Checklists for correcting an ARTG entry for a listed medicine under paragraph 9D(1)(a) of the Act

Under section 9D of the *Therapeutic Goods Act 1989* (the Act), changes can be made to a listed medicine's entry in the Australian Register of Therapeutic Goods (ARTG), provided they do not make the medicine a separate and distinct good.

Requests can be made in the TGA Business Services (TBS) portal and a fee applies – see Changing a listed or assessed listed medicine and Schedule of fees and charges to identify the applicable change type and relevant fee for your proposed change (note that changes categorised as 'ARTG' or 'Vary' can be directly submitted in TBS and are automatically approved).

The two checklists below relate to requests for corrections (or updates) made under paragraph 9D(1)(a) of the Act and help determine if a request meets the general eligibility requirements for variation under this pathway. The checklists should be used by a sponsor (or agent) who wants to request an update of their medicine's ARTG entry to:

1. Correct omissions or mistakes that were made at the time of listing the medicine; and/or
2. Replace a Proprietary Ingredient (PI) with the individual ingredients included in the PI's formulation where there is no change to the formulation, ingredients or quantity.

If you cannot tick all applicable items in the checklist relevant to your request, then you should reconsider submitting this application.
Refer to "Changing a listed or assessed listed medicine" to help you decide if another application change type is suitable.
Please be aware if you proceed with your request and it is refused, the fee you have paid will not be refunded.

Please provide a single ZIP file if you need to submit multiple documents in your application.

1. Checklist to correct an omission or mistake made at the time the medicine was listed

Yes ☐	The error occurred at the time of listing.
Yes ☐	I have provided details of the change(s) requested in the application.
Yes ☐	I have attached original documentation available at the time of listing relating to the change requested (e.g. the original signed and dated product specification, label or ARTG summary certificate).
Yes ☐ NA ☐	I have attached documentation to support the change requested (e.g. a signed and dated revised product specification, communication from the manufacturer explaining why the error occurred or revised label).
Yes ☐ NA ☐	I have attached a signed certified copy of translation for any document that is not in English.

2. Checklist to replace a Proprietary Ingredient (PI) with the individual ingredients included in the PI's formulation

Yes ☐	I confirm that there is no change to the product formulation, ingredients or their quantities.
Yes ☐	I have attached the signed and dated product specification at the time of listing showing the PI used in the product.
Yes ☐	I have attached the most recent signed and dated product specification showing the individual ingredients in the PI.
Yes ☐ NA ☐	I have attached other evidence to support the change requested (e.g. communication from the manufacturer).

Note: A successful electronic submission in TBS does not mean that the request has been approved. It is the responsibility of the applicant to ensure that relevant information is provided to support the request. A Delegate of the Secretary of the Department of Health and Aged Care will assess the request, including whether sufficient evidence has been provided, and decide whether to approve or refuse the request.