Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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>.

Comparable Overseas Bodies (COB) report-based process – Substance evaluation checklist

You must complete and submit this checklist as part of your dossier submission. If you are providing multiple COB evaluation reports (i.e. separate for Quality and Safety), you will need to complete this checklist for each COB report. 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.

COB report details	
Substance name:	
Date of COB approval:	
Type of COB Report:	Evaluation of quality AND safety ☐ Evaluation of quality only ☐ Evaluation of safety only ☐

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

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Reference/Publication # D18-10038455

TGA Health Safety Regulation

Criteria	Checklist
The COB evaluation report meets the following 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 · The application must not have been delayed, deferred, rejected, refused or withdrawn at any time, in any country.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.
Nomenclature: · Does the COB report use Australian approved terminology (e.g. AANs, ABNs or AHN, dosage forms)?	Yes ☐ No ☐ provide further information.
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 ☐

Criteria	Checklist
Substance characteristics	
The proposed substance is identical to that evaluated and approved within the COB report with regard to all of the following: · Route of administration · Therapeutic purpose · Dose form and range · Use (active/excipient) · Restrictions (e.g. target population, dosage, or warning statements) · Manufacturing process and process controls	Yes ☐ No ☐ provide justification.
For complex substances (e.g. from biological origin, herbal origin etc.), the formulation/ composition of the proposed substance is identical to that evaluated and approved within the COB evaluation report.	Yes ☐ No ☐ provide justification. N/A ☐
International alignment of guidelines & standards	
The COB evaluation report 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 contains all information necessary to meet the TGA's technical requirements.	Yes ☐ No ☐ provide details and justification.
Stability	
Are the stability studies conducted according to Australian climatic zones?	Yes ☐ No ☐ submit additional stability data. N/A ☐ COB evaluation report only pertains to safety evaluation of the substance.

Criteria	Checklist
New evidence/updates	
Have there been any variations or updates to the substance since it was evaluated by the COB (e.g. changes to recommended daily dose, restrictions, 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 safety of the substance?	Yes ☐ provide details. No ☐ N/A ☐ COB evaluation report only pertains to quality evaluation of the substance.
Is there any additional information available relevant to the risk-benefit of the substance since COB approval (e.g. adverse events, additional Periodic Safety Update Report or long term safety study)?	Yes ☐ provide details. No ☐

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	