
Declaration to accompany a DATA SHEET submitted for PUBLICATION

A completed and signed copy of this form must accompany every new and revised data sheet submitted for publication on the Medsafe website.
One declaration should be submitted for each data sheet.

Medicine: (Trade name, dose form, strength)

File No:
TT50-

Product currently available¹: **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**

Sponsor: (Name and postal address)

Name:

Address:

Date of Revision of 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 www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/sort-of-application-required.pdf
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