

Cancellation Request Details

Request Source:	19/06/2020 s 22				
Licence Info:	289159 - Bioglan Astragalus				
Type:	Medicine				
Product Info:	<div>Products<table><tr><th>Id</th><th>Name</th></tr><tr><td>663856</td><td>Bioglan Astragalus</td></tr></table></div>	Id	Name	663856	Bioglan Astragalus
Id	Name				
663856	Bioglan Astragalus				
Sponsor Id:	40346				
Sponsor Name:	Natural Bio Pty Limited				
User Name:	s 22				
Location:	52914 PO Box 384 MONA VALE NSW 1660				
Contact Name:	s 22				
Contact Email:	s 22 @pharmacare.com.au				
Contact Phone:	s 22				
Effective Date:	22/06/2020				
Approved By:	s 22 at 22/06/2020 08:35:41 AM				
Oracle Write:	Successful at 22/06/2020 08:42:02 AM				
Confirmation Email Sent:	22/06/2020 09:03 PM				
TRIM Reference:	D20-917386				
TRIM Container:	E20-105687: Therapeutic Listing - Cancellation of ARTG Entries - 2020-06-19 Sponsor: 40346 - Natural Bio Pty Limited Contact s 22				
Processing Notes:	Notification email attachment uploaded to TRIM (22/06/2020 9:03:21 PM) Confirmation email sent (22/06/2020 9:03:21 PM) Writing of cancellation to Oracle successful (22/06/2020 8:42:02 AM)				



22/06/2020

Client ID:40346

Natural Bio Pty Limited
PO Box 384
MONA VALE NSW 1660

Dear **s22**

NOTIFICATION OF THE CANCELLATION OF A MEDICINE FROM THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG)

This letter is in response to your request of 19/06/2020 in which you requested the cancellation of a medicine from the Australian Register of Therapeutic Goods (ARTG).

Decision

The Secretary has cancelled the following entry/ies from the ARTG in accordance with section 30(1)(c) of the *Therapeutic Goods Act 1989*(the **Act**):

ARTG Number	ARTG Name
s 22	
289150	Bioglan Astragalus
s 22	

ARTG Number	ARTG Name
s 22	

As the recorded sponsor of these goods you should note the cancellation is effective from 22/06/2020.

You should note that you remain liable for any outstanding annual charges relating to this entry on the ARTG.

You are reminded that under the Act, both criminal and civil penalties may apply to the import, export, or supply of therapeutic goods that are not included in the ARTG and are not the subject of an exemption, approval or authority under the Act.

Other matters

If your request is to cancel a prescription medicine then you are reminded that it is your responsibility to ensure that the Product Information/Consumer Medicine Information lodged with the TGA is correct, up to date, current and fit for purpose.

Accordingly you are requested to update your Product Information/Consumer Medicine Information lodgement on the TGA eBusiness Services (eBS) facility at www.ebs.tga.gov.au to reflect the cancellation of the above product/s. Within 2 weeks of this letter please do the following:

- For a Product Information / Consumer Medicine Information lodgement relating to a single entry please email your removal request (including the lodgement identification number) to prescriptions.pi@tga.gov.au
- For a Product Information / Consumer Medicine Information lodgement relating to multiple entries please use the "Replace" function and update the lodgement by un-checking the above cancelled entries.

If you have any further enquiries concerning these amendments to the ARTG record please contact 1800 010 624.

Requesting revocation of this cancellation under section 30A

If you wish to have the inclusion of the medicine/s referred to above reinstated in the ARTG, you can make a request under section 30A of the Act. Any such request must:

- be made within 90 days of the cancellation; and
- be accompanied by the prescribed fee which is \$150 for the first entry and \$50 for each additional entry.

Should you wish to request reinstatement of your entry, please complete the [reinstatement form](https://www.tga.gov.au/form/request-reinstate-entry-australian-register-therapeutic-goods-artg) at <https://www.tga.gov.au/form/request-reinstate-entry-australian-register-therapeutic-goods-artg> and send it to accountsrec@health.gov.au

If the entries are reinstated under section 30A the cancellation is taken never to have occurred.

Review Rights

This decision is an initial decision within the meaning of subsection 60(1) of the Act. You may request the Minister to reconsider the decision within 90 days after the date of receipt of this letter. Attachment A sets out the details of how to apply for a Ministerial review of the decision.

However, as stated above, if you wish to have your entry reinstated you may prefer to simply make a request under section 30A.

Please note that under section 30C of the Act, the TGA is required to publish in the Commonwealth Gazette or on the TGA website particulars about all cancellations of medicines including those initiated by the sponsor.

Attachment A**Request for reconsideration of an initial decision**

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Please note that in relation to reinstatement of an entry on the ARTG under section 60, if the delegate agrees to reinstate the entry the reinstatement will become effective from a future prescribed date i.e. the cancellation remains effective until the reinstatement date.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.