**Schedule 5: Supporting documents**

An electronic version of this form is available on [GETS](http://www.gets.govt.nz) or on [PHARMAC’s website](https://www.pharmac.govt.nz/news).

1. Suppliers must submit the following documents for the proposed DES:
2. Product specifications; and
3. Instructions for use (**IFU**) / Directions for use (**DFU**);
4. Suppliers must submit evidence of the effectiveness and safety of the proposed DES in accordance with [Section 5.8 PHARMAC Guidelines for Funding Applications](https://www.pharmac.govt.nz/assets/guidelines-for-funding-applications-2017-09.pdf), including but not limited to:
5. all identified Randomised Control Trials (**RCTs**) published as full articles in peer-reviewed journals in the English language that report (or give sufficient data to calculate) outcomes by intention-to-treat (**ITT**);
6. one complete electronic copy of the clinical study report summaries from the pivotal RCTs;
7. a register of all ongoing trials on the pharmaceutical for the relevant indication(s) known to the supplier, including trials not directly funded by the supplier (this can be in the form of a print-out from clinicaltrials.gov);
8. copies of all published errata (or corrections), retractions, editorials, and journal correspondence directly relating to the published trials submitted as part of a supplier’s proposal;
9. if including data from unpublished trials, specify why each trial has not been published and expected dates of publication (if applicable);
10. a declaration that all unpublished clinical trials known to the supplier have been disclosed, including those known to the supplier to have been undertaken by other companies that may distribute, market or license the pharmaceutical in New Zealand; and
11. information on the incidence and descriptions of adverse reactions including data collected from observational longitudinal clinical studies, RCTs, case reports on adverse drug reactions and expected/unexpected side effects and post-marketing surveillance data.

Note: The New Zealand Health and Disability Act 2000 defines a pharmaceutical as a “medicine, therapeutic medical device, or related product or related thing”.

1. Supporting documents must be submitted electronically and preferably in a searchable (non-scanned) format.
2. The file name of all supporting documents must include an Appendix Reference Number and refer to content of the document (e.g. Appendix 1 - Product Specifications, Appendix 2 - Instructions for Use).
3. Suppliers must record a list of all supporting documents attached to its submission in the table below. Additional rows can be inserted as required.

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| **File names of supporting document attached to our submission** |
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