



Australian Government
Department of Health
Therapeutic Goods Administration

Approval of forms for 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)(a) of the Act, hereby

1. **REVOKE the approval** of Peter Bird dated 1 October 2013 of the of the forms for 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)(a) from the date of this determination;
2. **APPROVE the following to be the forms** for the purpose of requests under section 9D(3) of the Act of the kind referred to in regulation 16D of the Therapeutic Goods Regulations 1990, to vary an entry in the Australian Register of Therapeutic Goods (ARTG) for a medicine that is a product of a kind specified in Part 1 of Schedule 10 of the Regulations:
 - a. the [Pre-submission planning form - Category 1 and Category 2 applications](#) dated April 2014 and described as Version 2.1; and
 - b. the attached 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.

Note 1: The reference to requests 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