

**Declaration to accompany a DATA SHEET**

A completed and signed copy of this form must accompany every new and revised

data sheet submitted.

One declaration should be submitted for each data sheet.

|  |  |
| --- | --- |
| **Medicine(s):** (Trade name, dose form, strength)    **Application ID:**  **Product currently available[[1]](#footnote-2):** **Yes**  **No**  If no, please state the date the product was last supplied in New Zealand:  If no, is the data sheet being maintained:  **Yes**  **No**  *NB: only data sheets that are being maintained will be published for not available products.*  **Data sheet to be published on Medsafe website:**  **Yes**  **No** | **File No(s):**  TT50- |
| **Sponsor:** (Name and postal address)  **Name:**        **Address:** | **Date of Revision of the Text:**  (as shown on data sheet) |

**Submitted by:**

|  |  |  |
| --- | --- | --- |
| **Name:** | **Phone:** | **E-mail:** |
|  |  |  |

**Please tick the appropriate boxes, enter any required dates and sign declaration.**

**I declare that:**

This is the approved data sheet for a newly-approved medicine for which Ministerial consent was granted on:

      (insert date of publication in *Gazette*)

**OR**

This is a revised data sheet approved by the Director-General in a Consent to Sell and Supply a Changed Medicine letter dated:

      (insert date of letter)

**OR**

This is a revised data sheet approved by the Director-General in an Acknowledgement of a Self-Assessable Change Medicine Notification letter dated:

      (insert date of letter)

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**

(Sponsor or authorised agent)

1. For further information on the meaning of not available please refer to http://www.medsafe.govt.nz/Medicines/registration-situation.asp

   December 2023 version [↑](#footnote-ref-2)