Declarations 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)
- Stemretil Injection, solution 12.5mg/mL
- Stemretil Suppository 25mg

**Product currently available:** Yes ☒ No ☐
If no, please state the date the product was last supplied in New Zealand:
Suppositories not available, last supplied in NZ June 2016
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: sanofi-aventis new zealand limited
Address: Level 8, 56 Cawley Street, Ellerslie, Auckland

**Date of Preparation:**
(as shown on data sheet)
17 August 2017

**Submitted by:**
Name: Alice Brian
Phone: +61 2 9889 0060
E-mail: alice.brian@sanofi.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:
   (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:** [Signature]
(Sponsor or authorised agent)
**Date:** [Date]

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1 For further information on the meaning of not available please refer to
http://www.medsafe.govt.nz/regulatory/EvaluationTimeframesAndRegistrationSituation.asp#Registration
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