Australian Government

Department of Health

Therapeutic Goods Act 1989

Approved manner of making an application under section 23 of the Therapeutic Goods Act 1989 for a registered OTC medicine

I, Trisha Garrett, Assistant Secretary, Complementary and OTC Medicines Branch, a delegate of the Secretary of the Department of Health for the purposes of section 23 of the *Therapeutic Goods Act 1989* (the Act):

1. REVOKE the approval of Trisha Garrett, made for the purposes of subsection 23(1) of the Act and dated 7 December 2015, of the manner of making an application under section 23 of the Act to register an OTC medicine.

2. APRROVE, under subsection 23(1)(a) of the Act, the manner specified below as the manner in which a C1 (section 23) application, a C2 (section 23) application, a C3 (section 23) application, a C4 (section 23) application, an N1 application, an N2 application, an N3 application, an N4 application or an N5 application under subsection 23(1) of the Act to register an OTC medicine must be made.

Approved manner of making a C1 (section 23) application

A C1 (section 23) 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) for single component OTC medicines, by selecting –
    (i) "Non-prescription Medicine – non-prescription medicine" and
    (ii) "change a current ARTG entry"; and
(e) for multi-component OTC medicines, by selecting –
    (i) "Non-prescription Medicine – non-prescription composite pack"; and
    (ii) "change a current ARTG entry"; and
(f) by completing the electronic form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instruction in that form that are applicable to C1 (section 23) applications.

Approved manner of making a C2 (section 23) application

A C2 (section 23) 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) for single component OTC medicines, by selecting –
    (i) "Non-prescription Medicine – non-prescription medicine" and
    (ii) "change a current ARTG entry"; and
(e) for composite packs, by selecting –
    (i) "Non-prescription Medicine – non-prescription composite pack"; and
    (ii) "change a current ARTG entry"; and
(f) by completing the electronic form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instruction in that form that are applicable to C2 (section 23) applications.

Approved manner of making a C3 (section 23) application

A C3 (section 23) 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) for single component OTC medicines, by selecting –
    (i) "Non-prescription Medicine – non-prescription medicine" and
    (ii) "change a current ARTG entry"; and
(e) for composite packs, by selecting –
    (i) "Non-prescription Medicine – non-prescription composite pack"; and
    (ii) "change a current ARTG entry"; and
(f) by completing the electronic form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instruction in that form that are applicable to C3 (section 23) applications.

Approved manner of making a C4 (section 23) application

A C4 (section 23) 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) for single component OTC medicines, by selecting –
    (i) "Non-prescription Medicine – non-prescription medicine" and
    (ii) "change a current ARTG entry"; and
(e) for composite packs, by selecting –
    (i) "Non-prescription Medicine – non-prescription composite pack"; and
    (ii) "change a current ARTG entry"; and
(f) by completing the electronic form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in

accordance with the instruction in that form that are applicable to C4 (section 23) applications.

Approved manner of making an N1 application

An N1 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) for single component OTC medicines, by selecting –
  (i) "Non-prescription Medicine – non-prescription medicine"; and
  (ii) "create a new ARTG entry"; and
(e) for composite packs, by selecting –
  (i) "Non-prescription Medicine – non-prescription composite pack"; and
  (ii) "create a new ARTG entry"; and
(f) by completing the electronic application form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instructions in that form that are applicable to N1 applications.

Approved manner of making an N2 application

An N2 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) for single component OTC medicines, by selecting –
  (i) "Non-prescription Medicine – non-prescription medicine"; and
  (ii) "create a new ARTG entry"; and
(e) for composite packs, by selecting –
  (i) "Non-prescription Medicine – non-prescription composite pack"; and
  (ii) "create a new ARTG entry"; and
(f) by completing the electronic application form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instructions in that form that are applicable to N2 applications.

Approved manner of making an N3 application

An N3 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) for single component OTC medicines, by selecting –
  (i) "Non-prescription Medicine – non-prescription medicine"; and

(ii) "create a new ARTG entry"; and

(e) for composite packs, by selecting –
   (i) "Non-prescription Medicine – non-prescription composite pack"; and
   (ii) "create a new ARTG entry"; and

(f) by completing the electronic application form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instructions in that form that are applicable to N3 applications.

Approved manner of making an N4 application

An N4 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) for single component OTC medicines, by selecting –
   (i) "Non-prescription Medicine – non-prescription medicine"; and
   (ii) "create a new ARTG entry"; and
(e) for composite packs, by selecting –
   (i) "Non-prescription Medicine – non-prescription composite pack"; and
   (ii) "create a new ARTG entry"; and
(f) by completing the electronic application form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instructions in that form that are applicable to N4 applications.

Approved manner of making an N5 application

An N5 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) for single component OTC medicines, by selecting –
   (i) "Non-prescription Medicine – non-prescription medicine"; and
   (ii) "create a new ARTG entry"; and
(e) for composite packs, by selecting –
   (i) "Non-prescription Medicine – non-prescription composite pack"; and
   (ii) "create a new ARTG entry"; and
(f) by completing the electronic application form, that is created within that portal for the purpose of making an application under section 23 of the Act to register an OTC medicine, in accordance with the instructions in that form that are applicable to N5 applications.

Definitions

A **C1 (section 23) application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the applicant seeks to make changes to a registered OTC medicine (the existing medicine) the effect of which is to create a separate and distinct good (the new medicine); and
(b) the only changes sought are described as C1 level changes in the documents *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); and
(c) the new medicine, if registered, will form part of the same gazetted therapeutic goods group as the existing medicine.

A **C2 (section 23) application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the applicant seeks to make changes to a registered OTC medicine (the existing medicine) the effect of which is to create a separate and distinct good (the new medicine); and
(b) the changes sought include at least one change described 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), but do not include any changes that are described as a C3 level change or a C4 level change in that document; and
(c) the new medicine, if registered, will form part of the same gazetted therapeutic goods group as the existing medicine.

A **C3 (section 23) application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the applicant seeks to make changes to a registered OTC medicine (the existing medicine) the effect of which is to create a separate and distinct good (the new medicine); and
(b) the changes sought include at least one change described as a C3 level change in the documents *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), but do not include any changes that are described as a C4 level change in that document; and
(c) the new medicine, if registered, will form part of the same gazetted therapeutic goods group as the existing medicine.

A **C4 (section 23) application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the applicant seeks to make changes to a registered OTC medicine (the existing medicine) the effect of which is to create a separate and distinct good (the new medicine); and

(b) the changes sought include at least one change described as a C4 level change in the documents *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); and
(c) the new medicine, if registered, will form part of the same gazetted therapeutic goods group as the existing medicine.

An **N1 application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the type of application is classified as an N1 level application in accordance with the documents *OTC application categorisation framework* (dated 30 November 2015 and described as version 1.1) and *OTC new medicine N1 applications* (dated 30 November 2015 and described as Version 1.0); and
(b) the medicine that is the subject of the application, if registered, will not form part of a gazetted therapeutic goods group.

An **N2 application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the type of application is classified as an N2 level application in accordance with the documents *OTC application categorisation framework* (dated 30 November 2015 and described as version 1.1); *Requirements for OTC new medicines N2 applications (using OTC medicine monographs)* (dated 6 September 2013 and described as Version 1.0) and *OTC N2 applications and OTC medicine monographs* (dated 10 June 2014); and
(b) the medicine that is the subject of the application, if registered, will not form part of a gazetted therapeutic goods group.

An **N3 application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the type of application is classified as an N3 level application in accordance with the document *OTC application categorisation framework* (dated 30 November 2015 and described as version 1.1); and
(b) the medicine that is the subject of the application, if registered, will not form part of a gazetted therapeutic goods group.

An **N4 application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the type of application is classified as an N4 level application in accordance with the document *OTC application categorisation framework* (dated 30 November 2015 and described as version 1.1); and
(b) the medicine that is the subject of the application, if registered, will not form part of a gazetted therapeutic goods group.

An **N5 application** means an application made under subsection 23(1) of the Act to register an OTC medicine where:

(a) the type of application is classified as an N5 level application in accordance with the document *OTC application categorisation framework* (dated 30 November 2015 and described as version 1.1); and
(b) the medicine that is the subject of the application, if registered, will not form part of a gazetted therapeutic goods group.

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

Trisha Garrett
Delegate of the Secretary
/ February 2016