



Australian Government
Department of Health

Therapeutic Goods Act 1989

Approved manner of, and form for, making requests under section 9D of the Therapeutic Goods Act 1989 for a registered OTC medicine

I, Trisha Garrett, Assistant Secretary, Complementary and OTC Medicines Branch, on behalf of the Secretary of the Department of Health for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), approve, under subsection 9D(6) of the Act, the manner and form specified below as the manner of, and form for, making a C1 (section 9D) application, a C2 (section 9D) application, a C3 (section 9D) application or a C4 (section 9D) application in respect of a request under subsections 9D(1), (2) or (3) of the Act to vary information included in an entry in the Australian Register of Therapeutic Goods (the Register) for a registered OTC medicine.

Approved manner of making a C1 (section 9D) application

A C1 (section 9D) application must be made:

- (a) by using the OTC medicine online application portal on the website of the Therapeutic Goods Administration; and
- (b) by logging in to “business services”; and
- (c) by selecting “applications”; and
- (d) by completing the electronic application form, that is created within that portal for the purpose of making a request under section 9D in relation to a registered OTC medicine, in accordance with the instructions in that form that are applicable to C1 (section 9D) application.

Approved C1 (section 9D) application form

The approved C1 (section 9D) application form is the electronic form that is created within the OTC medicine online application portal when, after logging on to “business services”:

- (a) an applicant selects “applications”; and
- (b) for single component OTC medicines – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription medicine”; and
 - (ii) “change a current ARTG entry”; or
- (c) for composite packs – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription composite pack”; and
 - (ii) “change a current ARTG entry”; or
- (d) for identical variations to more than one ARTG entry – the applicant selects “Over the Counter Medicine – change multiple ARTG entries”.

Approved manner of making a C2 (section 9D) application

A C2 (section 9D) application must be made:

- (a) by using the OTC medicine online application portal on the website of the Therapeutic Goods Administration; and

- (b) by logging in to “business services”; and
- (c) by selecting “applications”; and
- (d) by completing the electronic application form, that is created within that portal for the purpose of making a request under section 9D in relation to a registered OTC medicine, in accordance with the instructions in that form that are applicable to C2 (section 9D) applications.

Approved C2 (section 9D) application form

The approved C2 (section 9D) application form is the electronic form that is created within the OTC medicine online application portal when, after logging on to “business services”:

- (a) an applicant selects “applications”; and
- (b) for single component OTC medicines – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription medicine”; and
 - (ii) “change a current ARTG entry”; or
- (c) for composite packs – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription composite pack”; and
 - (ii) “change a current ARTG entry”; or
- (d) for identical variations to more than one ARTG entry – the applicant selects “Over the Counter Medicine – change multiple ARTG entries”.

Approved manner of making a C3 (section 9D) application

A C3 (section 9D) application must be made:

- (a) by using the OTC medicine online application portal on the website of the Therapeutic Goods Administration; and
- (b) by logging in to “business services”; and
- (c) by selecting “applications”; and
- (d) by completing the electronic application form, that is created within that portal for the purpose of making a request under section 9D in relation to a registered OTC medicine, in accordance with the instructions in that form that are applicable to C3 (section 9D) applications.

Approved C3 (section 9D) application form

The approved C3 (section 9D) application form is the electronic form that is created within the OTC medicine online application portal when, after logging on to “business services”:

- (a) an applicant selects “applications”; and
- (b) for single component OTC medicines – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription medicine”; and
 - (ii) “change a current ARTG entry”; or
- (c) for composite packs – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription composite pack”; and
 - (ii) “change a current ARTG entry”; or
- (d) for identical changes to more than one ARTG entry – the applicant selects “Over the Counter Medicine – change multiple ARTG entries”.

Approved manner of making a C4 (section 9D) application

A C4 (section 9D) application must be made:

- (a) by using the OTC medicine online application portal on the website of the Therapeutic Goods Administration; and
- (b) by logging in to “business services”; and
- (c) by selecting “applications”; and

(d) by completing the electronic application form, that is created within that portal for the purpose of making a request under section 9D in relation to a registered OTC medicine, in accordance with the instructions in that form that are applicable to C4 (section 9D) applications.

Approved C4 (section 9D) application form

The approved C4 (section 9D) application form is the electronic form that is created within the OTC medicine online application portal when, after logging on to “business services”:

- (a) an applicant selects “applications”; and
- (b) for single component OTC medicines – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription medicine”; and
 - (ii) “change a current ARTG entry”; or
- (c) for composite packs – an applicant selects:
 - (i) “Over the Counter Medicine – non-prescription composite pack”; and
 - (ii) “change a current ARTG entry”; or
- (d) for identical changes to more than one ARTG entry – the applicant selects “Over the Counter Medicine – change multiple ARTG entries”.

Definitions

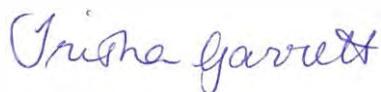
A C1 (section 9D) application means a request under subsection 9D(1), (2) or (3) of the Act to vary information in the Register for a registered OTC medicine where the variation is of a kind classified as a C1 level change in the document *OTC application categorisation framework* (dated 30 November 2015 and described as Version 1.1) and *Changing an OTC medicine: using the Changes Table* (dated 30 November 2015 and described as Version 2.0).

A C2 (section 9D) application means a request under subsection 9D(3) of the Act to vary information in the Register for a registered OTC medicine where the variation is of a kind classified as a C2 level change in the document *OTC application categorisation framework* (dated 30 November 2015 and described as Version 1.1) and *Changing an OTC medicine: using the Changes Table* (dated 30 November 2015 and described as Version 2.0).

A C3 (section 9D) application means a request under subsection 9D(3) of the Act to vary information in the Register for a registered OTC medicine where the variation is of a kind classified as a C3 level change in the document *OTC application categorisation framework* (dated 30 November 2015 and described as Version 1.1) and *Changing an OTC medicine: using the Changes Table* (dated 30 November 2015 and described as Version 2.0).

A C4 (section 9D) application means a request under subsection 9D(3) of the Act to vary information in the Register for a registered OTC medicine where the variation is of a kind classified as a C4 level change in the document *OTC application categorisation framework* (dated 30 November 2015 and described as Version 1.1) and *Changing an OTC medicine: using the Changes Table* (dated 30 November 2015 and described as Version 2.0).

OTC medicine has the same meaning as in the *Therapeutic Goods Regulations 1990*.



Trisha Garrett
Delegate of the Secretary

7 December 2015