**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

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