Australian Government

Department of Health
Therapeutic Goods Administration

Approval of the manner of making requests under subsection 9D(3) of the *Therapeutic Goods Act 1989* to vary the entry in the Australian Register of Therapeutic Goods of registered therapeutic goods

I, Peter Bird, Head, Office of Medicines Authorisation in the Therapeutic Goods Administration and delegate under subsection 57(1) of the *Therapeutic Goods Act 1989* (the Act) of the Secretary of the Department of Health, for the purposes of paragraph 9D(6)(b) of the Act, hereby:

1. **REVOKE the approval** of Peter Bird dated 1 October 2013 of the of the manner of making requests under subsection 9D(3) of the *Therapeutic Goods Act 1989* to vary the entry in the Australian Register of Therapeutic Goods of registered therapeutic goods listed in Part 1 of Schedule 10 of the Therapeutic Goods Regulations 1990 (the Regulations) for the purposes of paragraph 9D(6)(b) from the date of this determination;

2. **APPROVE** in relation to requests under subsection 9D(3) of the Act of the kind referred to in regulation 16D of the Therapeutic Goods Regulations 1990 (the Regulations) to vary an entry in the Australian Register of Therapeutic Goods for a medicine that is a product of a kind specified in Part 1 of Schedule 10 of the Regulations, **the manner in which such requests must be made** (other than requests of the kind in relation to which the Secretary has made another determination under paragraph 9D(6)(b) of the Act) as follows:

   a. where a Pre-submission planning form – Category 1 and category 2 applications, **has not been provided** to the Secretary in relation to the request - a ***Pre-submission planning form – Category 1 and Category 2 applications,*** approved by the Secretary's delegate under the instrument *Approval of forms for request under subsection 9D(3) of the Act to vary the entry into the Australian Register of Therapeutic Goods of registered therapeutic goods* completed in accordance with relevant instructions (including any documentation required to be provided with that form) is to be **delivered to the office to the Therapeutic Goods Administration at:**

   PO Box 100
   Woden ACT 2606
   Australia
   OR
   136 Narrabundah Lane
   Symonston ACT 2609.

   b. where a Pre-submission planning form – Category 1 and Category 2 applications, **has been provided** to the Secretary in relation to the application:

(i) the form ***Application for the Registration, or to vary the Conditions of Registration, of Prescription Medicines dated October 2007***, to the extent that it applies in relation to such requests, being the form approved by the Secretary's delegate under the instrument *Approval of form for request under subsection 9D(3) of the Act to vary the entry into the Australian Register of Therapeutic Goods of registered therapeutic goods,* completed in accordance with relevant instructions (including any documentation required to be provided with that form);

(ii) the following documents:

- ***CTD Module I: Administrative information and prescribing information for Australia*** dated April 2014 and described as Version 2.2, completed in accordance with relevant instructions;
- **Module 2**: being overviews, written summaries and tabulated summaries of the data contained in the Modules 3, 4 and 5 as described below completed in accordance with relevant instructions;
- **Module 3**: *ICH M4Q Common Technical Document for the Registration Of Pharmaceuticals For Human Use - Quality* (CPMP/ICH/2887/99 Rev 1 Quality), completed, to the extent that it is applicable to a medicine of the nature and type of the medicine the subject of the application, in accordance with relevant instructions;
- **Module 4**: *ICH M4S Common Technical Document for the Registration of Pharmaceuticals for Human Use - Safety* (CPMP/ICH/2887/99 Rev 1 Safety) completed, to the extent that it is applicable to a medicine of the nature and type of the medicine the subject of the application, in accordance with relevant instructions; and
- **Module 5**: *ICH M4E Common Technical Document for the Registration of Pharmaceuticals for Human Use - Efficacy* (CPMP/ICH/2887/99 Rev 1 Efficacy), completed, to the extent that it is applicable to a medicine of the nature and type of the medicine the subject of the application, in accordance with relevant instructions; and

(iii) **any other information** specified in the document ***Mandatory requirements for an effective application***, dated April 2014 and described as Version 2.1, being required to be provided with a request of that kind in order for the request to be effective,

are to be delivered to the office to the Therapeutic Goods Administration at:

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Note 1: The reference to applications referred to in regulation 16D of the Regulations means that only requests to which the 255 working day or 175 working day completion time for evaluation applies are covered by this determination ie Category 1 and Category 2 applications.

Note 2: The reference to Part 1 of Schedule 10 of the Regulations indicates that this form is not relevant to requests under subsection 9D(3) for variations to an entry in the ARTG of over-the-counter medicines or registered complementary medicines.

Peter Bird
Delegate of the Secretary
1 May 2014