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:** (Trade name, dose form, strength)

Voltaren Ophtha Eye Drops solution, 1 mg in 1 mL.

**Product currently available:** 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

**Classification:** Prescription Only Medicine

☑ Yes No ☐

**Sponsor:** (Name and postal address)

Name: Novartis New Zealand Limited

Address: 109 Carlton Gore Road

Newmarket

Auckland 1023.

PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335.

**Date of Preparation:**

(as shown on data sheet)

21 November 2017

Submitted by:

Name: Robyn Mehanna

Phone: +61 2 9987 1150

E-mail: dra.aunz@novartis.com

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:

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1 For further information on the meaning of not available please refer to http://www.medsafe.govt.nz/Medicines/registration-situation.asp September 2016 version
OR

✓ This is a revised data sheet approved by the Director-General in an Acknowledgement of a Self-Assessable Change Medicine Notification letter dated: 04 December 2017

Signature: [Signature]
(Sponsor or authorised agent)  Date: 12 December 2017