Australian Government
Department of Health
Therapeutic Goods Administration

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This form, when completed, will be classified as '**For official use only**'.
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Comparable Overseas Bodies (COB) report-based process – Registered complementary medicines checklist

You must complete and submit this checklist as part of Module 1.2 of your dossier submission. This checklist will enable the TGA to assess whether the application meets the requirements of the selected application category. If certain criteria are not met, the application must include appropriate justification.

Where further information or justification is required, please provide a hyperlink or reference to the application dossier next to the relevant check box below.

See the Guidance on using evaluation reports from Comparable Overseas Bodies: Evaluations of registered complementary medicines, assessed listed medicines and substances for use in listed medicines for further information.

Criteria	Checklist
General	
The evaluation report is from a COB as published on the TGA website.	Yes ☐ Name of COB: Date of approval: No ☐ not eligible for the COB report-based process

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Reference/Publication # D18-10038459

TGA Health Safety Regulation

The application meets the following general application criteria: · The COB evaluation package is complete (including the original dossier submitted to the COB), in English (or accompanied by a certified translation to English) and un-redacted. · The COB assessment package must have received full marketing approval following a *de novo* assessment made by a COB, and presents an independent assessment of data provided to that COB. · The application must not have been delayed, deferred, rejected, refused or withdrawn at any time, in any country. · The application should not be subject to any further restrictions or conditions following approval, that have not been identified in the report. · The COB evaluation report is not subject to any restrictions on use or disclosure by the TGA.	Yes ☐ No ☐ not eligible for the COB report-based process.
For dossiers that include proprietary information from a third party, evidence to confirm that all proprietary information, including the COB evaluation and relevant communication between the third party and the COB, has been provided to the TGA.	Yes ☐ No ☐ not eligible for the COB report-based process. N/A ☐
Nomenclature: · Does the COB report use Australian approved terminology (e.g. AANs, ABNs, dosage forms)?	Yes ☐ No ☐ provide further information.
Indications	
The proposed indications are equivalent to those approved by the COB, including equivalent dosing and administration details, directions for use, target population demographics, disease profiles, expected health outcomes and intent and meaning.	Yes ☐ specify approved indications in evaluation report. No ☐ not eligible for the COB report-based process.
For generic medicines: The proposed indications are identical to the indications approved for the Australian originator.	Yes ☐ No ☐ not eligible for the COB report-based process.

Medicine characteristics	
The proposed medicine is identical to that evaluated and approved within the COB assessment package with regard to all of the below: · Dosage form · Strengths · Formulation/s (active substance and excipients) · Quality aspects	Yes ☐ No ☐ not eligible for the COB report-based process.
Are the manufacturers and manufacturing process (drug substance and drug product, including finished product container) identical to that evaluated and approved by the COB?	Yes ☐ No ☐ provide details and justification
International alignment of guidelines and standards	
The COB evaluation report only cites international guidelines and standards consistent with those adopted by the TGA. Quality Guidelines, Nonclinical Guidelines Clinical Guidelines	Yes ☐ No ☐ provide justification where COB guidelines (such as country specific guidelines) do not align with TGA adopted guidelines and submit a full copy of the relevant COB guidelines.
The COB evaluation report is consistent with the methodology used by the TGA e.g. contains information consistent with the Common Technical Document (CTD).	Yes ☐ No ☐ provide details and justification.
The COB evaluation report contains all information necessary to meet the TGA's technical requirements.	Yes ☐ No ☐ provide details and justification.
Generic medicines	
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 COB dossier a medicine currently registered on the ARTG and sourced from Australia?	No ☐ continue to next question. Yes ☐ insert ARTG number:

Did the dossier submitted to the COB include biopharmaceutic data?	Yes ☐ continue to next question. No ☐ specify and provide justification for not supplying biopharmaceutic data.
Is evidence provided that the reference product used in any evaluation of bioequivalence identical to the Australian reference product	Yes ☐ No ☐ not eligible for the COB report-based process.
Additional manufacturing sites	
Are additional manufacturing sites (i.e. not included in the dossier sent to the COB) 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 any of the following: · labelling · secondary packaging · release for supply	Yes ☐ No ☐ provide details of other steps.
Has validation data (including batch analysis data) for the additional sites been provided for evaluation? ***Note**: Additional evaluation may be required*	Yes ☐ No ☐ provide details.
Good Manufacturing Practice (GMP)	
All nominated manufacturing sites have either a current: · GMP licence; or · GMP clearance	Yes ☐ No ☐ 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?	Yes ☐ No ☐ submit additional stability data.
Are the proposed shelf life, in-use shelf life and storage conditions identical to those accepted by the COB?	Yes ☐ No ☐ provide details and justification.

If the medicine evaluated by the COB is packaged with a child-resistant closure (CRC), does it meet the requirements of TGO 80/95?	Yes ☐ No ☐ provide details in your application. N/A ☐ CRC not required in Australia.
New evidence/updates	
Have there been any variations or updates to the medicine since it was evaluated by the COB (e.g. directions for use, ingredients, indications, label warning statements)?	Yes ☐ provide details. No ☐
Are any updates to pivotal studies or supportive studies available that were not considered in the COB approval supporting the proposed indications?	Yes ☐ provide details. No ☐
Is there any additional information available relevant to the risk-benefit of the medicine since COB approval (e.g. additional Periodic Safety Update Report (PSUR) or long term safety study)?	Yes ☐ provide details. No ☐
Product Information (PI)	
Include as annotated commentary in the draft PI document if applicable: · 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 COB report). · Any differences between the proposed Australian indications, dosing and administration details and those approved in the COB report. · Any new studies or data updates from what was assessed by the COB.	Completed ☐

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

Name			
Signature		Date	