|  |  |
| --- | --- |
| Therapeutic Goods Administration |  |
|  | TGA use only |  |
|  |  |  |

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 <<http://www.tga.gov.au/about/tga-information-to.htm>>.

# 9D(1) Request to correct an ARTG entry

Application form

**Note:** Use this application to request a correction to information that is incorrect or incomplete in an existing ARTG entry for a registered prescription medicine.

Please refer to the *Australian Regulatory Guidelines for Prescription Medicines (ARGPM)* to determine the type of request or application relevant to the variation you would like to make. Further guidance can be found in [*Minor variations to registered prescription medicines: chemical entities*](http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm)[[1]](#footnote-1)and [*Minor variations to registered prescription medicines: biological medicines*](http://www.tga.gov.au/industry/pm-minor-variations-biological.htm)[[2]](#footnote-2).

## Section 1. Sponsor and product details

### 1.1 Sponsor details

|  |  |
| --- | --- |
| Sponsor name |       |
| eBS Client ID |       |
| Postal address |       |
| Contact person |       |
| Position (for example: regulatory affairs officer, agent of the sponsor) |       |
| Telephone number |       |
| Fax number |       |
| Email address |       |

## 1.2 Product details

### Medicinal product details

Single active ingredient [ ]  Multi-active ingredient [ ]  Multi-component [ ]

Is the product: a biological medicine [ ]  OR a chemical medicine [ ]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| AUST R | Product name | Active ingredient(s) | Strength | Dosage form | Pack/Container |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

Please attach additional pages to the form if there are more than six products.

### 1.3 Payment details

|  |  |
| --- | --- |
| Relevant requests/applications in submission (for calculation of fees payable): |       |

A single fee may be payable for multiple applications in some cases, if the combination of applications meets the definition of “submission” in Part 1 of Schedule 9 to the Therapeutic Goods Regulations 1990. Further guidance is available in [*Minor variations to registered prescription medicines: chemical entities*](http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm)[[3]](#footnote-3)and [*Minor variations to registered prescription medicines: biological medicines*](http://www.tga.gov.au/industry/pm-minor-variations-biological.htm)[[4]](#footnote-4).

Please make cheques payable to the Therapeutic Goods Administration (TGA).

For credit card payments, please use the [credit card authorisation form](http://www.tga.gov.au/about/fees-forms-creditcard-authorisation.htm)[[5]](#footnote-5) which is available on the TGA website.

A summary of [fees and charges](http://www.tga.gov.au/about/fees-forms-creditcard-authorisation.htm)[[6]](#footnote-6) is also available on the TGA website.

## Section 2. Details of request

### 2.1 Details of correction/how entry is to be made complete

Please provide specific details of the correction(s)/additional information to make entry complete being requested in the box below. Please provide sufficient information, such that, if your request is approved, the TGA can correct or complete information in the ARTG entry[[7]](#footnote-7):

|  |
| --- |
|       |

Please provide a justification for the proposed request:

|  |
| --- |
|       |

If the request is approved, will the Product Information (PI) require amendment as a consequence[[8]](#footnote-8)? Yes [ ]  No [ ]

If ‘**yes**’, you must attach a clean copy and a marked-up copy of the draft revised PI with this request.

Please refer to the ARGPM for details on requirements for PI documents.

### 2.2 Information provided

Evidence to support your request is required including details of when the entry became incorrect or how it is incomplete and (proposed) corrected information/information to make complete.

Information on specific requirements is detailed in [*Minor variations to registered prescription medicines: chemical entities*](http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm)[[9]](#footnote-9)and [*Minor variations to registered prescription medicines: biological medicines*](http://www.tga.gov.au/industry/pm-minor-variations-biological.htm)[[10]](#footnote-10).

Have you provided all the required information? Yes [ ]  No [ ]

If ‘**no**’, please provide a justification:

|  |
| --- |
|       |

### 2.3 Related submissions

#### 2.3.1 Submissions currently under evaluation

If your submission is related to any other submissions currently under evaluation with the TGA, please provide applicable submission numbers:

|  |  |
| --- | --- |
| Submission ID | Details of submission |
|       |       |
|       |       |

Please attach additional pages to the form if there are more than two submissions.

#### 2.3.2 Concurrent section 9D submissions

Are you submitting this request with other requests under section 9D? Yes [ ]  No [ ]

If ‘**yes**’, please provide details:

|  |
| --- |
|       |

## Section 3. Sponsor declaration

|  |
| --- |
| Sponsors should note that section 9G and section 9H of the *Therapeutic Goods Act 1989* provides criminal and civil penalties for making statements that are false or misleading in a material particular in relation to a request under section 9D of the Act. |

I am the sponsor for the purposes of this request OR Yes [ ]  No [ ]

I am authorised to act on behalf of the sponsor for the purposes of this request. Yes [ ]  No [ ]

### (Tick boxes below, if applicable)

I declare that the information provided for the purposes of this request is, to the best
of my knowledge, current and correct[[11]](#footnote-11). [ ]

I certify that, to the best of my knowledge, the variations requested to the entry or entries
in this application are of a kind that can be made under subsection 9D(1)[[12]](#footnote-12). [ ]

I certify that the PI provided with this request is the most recently-approved version, that
all of the proposed changes relate to the requested correction to the ARTG entry, and no
other unidentified changes are being proposed or are being made to the PI. [ ]

|  |  |  |  |
| --- | --- | --- | --- |
| Signature of authorised officer |  | Date |       |
| Name |       |
| Email |       |
| Telephone number |       |
| Fax number |       |
| Position/Relationship to sponsor(if different to front page) |       |

1. <<http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm>> [↑](#footnote-ref-1)
2. <<http://www.tga.gov.au/industry/pm-minor-variations-biological.htm>> [↑](#footnote-ref-2)
3. <<http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm>> [↑](#footnote-ref-3)
4. <<http://www.tga.gov.au/industry/pm-minor-variations-biological.htm>> [↑](#footnote-ref-4)
5. <<http://www.tga.gov.au/about/fees-forms-creditcard-authorisation.htm>> [↑](#footnote-ref-5)
6. <<http://www.tga.gov.au/about/fees.htm>> [↑](#footnote-ref-6)
7. The TGA will only review variations that are described in the application form at the time of submission. [↑](#footnote-ref-7)
8. An amendment to the PI must be approved by a delegate under subsection 25AA(4) of the Act. [↑](#footnote-ref-8)
9. <<http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm>> [↑](#footnote-ref-9)
10. <<http://www.tga.gov.au/industry/pm-minor-variations-biological.htm>> [↑](#footnote-ref-10)
11. It is a condition of registration that information on the ARTG about a registered prescription medicine cannot be changed (apart from limited exceptions) without the approval of the Secretary. [↑](#footnote-ref-11)
12. As set out in Minor variations to registered prescription medicines: chemical entities (<<http://www.tga.gov.au/industry/pm-minor-variations-chemical.htm>>) or Minor variations to registered prescription medicines: biological medicines (<<http://www.tga.gov.au/industry/pm-minor-variations-biological.htm>>). [↑](#footnote-ref-12)