



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Instructions for completing a Certificate for subsection 41JA(1C) of the *Therapeutic Goods Act 1989*

Following amendments to the *Therapeutic Goods Act 1989* (the Act) that commenced on 1 December 2009, the Secretary, or delegate, may, under subsection 41JA(1C) of the Act, by written notice given to a person who holds a Conformity Assessment Certificate, require the holder to give the Secretary, or delegate, within a reasonable period, specified information or documents to be used by the Secretary, or delegate, in deciding whether to revoke under section 41ET of the Act, or suspend under section 41EM of the Act, the holder's Conformity Assessment Certificate in the circumstances referred to in paragraph 41ET(1)(e) of the Act.

Subsection 41JA(1C), and all other provisions of the Act, may be viewed through the TGA website at <<https://www.tga.gov.au>> or at <<https://www.comlaw.gov.au>>.

Holders of a Conformity Assessment Certificate who are required by the Secretary, or delegate, to complete this Certificate are expected to self-assess whether they, or certain other persons associated with the holder, meet the criteria set out below (i.e. the criteria set out in paragraph 41ET(1)(e) of the Act), and to certify the outcome by submitting this Certificate to the Therapeutic Goods Administration (the TGA).

Steps to submitting this certificate

1. Read and understand this Certificate and in particular the matters set out below that applicants are required to certify in completing this Certificate. Make enquiries necessary in order to answer the matters set out in this Certificate;
2. Complete the required details and sign and attach any additional information. The signatory must mark the relevant box to either certify (i.e. "I hereby certify that"), or signal their inability to certify (i.e. "I am unable to certify"), when completing the document. Marking both boxes invalidates the certification.
3. To reduce processing times, please send the completed Certificate by email to dcas@tga.gov.au. Please ensure that your email identifies the number of the associated Conformity Assessment Certificate.

Note the signatory must:

- if the Conformity Assessment Certificate holder is an individual, be that individual; or
- if the Conformity Assessment Certificate holder is a body corporate, hold a senior position in that body corporate (e.g. Chief Executive Officer or Managing Director) and be authorised to make the certification on behalf of the body corporate.

Further information

If the Secretary, or delegate, requires further information following completion and submission of this Certificate, the Secretary, or delegate, may, under paragraph 41JA(1C) of the Act, require a Conformity Assessment Certificate holder to give the Secretary, or delegate, further specified information to be used in deciding whether to suspend or revoke the holder's Conformity Assessment Certificate.

Avoiding an invalid certificate

Your Certificate will **not** be considered to be valid if this Certificate:

- is not used;
- is incomplete;
- is unclear or ambiguous;
- has not been signed by the appropriate person (refer to the Note above); or
- has been submitted more than a month since the date of its signing.

Privacy Information

- For general privacy information, go to <<https://www.tga.gov.au/privacy>>.

Personal information in applications relating to Conformity Assessment Certification:

- The personal information is used to maintain a record of Conformity Assessment Certificate applications, to consider applications, and to contact applicants about their application.
- Personal information provided in applications may also be used to contact sponsors or manufacturers of goods in the Register where there is a need to do so – for example, in the event of a safety, quality or efficacy issue concerning the manufacture of certain goods, or to administer fees and payments relating to the licence.
- Personal information relating to manufactures who hold Conformity Assessment Certificates to manufacturer therapeutic goods may be disclosed where authorised or required by an Australian law, Court or Tribunal order; or with the consent of the person the information is about.

Note: A "major interest holder" of a body corporate means a person who:

- (a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or
- (b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital).

Certificate for subsection 41JA(1C) of the *Therapeutic Goods Act 1989*

I, _____ 1
hold the position of _____ 2
in _____ 3
at _____ 4

EITHER

hereby certify that, in relation to the holder of a Conformity Assessment Certificate,

_____ 5 **dated** _____

none of the following people:

- i. the person in relation to whom the Conformity Assessment Certificate is issued (the Holder);
- ii. a person (a manager) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Holder's affairs;
- iii. if the Holder is a body corporate, a person who is a major interest holder of the body corporate;

has:

- iv. been convicted of an offence against the *Therapeutic Goods Act 1989* (the Act) or a corresponding State law; or
- v. been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
- vi. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of the Act or a corresponding State law; or
- vii. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
- viii. breached a condition of a Conformity Assessment Certificate; or
- ix. had a Conformity Assessment Certificate suspended or revoked; or
- x. been a manager, or major interest holder, of a body corporate in respect of which paragraphs (iv), (v), (vi), (vii), (viii) or (ix), noted above, applied, if the conduct resulting in that paragraph applying occurred when the person was a manager or major interest holder of the body corporate.

OR

I am **unable** to certify that paragraphs (iv) - (x) can be met as set out above.

I hereby declare that the above information is true and correct:

1 Insert full name of CEO / Managing Director / or equivalent.

2 Insert position title

3 Insert name of certificate holder

4 Insert certificate holder's street address

5 Insert certificate number

Full name (printed)			
Signature		Date	

Witness full name			
Witnessed by (Signature)		Date	

Note: Giving false or misleading information is a criminal offence under the Criminal Code.