Australian Government
Department of Health
Therapeutic Goods Administration

Approval of form in which information sufficient for determination of applications in the eCTD format made under section 23 of the *Therapeutic Goods Act 1989* for the registration of therapeutic goods must be delivered

I, Rochelle Christian, Assistant Secretary, Scientific Evaluation Branch 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 purpose of paragraph 23(2)(b) of the Act hereby:

1. **REVOKE the approval** of Jane Cook, made for the purposes of s.23(2)(b) of the Act and dated 21 December 2017, of the form of information sufficient to allow the determination of applications, in the eCTD format, for the registration of medicines listed in Part 1 of Schedule 10 of the Therapeutic Goods Regulations 1990 (the Regulations);

2. **APPROVE**, for the purposes of paragraph 23(2)(b) of the Act, for applications in the eCTD format and a medicine of a kind specified in Part 1 of Schedule 10 of the Regulations, the following electronic specifications:

    a. ICH M2 EWG Electronic Common Technical Document Specification dated July 2008 and described as Version 3.2.2;

    b. For information delivered on or before 31 December 2017:

        i. AU eCTD specification: Module 1 and regional information, dated June 2015 and described as Version 3.0; and
        Australian eCTD Regional Specification and Validation Criteria, described as Version 3.0

    c. For information delivered between 1 January 2018 and 30 June 2018:

        i. AU eCTD specification: Module 1 and regional information, dated June 2015 and described as Version 3.0; and
        Australian eCTD Regional Specification and Validation Criteria, described as Version 3.0; or

        ii. eCTD AU module 1 and regional information, dated October 2017 and described as Version 3.1; and

Australian eCTD Regional Specification and Validation Criteria, described as Version 3.1

d. For information delivered after 30 June 2018:

   i. eCTD AU module 1 and regional information, dated October 2017 and described as Version 3.1; and
   Australian eCTD Regional Specification and Validation Criteria, described as Version 3.1

3. **APPROVE**, for the purposes of paragraph 23(2)(b) of the Act, for applications in the eCTD format of the kind referred to in regulation 16C of the Regulations for **an additional trade name** for a medicine of a kind specified in Part 1 of Schedule 10 of the Regulations registered to the same sponsor, the following information, being such information as will allow the determination by the Secretary of an application for or in relation to the registration of medicines of that kind:

   a. the **application** in the form approved by the Secretary's delegate under the instrument *Approval of forms for applications in the eCTD format made under section 23 of the Therapeutic Goods Act 1989 for registration of therapeutic goods* for applications of that kind **completed in accordance with the relevant instructions**, and

   b. the information specified in the document *CTD Module 1: Administrative information and prescribing information for Australia* dated February 2018 and described as Version 4.0, completed in accordance with relevant instructions; and

   c. **any other information** specified in the document *Mandatory requirements for an effective application*, dated February 2018 and described as Version 4.0, other than the requirement that the electronic dossier must comply with the NeeS format, being required to be provided with an application of that kind in order for the application to be effective.

4. **APPROVE**, for the purposes of paragraph 23(2)(b) of the Act, for applications in the eCTD format for or in relation to the registration of a medicine of the kind referred to in regulation 16C of the Regulations that is a product of a kind specified in Part 1 of Schedule 10 of the Regulations (other than applications referred to in paragraph 3 or of the kind in relation to which the Secretary has made another determination under paragraph 23(2)(b) of the Act), the following information, being such information as will allow the determination by the Secretary of the application:

   a. for all such applications where a *Pre-submission planning form*, **has not been provided** to the Secretary in relation to the application - a *Pre-submission planning form*, approved by the Secretary's delegate under the instrument *Approval of form for applications in the eCTD format made under section 23 of the Therapeutic Goods Act 1989* for registration of therapeutic goods completed in accordance with relevant instructions (including any documentation required to be provided with that form), and

b. for all such applications where a *Pre-submission planning form*, **has been provided** to the Secretary in relation to the application:

i. the form *Module 1.2.1: Application form to register or vary the registration of prescription medicines*, dated January 2018, to the extent that it applies in relation to such applications, being the form approved by the Secretary's delegate under the instrument *Approval of form for applications in the eCTD format made under subsection 23 of the Therapeutic Goods Act 1989* for registration of therapeutic goods, completed in accordance with relevant instructions (including any documentation required to be provided with that form);

ii. for all applications covered by this paragraph, the following information:

1. – the information specified in *CTD Module 1: Administrative information and prescribing information for Australia* dated February 2018 and described as Version 4.0, completed in accordance with relevant instructions;

2. 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;

3. 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;

4. 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

5. 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 February 2018 and described as Version 4.0, being information required to be

provided with an application of that kind in order for the application to be effective.

Note 1: The reference to applications referred to in regulation 16C of the Regulations means that only applications to which the 255 working day or 175 working day or 120 working day completion time for evaluation applies are covered by this determination i.e. Category 1 and Comparable Overseas Regulator (COR) report-based applications.

Note 2: The reference to Part 1 of Schedule 10 of the Regulations indicates that this form is not relevant to applications for registration made under section 23 of the Act for over-the-counter medicines or registered complementary medicines.

Rochelle Christian
Delegate of the Secretary

~~February~~ 2018

2 March