Australian Government
Department of Health and Aged Care
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.

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

Criteria	Checklist
• The COB report is in English (or accompanied by a certified translation by the COB to English) and un-redacted. • The COB evaluation report is not subject to any restrictions on use or disclosure by the TGA. • The medicine must have received full marketing approval following an independent *de novo* assessment of data by the COB. • The medicine should not have resulted in a rejected, refused, cancelled, or withdrawn marketing approval at any time, or received a 'refusal to approve', or be the subject of an application that is currently delayed or deferred, in any jurisdiction (unless otherwise justified). • The medicine is not subject to any further restrictions or conditions (e.g. changes to recommended daily dose, label warning statements) following approval, that have not been identified in the report.	Yes ☐ No ☐ not eligible for the COB report-based process.
The medicine has a current approval by the COB that has evaluated the medicine.	Yes ☐ provide full details. No ☐ provide justification.
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.

Criteria	Checklist
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.
Are any indications proposed beyond those approved by the COB?	Yes ☐ Not eligible for the COB report-based process. No ☐
For generic medicines: The proposed indications are the same as 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 report with regard to the below: • Formulation/s (active substance and excipients) • Quality aspects • Dosage form • Strength • Directions for use • Route of administration	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
Generic medicines	

Criteria	Checklist
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 is identical to the Australian reference product	Yes ☐ No ☐ not eligible for the COB report-based process.
Gap analysis	
A gap analysis has been provided with the application discussing how the COB evaluation report addresses the technical information that is required in Appendix A in the Mandatory requirements for an effective registered complementary medicine application for the relevant application type. If there is missing information, you may provide a justification outlining why the missing information is not required to adequately demonstrate the quality and/or safety and/or efficacy of the medicine.	Yes ☐ No ☐ not eligible for the COB report-based process.
The COB evaluation report is prepared using guidelines and standards consistent with those adopted by the TGA e.g. contains information consistent with the Common Technical Document (CTD).	Yes ☐ No ☐ provide details and justification.
Are any updates to pivotal studies or supportive studies available (e.g. safety and/or efficacy studies identified from an updated literature search, or adverse events) 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 overseas medicine since COB approval?	Yes ☐ provide details No ☐

Criteria	Checklist
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:

Criteria	Checklist
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	