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|  | **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 – 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](https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-non-prescription-medicine/compile-and-keep-evidence/safety-and-quality/comparable-overseas-bodies-cobs) for further information.

| Criteria | Checklist |
| --- | --- |
| **General** |
| The evaluation report is from a [COB as published on the TGA website](https://www.tga.gov.au/list-cobs). | Yes [ ]  Name of COB:       Date of approval:      No [ ]  not eligible for the COB report- based process |
| * 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* The medicine should not have resulted in a rejected, refused, cancelled, or withdrawn marketing approval at any time, or received a ‘refusal to approve’, or be the subject of an application that is currently delayed or deferred, in any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 processN/A [ ]  |
| Nomenclature:Does the COB report use [Australian approved terminology](https://www.tga.gov.au/resources/resource/guidance/tga-approved-terminology-therapeutic-goods) (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. | No [ ]  not eligible for the COB report-based process.Yes [ ]  specify approved indications in COB report. |
| 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 product. | 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 [ ]  specify and provide details. |
| Are additional manufacturing sites nominated in the application for Australia? | No [ ] Yes [ ]  specify and provide details. |
| **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 listed 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 data requirements in Appendix A in the [Mandatory requirements for an assessed listed medicine application to pass preliminary assessment](https://www.tga.gov.au/resources/publication/publications/mandatory-requirements-assessed-listed-medicine-application-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 [ ] 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 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 [ ]  |

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.

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| --- | --- |
| Name  |       |
| Signature |       | Date |       |