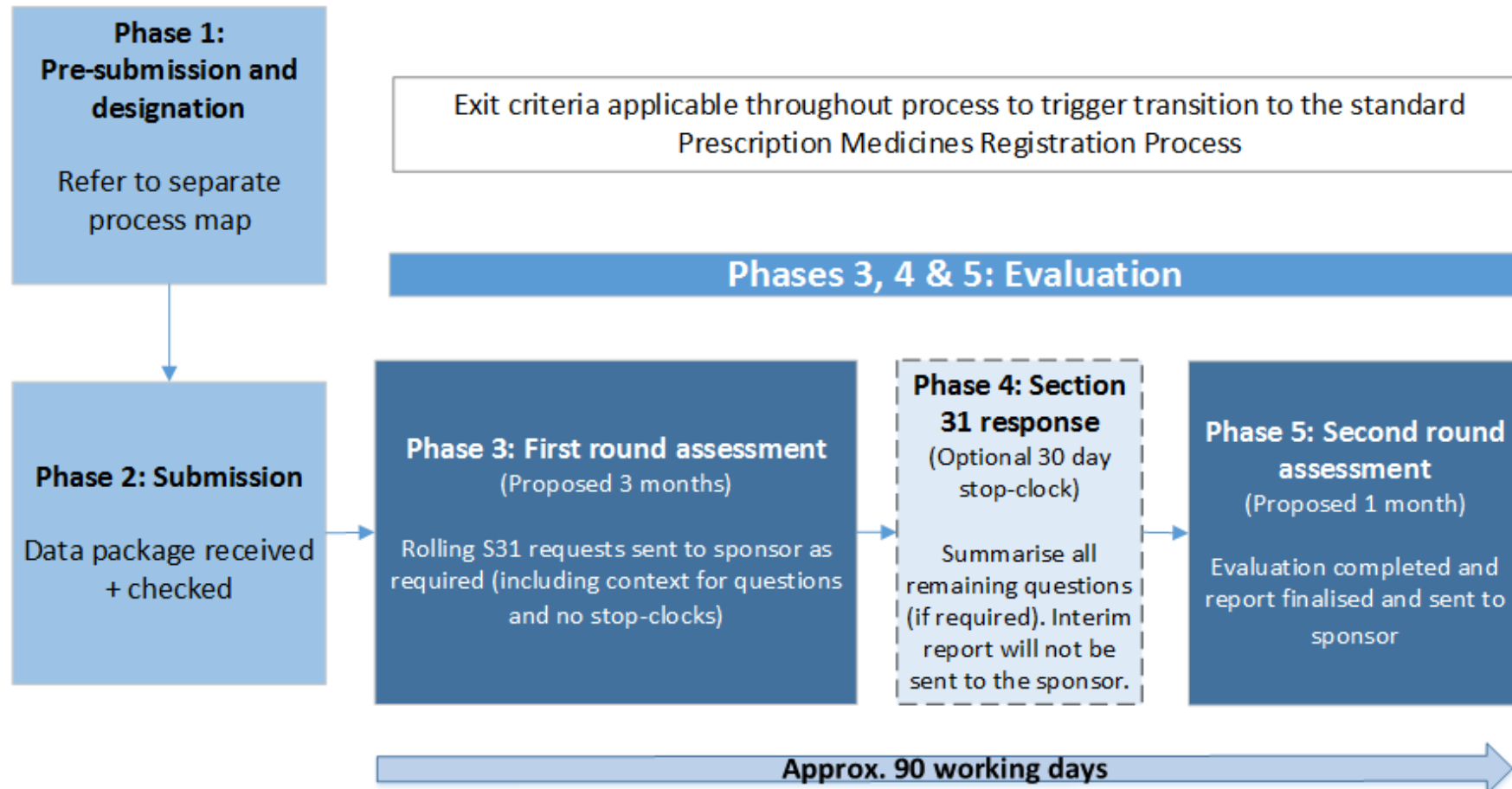
Priority Review

- Priority Review is currently scheduled to be implemented within the next 12 months, subject to consultation feedback, and will involve:
 - New and flexible business processes to reduce the timeframe for assessing certain medicines with a full data dossier
 - Decision regarding registration in the ARTG to be made more quickly
 - Target of 150 working days recommended by the expert panel, consistent with benchmarks set by the FDA and EMA
 - More flexible and timely arrangements for seeking external expert advice in order to facilitate the shorter timeframe
 - Exit pathways if the sponsor does not meet requirements for Priority Review
 - Full registration in the ARTG

Priority Review: Proposed registration process for consultation

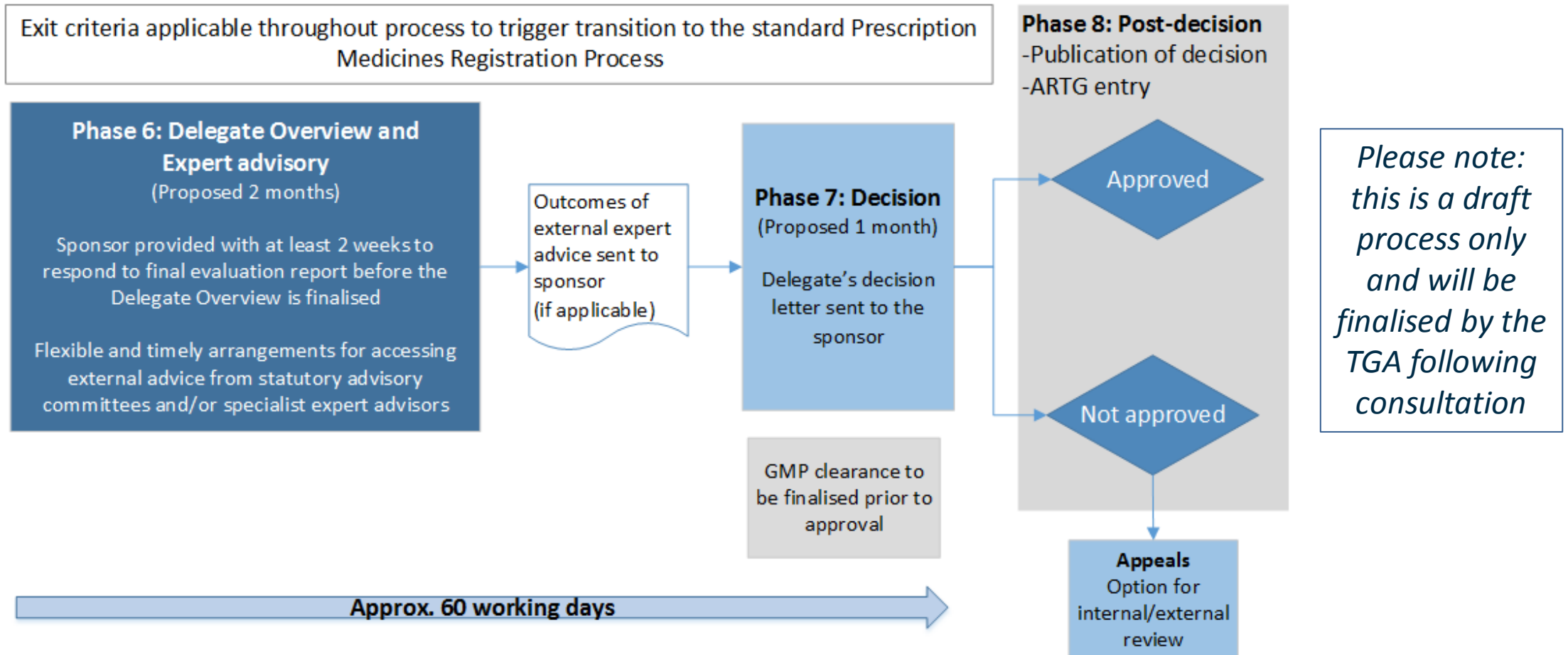


Proposed submission and evaluation phases



*Please note:
this is a draft
process only
and will be
finalised by the
TGA following
consultation*

Proposed expert advisory and decision making phases



Questions?



Further questions about these reforms can be sent to
MMDR.consultation@health.gov.au



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Prescription Medicines MMDR Reforms

Enhanced Post-Market Monitoring and Unapproved Goods

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ARCS Webinar

13 December 2016

TGA Health Safety
Regulation

Enhanced post-market monitoring scope

- TGA intends consulting on a number of enhancements to our Medicines Vigilance Framework in response to MMDR.
- This includes the introduction of a number of new vigilance tools.
- Like our existing vigilance tools, they will be applied on a risk management basis.
- We continue to see post-market monitoring as a collaborative activity TGA shares with sponsors, health professionals and consumers.



Areas for consideration

- RMP Compliance Monitoring Program
- Black Triangle Scheme ▼
- Pharmacovigilance Inspections Program

RMP compliance monitoring program

- TGA to follow up with sponsors where RMP activities have not been completed within the timeframes given in the RMP
- Will operate within TGA's existing Regulatory Compliance Framework, where we will seek to work with the sponsor in the first instance to achieve compliance.
- Risk based prioritisation
 - Provisionally registered products
 - First in pharmacological class
 - Identified safety concern of special interest that requires additional monitoring/mitigation



Black Triangle scheme ▼

- To alert health professionals and consumers that the medicine is subject to intensive monitoring by TGA
- Encourage health professionals and consumers to report adverse events for medicines in the scheme
- Targeted use to maintain potency of the symbol, such as
 - first in pharmacological class NCEs
 - new medicines with safety concerns
- Will require the assistance of sponsors, health professional and consumer groups to implement the communication strategy to support the Scheme.

Pharmacovigilance Inspections program

- Full implementation following the PV Inspection Pilot
- Program will apply to Sponsors of:
 - prescription medicines
 - over-the-counter medicines
 - listed and registered complementary medicines
- Risk-based prioritisation of sponsors for inspection, considering:
 - the risk that non-compliance is occurring, and
 - the potential consequences of this
- Again, TGA will take a cooperative compliance approach to work with sponsors in the first instance where there are non-compliance findings



What else?

- A new Adverse Events Management System
 - This will cover both medicine and medical device adverse events.
 - Will enable system to system exchange of adverse event reports using standardised international message formats such as ICH E2B R2 and R3. This functionality will make it easier for sponsors to send and receive adverse event information to/from the TGA.
 - Will assist the TGA in enhancing its signal management capabilities through more advanced signal detection and data analysis processes.

Unapproved goods

Special Access Scheme (SAS) and Authorised Prescriber (AP)

- Legislation will be amended to allow for notifications for identified unapproved therapeutic goods where the patient does not have a life threatening condition.
- TGA will implement a list of unapproved goods against which SAS Category B notifications will be allowed. To maintain the integrity of the ARTG, TGA will be responsible for nominating unapproved goods for inclusion on the list. TGA will need to be satisfied that these goods have a history of established use in Australia or overseas for inclusion on the list.
- Enhanced compliance processes will be put in place to ensure the scheme is being used as intended.
- An online portal will be developed to facilitate improved efficiency in the SAS and AP processes.

Next Steps

- Early 2017
 - TGA will undertake targeted and public consultation on the proposed changes
- January 2018
 - RMP Compliance Monitoring comes into effect
 - Black Triangle Scheme comes into effect
 - New online adverse event reporting system goes live
- July 2018
 - New online system for unapproved goods goes live
 - Pharmacovigilance Inspection Program comes into effect

Questions?



Further questions about these reforms can be sent to
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Scientific Evaluation Branch

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Medicine regulation reforms

Scientific Evaluation Branch - 3 of 5 projects



Work-sharing

- Simultaneous submissions to multiple agencies
- Independent decision-making



Use of overseas assessment reports

- Submitted by the applicant in Australia
- Complete reports, unredacted



Variations to registered medicines – a risk-based approach

- A notification process for negligible-risk changes

Use of overseas reports and work-sharing

Scope

- Identify 'Comparable Overseas Regulators'
 - Consultation on criteria
- Further developing business processes
 - Work-sharing
 - COR reports submitted by applicant in Australia
- Build on existing cooperation initiatives, e.g.
 - Australia-Canada Regulatory Cooperation Initiative
 - International Generic Drug Regulators Programme



Benefits

- Removing 'submission lag'
- Reducing evaluation times
- Aligning regulatory requirements between regulators

Variations to registered medicines – risk-based

- ‘Notification’ rather than ‘request for variation’
 - Staged implementation
 - Review of existing change codes
 - Amendment to therapeutic goods legislation
 - Appropriate fees
- Applies to all registered medicines
 - Enhancements to existing portal for non-prescription medicines
 - New e-form for prescription medicines



Questions?



Find out more:



www.tga.gov.au/mmdr



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