Australian Government
Department of Health
Therapeutic Goods Administration

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This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

COR report-based process – prescription medicines

COR-A and COR-B application checklist

You must complete and submit this checklist as part of your Module 1.2.1 application form. This will enable the TGA to assess whether the application is eligible for the COR-A or COR-B process. If certain criteria are not met, the application can then only be submitted as a Category 1.

See guidance on the COR report-based process for further information.

Criteria	Checklist
General	
The assessment package is from a comparable overseas regulator (COR), as published on the TGA website. **Note**: Overseas approval older than 1 year is only eligible for COR-B.	Yes ☐ Name of COR: Choose an item. Date of approval:
The application meets the following general application criteria: • The COR assessment package relates to a *de novo* evaluation for full marketing approval of the medicine (i.e. not provisionally approved). • The COR assessment package is complete, in English and unredacted. • An application for marketing approval for the medicine that is the subject of this application has not been delayed, deferred, rejected, refused or withdrawn in any country.	Yes ☐ eligible for COR-A or COR-B No ☐ not eligible for the COR report-based process.
Nomenclature: • Does the COR report use Australian approved terminology (e.g. AANs, ABNs, dosage forms)?	Yes ☐ No ☐ include further information:

Criteria	Checklist
Elements not previously evaluated by the TGA: Does the application contain elements novel to Australia (first in class, incorporating novel or emerging technologies or containing active ingredients or excipients not previously registered in Australia).	No ☐ Yes ☐ please include further details of novel elements: ***Note**: Additional evaluation may be required*
Third party proprietary information - e.g. Drug Master Files (DMFs)	
For dossiers that include proprietary information from a third party, evidence to confirm that all proprietary information, including the COR evaluation and relevant communication between the third party and the COR, has been provided to the TGA.	N/A ☐ skip to next section Yes ☐ eligible for COR-A or COR-B. Include DMF number No ☐ not eligible for the COR report-based process.
Will a Certificate of Suitability (CEP) be provided to the TGA?	N/A ☐ skip to next section Yes ☐ No ☐ provide the full DMF and COR assessment.
Was the CEP also provided to the COR?	Yes ☐ No ☐ provide the full DMF and COR assessment.
Indications and Directions for Use	
The proposed indications are equivalent to that approved by the COR, including equivalent dosing and administration details (directions for use).	No ☐ not eligible for the COR report-based process. Yes ☐ include hyperlink to approved indication in COR report. *Hyperlink*
For generics and biosimilars The proposed indications are identical to the indications for the Australian originator product.	Yes ☐ No ☐ not eligible for the COR report-based process.
Medicine characteristics	
The proposed medicine is identical to that evaluated and approved within the COR assessment package with regard to all of the below: • Dosage form	Yes ☐ eligible for COR-A or COR-B No ☐ not eligible for the COR report-based process.

Criteria	Checklist
• Strength or size (disregarding pack size) • Formulations (active substance and excipients) • Manufacturers and manufacturing process (drug substance and drug product, including finished product container, disregarding container size) **Note**: Applications in which there are changes to a *site* of manufacture are only eligible for COR-B (see Additional manufacturing sites section below).	
Viral safety	
Does the therapeutic good contain, or is it produced from, human blood or plasma?	No ☐ eligible for COR-A or COR-B Yes ☐ eligible for COR-B only. Submit additional data to meet Australian-specific TGOs 81 and 88 and TSE requirements. Include hyperlink to relevant location in the relevant Module. *Hyperlink*:
Generic medicines (see Guidance 15)	
Is your Australian application for a generic medicine?	No ☐ skip to next section Yes ☐ complete the generic medicines section below
Was the reference medicine used in the comparative studies in the COR dossier a medicine currently registered on the ARTG and sourced from Australia?	No ☐ continue to next question Yes ☐ skip to next section. Insert ARTG number
Did the dossier submitted to the COR include biopharmaceutic data?	Yes ☐ continue to next question No ☐ provide hyperlink to justification for not supplying biopharmaceutic data. *Hyperlink*:
Is an Australian-sourced reference medicine used for bridging studies?	Yes ☐ eligible for COR-B only. No ☐ not eligible for the COR report-based process. N/A ☐ evidence is provided that the COR (e.g. US/EU) reference and the AU reference are manufactured at a single site for global distribution. Eligible for COR-A or COR-B.

Criteria	Checklist
Biosimilars (see Regulation of Biosimilars)	
Is your Australian application for a biosimilar product?	No ☐ skip to next section Yes ☐ complete the biosimilars section below
Is the reference medicine used in comparability studies the same as the reference biological medicine already registered in Australia?	Yes ☐ continue to next question. ARTG number: No ☐ not eligible for the COR report-based process.
Is an Australian-sourced reference medicine used for bridging studies?	Yes ☐ eligible for COR-B only. No ☐ not eligible for the COR report-based process. N/A ☐ evidence is provided that the COR (e.g. US/EU) reference and the AU reference are manufactured at a single site for global distribution. Eligible for COR-A or COR-B.
International alignment of guidelines	
The COR report cites international quality guidelines that have been adopted by the TGA. See Quality Guidelines and Biological Medicines Guidelines	Yes ☐ eligible for COR-A or COR-B No ☐ eligible for COR-B only. Include further information and hyperlink to relevant section within report *Hyperlink:*
The COR report cites international nonclinical guidelines that have been adopted by the TGA. See Nonclinical Guidelines	Yes ☐ eligible for COR-A or COR-B No ☐ eligible for COR-B only. Include further information and hyperlink to relevant section within report *Hyperlink:*
The COR report cites international clinical efficacy and safety guidelines that have been adopted by the TGA. See Clinical Efficacy and Safety Guidelines	Yes ☐ eligible for COR-A or COR-B No ☐ eligible for COR-B only. Include further information and hyperlink to relevant section within report. *Hyperlink:*

Criteria	Checklist
Are there any country-specific guidelines cited in the COR report?	No ☐ eligible for COR-A or COR-B Yes ☐ include justification where COR guidelines do not align with Australian guidelines and submit a full copy of the relevant COR guidelines.
Additional manufacturing sites	
Are additional manufacturing sites (i.e. not included in the dossier sent to the COR) nominated in the application for Australia?	No ☐ skip to next section Yes ☐ continue to next question
Is the additional site only for the performance of: • Labelling and/or • Secondary packaging and/or • Release for supply	Yes ☐ eligible for COR-A or COR-B No, other steps ☐ eligible for COR-B only. Which other steps:
Have validation data (including batch analysis data) for the additional sites been provided? ***Note**: Additional evaluation may be required*	Yes ☐ eligible for COR-B only. No ☐ not eligible for the COR report-based process.
Good Manufacturing Practice (GMP)	
All nominated manufacturing sites have either: • a current GMP licence or; • current GMP clearance.	Yes ☐ eligible for COR-A or COR-B No ☐ eligible for COR-B only. Evidence is required that you have applied for the relevant clearance and paid the relevant fee. Application number:
Stability/shelf life/containers	
Are the stability studies conducted according to Australian climatic zones? See Stability testing for prescription medicines	Yes ☐ eligible for COR-A or COR-B No ☐ additional stability data will need to be submitted. Eligible for COR-B only.
Are the proposed shelf life, in-use shelf life and storage conditions identical to those accepted by the COR?	Yes ☐ No ☐ include hyperlink to proposed shelf life in Module 1.2.1 Application form *Hyperlink*

Criteria	Checklist
Are additional data required in this submission to support temperature excursion studies conducted as per Stability testing for prescription medicines?	No ☐ eligible for COR-A or COR-B Yes ☐ eligible for COR-B only. Include hyperlink to additional data. *Hyperlink*
The medicine evaluated by the COR is packaged with a child-resistant closure (CRC) which meets the requirements of TGO 80/95.	N/A ☐ CRC not required in Australia Yes ☐ eligible for COR-A or COR-B No ☐ not eligible for the COR report-based process.
Currency of clinical studies	
Are there any minor updates to pivotal studies or supportive studies available that were not considered in the COR approval supporting the proposed indication.	N/A ☐ Yes ☐ provide details as annotations within PI with references to relevant documentation.
Is there any additional information available relevant to the risk-benefit of the indication approved overseas (e.g. additional Periodic Safety Update Report (PSUR) or long term safety study available since COR approval)?	No ☐ eligible for COR-A or COR-B Yes ☐ eligible for COR-B only
No new studies, major variations or substantial updates have occurred since the goods were evaluated.	Yes ☐ eligible for COR-A or COR-B No ☐ this application is not eligible for the COR report-based process.
Product Information (PI)	
Include as annotated commentary in the draft PI document: • A justification for the proposed Australian Pregnancy Category. • Details of the species, sex, route, upper doses and relative exposure achieved in cited animal studies for Fertility, Use in Pregnancy and Carcinogenicity (where not included in the COR report). • Any differences between the proposed Australian indications, dosing and administration details and those approved in the COR report. • Any new studies or data updates from what	Completed ☐

Criteria	Checklist
was assessed by the COR.	
Risk Management Plan (RMP)[1] **Refer to RMP requirements within CTD module 1: Administrative and prescribing information for Australia and the RMP guidance.**	
RMP: NCE/NBE or EOI and Biosimilar Applications	
1. Is an RMP/Australian Specific Annex (ASA) required?	Yes ☐ continue to Q2 No ☐ no further RMP questions.
2. Have you submitted an ASA or an Australian RMP in Module 1.8.2?	ASA ☐ continue to Q3 Aus-RMP ☐ continue to Q7 No ☐ application is not effective.
3. Have you submitted a current approved EU-RMP in Module 1.8.2?	Yes ☐ continue to Q4 No ☐ continue to Q6
4. Are there any Australia-specific risk management issues that have been specifically addressed in the ASA?	Yes ☐ eligible for COR-B only No ☐ continue to Q5
5. Is the risk management system proposed for Australia in the ASA equivalent to that described in the approved EU-RMP?	Yes ☐ eligible for COR-A and COR-B No ☐ eligible for COR-B only
6. Have you submitted in Module 1.8.2 either: • a draft EU RMP, • a core/global RMP, or • an Australian RMP?	Yes ☐ continue to Q7 No ☐ application is not effective as it does not meet the mandatory requirements.
7. Does the COR report: • evaluate the RMP submitted in Module 1.8.2 (either the current version or an earlier version) and include comment on the adequacy of the	Yes ☐ eligible for COR-A or COR-B No ☐ ligible for COR-B only

[1] Sponsors planning to use the COR report-based pathways should seek advice from the TGA about whether an RMP/ASA will be required before submitting their application. If an RMP is not provided, but the TGA determines at screening that an RMP should have been submitted, the application will not be eligible for the COR report-based pathways.

Criteria	Checklist
Summary of Safety Concerns or • evaluate an RMP proposing an equivalent risk management system to that proposed in Australia (including equivalent pharmacovigilance and risk minimisation activities, and include comment on the adequacy of an equivalent summary of safety concerns)	
RMP: Generic applications	
1. Is an RMP/ASA required? RMPs are required for selected generics (e.g. additional risk minimisation is required).	Yes ☐ continue to Q2. No ☐ no further RMP questions.
2. Have you submitted an Australian RMP, or an ASA with an EU RMP or core/global RMP in Module 1.8.2?	Yes ☐ continue to Q3 No ☐ application is not effective.
3. Are there any Australia-specific risk management issues that have been specifically addressed in the ASA?	Yes ☐ eligible for COR-B only No ☐ eligible for COR-A or COR-B

Based on the completed checklist above, I am applying for the following process:

☐ COR-A

☐ COR-B

By completing and signing this form I give permission for the TGA to contact the above-mentioned COR and share information relating to my application.

Name			
Signature		Date	