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Comparable Overseas Bodies (COB) report-based process – Assessed listed medicines checklist

You must complete and submit this checklist as part of Module 1.2.1 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 <input type="checkbox"/> Name of COB: Date of approval: No <input type="checkbox"/> not eligible for the COB report-based process

Criteria	Checklist
<ul style="list-style-type: none"> 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 <i>de novo</i> 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 The medicine should not have resulted in a rejected, refused, cancelled, or withdrawn marketing approval at any time, or received a 'refusal to approve', or be the subject of an application that is currently delayed or deferred, in any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 <input type="checkbox"/> No <input type="checkbox"/> not eligible for the COB report-based process.
The medicine has a current approval by the COB that has evaluated the medicine.	Yes <input type="checkbox"/> provide full details. No <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/> not eligible for the COB report-based process N/A <input type="checkbox"/>
Nomenclature: Does the COB report use Australian approved terminology (e.g. AANs, ABNs, dosage forms)?	Yes <input type="checkbox"/> No <input type="checkbox"/> provide further information.

Criteria	Checklist
Indications	
<p>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.</p>	<p>No <input type="checkbox"/> not eligible for the COB report-based process.</p> <p>Yes <input type="checkbox"/> specify approved indications in COB report.</p>
<p>Are any indications proposed beyond those approved by the COB?</p>	<p>Yes <input type="checkbox"/> Not eligible for the COB report-based process.</p> <p>No <input type="checkbox"/></p>
<p>For generic medicines: The proposed indications are the same as the indications approved for the Australian originator product.</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/> not eligible for the COB report-based process.</p>
Medicine characteristics	
<p>The proposed medicine is identical to that evaluated and approved within the COB report with regard to the below:</p> <ul style="list-style-type: none"> • Formulation/s (active substance and excipients) • Quality aspects • Dosage form • Strength • Directions for use • Route of administration 	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/> not eligible for the COB report-based process.</p>
<p>Are the manufacturers and manufacturing process (drug substance and drug product, including finished product container) identical to that evaluated and approved by the COB?</p>	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/> specify and provide details.</p>

Criteria	Checklist
Are additional manufacturing sites nominated in the application for Australia?	No <input type="checkbox"/> Yes <input type="checkbox"/> specify and provide details.
Generic medicines	
Is your Australian application for a generic medicine?	No <input type="checkbox"/> skip to next section. Yes <input type="checkbox"/> complete the generic medicines section below.
Was the reference medicine used in the comparative studies in the COB dossier a medicine currently listed on the ARTG and sourced from Australia?	No <input type="checkbox"/> continue to next question. Yes <input type="checkbox"/> Insert ARTG number:
Did the dossier submitted to the COB include biopharmaceutical data?	Yes <input type="checkbox"/> continue to next question. No <input type="checkbox"/> specify and provide justification for not supplying biopharmaceutical data.
Is evidence provided that the reference product used in any evaluation of bioequivalence is identical to the Australian reference product?	Yes <input type="checkbox"/> No <input type="checkbox"/> 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 data requirements in Appendix A in the Mandatory requirements for an assessed listed medicine application to pass preliminary assessment . If there is missing information, you may provide a justification outlining why the missing information is not required to adequately demonstrate the efficacy of the medicine.	Yes <input type="checkbox"/> No <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/> provide details and justification
Are any updates to pivotal studies or supportive studies available that were not considered in the COB approval supporting the proposed indications.	Yes <input type="checkbox"/> provide details. No <input type="checkbox"/>

Criteria	Checklist
Is there any additional information available relevant to the risk-benefit of the overseas medicine since COB approval?	Yes <input type="checkbox"/> provide details. No <input type="checkbox"/>

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	