FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Australia	**Agency Name:** Therapeutic Goods Administration (TGA)	
Name of FRP: TGA Comparable Overseas Regulator (COR)-B		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: Click here to enter a date.		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☒	☒

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	Choose an item.
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	The TGA makes use of assessments from comparable overseas regulators (CORs), where possible, in the regulation of prescription medicines.
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	The application and evaluation fees for the applications submitted under the COR-A or COR-B procedure remain the same as a full application. TGA Schedule of Fees and Charges.
Total target (agency) time for assessment (calendar days)	Under the COR-B approach, the TGA regulatory decision will still be mostly based on a critical review of the COR assessment reports. The COR-B process has a 175 working day evaluation and decision timeframe, allowing for TGA evaluation of certain data, in addition to the label, PI and RMP.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

Select one of the following (* see definitions at end of document)

Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**
☐	☒	☐

If this is a reliance or recognition pathway, what are the accepted reference agencies?	1. European Medicines Agency (EMA) 2. Pharmaceutical and Medical Devices Agency (PMDA), Japan 3. Health Canada 4. Health Sciences Authority (HSA), Singapore

FRPath.org Country and FRP Information Input Form	
	5. Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom 6. SwissMedic, Switzerland 7. United States Food and Drug Administration (US FDA).
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	The amount and type of additional data requiring evaluation will determine whether the application is best processed under the COR-B approach or as a Category 1 application. Examples of additional data that may be considered under the COR-B process include updated stability data, validation data for an additional manufacturing site and updates to pivotal studies that support the proposed indication.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this process is not through a Regional Regulatory Initiative.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, the product has to have been marketed in another country. In Module 1.11.1, full details of whether the application has been approved, deferred, withdrawn, rejected, approved on appeal, delayed or received a 'refusal to approve' in another jurisdiction. Note: This requirement seeks to capture complicated or contentious applications that require a deeper consideration of the data in the Australian context. This includes applications that have been 'indefinitely' delayed, but not situations where the application has undergone a standard 'questions' process (e.g. Day 120 List of Questions). In Module 1.11.4, the complete and un-redacted set of final COR assessment reports, in English. *For COR-B applications, there is no time limit for how long ago the medicine had received overseas approval. Therefore, it is more likely that the medicine or the guidelines used by the COR to assess the medicine or both may have changed.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Always required

FRPath.org Country and FRP Information Input Form	
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- The COR report-based process is associated with a shortened evaluation and decision timeframe. The aim of this process is to reduce duplication of evaluation of prescription medicines that have already been approved by a COR, while maintaining existing quality, safety and efficacy standards for medicines supplied in Australia. - The intention is that the TGA will only need to evaluate data generated specifically for the Australian context. For example, Australian labels, product information and consumer medicine information. However, in some instances, additional data may need to be considered. For example, safety data generated since the COR approval. - The approach used will depend on the extent to which the COR report removes the need for the TGA to evaluate data. The applicant must complete and submit the COR application checklist to identify the extent of additional data which will require evaluation by the TGA. Completion of the checklist will indicate whether the application is eligible for either COR-A or COR-B. - COR report-based applications must use the PPF-only pre-submission phase option available for the standard prescription medicine registration process. This means that: (i) the submission must be in electronic Common Technical Document (eCTD) format; (ii) there will be no formal Milestone 1. Applicants should proceed to lodge their entire submission for registration as soon as the complete submission number is visible on TBS. This will occur once the TGA has added the relevant stream number to the Submission ID based on the proposed indication (i.e. 'PM-yyyy-xxxxx-z-stream number'). - Under the COR report-based process, the applicant must identify whether the application relies on a DMF. The reports on the restricted part of the dossier (including questions raised by, and the answers provided to, the COR) must be provided to the TGA by the DMF holder along with the DMF. - COR report-based process – prescription medicines. COR-A and COR-B application checklist: https://www.tga.gov.au/sites/default/files/application-checklist-for-cor-report-based-process.pdf
Date of this update	19 April 2020.

FRPath.org Country and FRP Information Input Form	
References	1. Comparable overseas regulators (CORs): Timeframes and milestones. https://www.tga.gov.au/comparable-overseas-regulators-cors-timeframes-and-milestones Accessed on 19 April 2020. 2. Comparable overseas regulators (CORs): Submission requirements. https://www.tga.gov.au/comparable-overseas-regulators-cors-submission-requirements Accessed on 19 April 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.