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**'.
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.

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.

Post: PO Box 100 Woden ACT 2606 ABN: 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
Reference/Publication # D22-5888160

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 substance must have received full marketing approval following an independent *de novo* assessment of data by the COB. • The substance 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 substance has a current approval by the COB that has evaluated the substance.	Yes ☐ provide full details. No ☐ provide justification.
The applicant has performed a search of relevant websites, including from the list of COBs; and to the applicant's knowledge, the substance has not resulted in a rejected, refused, cancelled or withdrawn application at any time, or received a 'refusal to approve', or is the subject of an application that is currently delayed or deferred, in any jurisdiction.	I have performed a search and the substance has **not** resulted in the outcomes mentioned ☐ I have performed a search and the substance has resulted in the outcomes mentioned ☐ provide justification and details.
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 the following: • The specifications/composition • Use (active/excipient) • Dosage form if relevant (e.g. spray) • Dose • Restrictions (e.g. target population, dosage, or warning statements) • Route of administration • Manufacturing process and process controls	Yes ☐ No ☐ provide justification.
Gap analysis	
A gap analysis has been provided with the application discussing how the COB evaluation report addresses the core safety and/or quality information requirements specified in Table 3 and/or 4 of Appendix A in the Mandatory requirements for an application to vary the Permissible Ingredients Determination 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 safety and/or quality of the substance.	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 (refer to 'SECTION B – Information requirements' in Application requirements for new substances in listed medicines – Australian regulatory 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.
Are any updates or additional safety information available (e.g. safety studies identified from an updated literature search, or adverse events) 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.

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	