28/06/2023

Client ID:60

Beiersdorf Australia Ltd
PO Box 139 (Head Office)
NORTH RYDE NSW 1670

Dear s22

NOTIFICATION OF THE CANCELLATION OF A MEDICINE FROM THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

This letter is in response to your request of 26/06/2023 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 or entries from the ARTG in accordance with section 30(1)(c) of the *Therapeutic Goods Act 1989* (the Act):

ARTG Number	ARTG Name
126550	Elastoplast ABC Heat Plaster

As the recorded sponsor of these goods you should note the cancellation is effective from 28/06/2023.

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.

Financial matters

It is important to note that you may have ongoing financial and related obligations in respect of the cancelled entry or entries:

- You will remain liable for any outstanding annual charges for any entry or entries which were active on the ARTG on or after 1 July of the financial year in which the entry or entries were cancelled.
- If an entry or entries were eligible to be exempt from annual charges under the TGA's annual charge exemption (ACE) scheme in the financial year in which the entry or entries were cancelled, you (the sponsor) must make a final declaration of $0 turnover for the entry or entries in the declaration period commencing on the next 1 July, but only if the entry or entries were of $0 turnover.
- Making a final declaration of $0 turnover will have the effect of confirming the ACE on the entry or entries for the financial year in which the entry or entries were cancelled. Similarly, the entry or entries will not incur any annual charges, and likewise you will not be required to provide any further declarations in respect of the entry or entries in later financial years after the year the entry or entries were cancelled.

Other matters

If your request is to cancel a prescription medicine, non-prescription medicine or biological 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.

Within 2 weeks of this letter please do whichever is applicable of 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) for prescription medicines and biologicals to prescriptions.pi@health.gov.au and for non-prescription medicines to otc.medicines@health.gov.au; or

- 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.

Accordingly you are requested to update your Product Information / Consumer Medicine Information lodgement on the TGA Business Services (TBS) facility at www.ebs.tga.gov.au to reflect the cancellation of the above product/s.

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 reinstatement fee.

Further information and the reinstatement form are available on the TGA website at https://www.tga.gov.au/form/request-reinstate-entry-australian-register-therapeutic-goods-artg. Should you wish to reinstate an entry, please send your request and completed form 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 in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. 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 this function 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 making 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.

Guidelines for requesting reconsideration of an initial decision
Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website <https://www.tga.gov.au/reconsideration-reviewable-initial-decisions> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

· a copy of the initial decision notification letter, i.e. this 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: '**decision.review@health.gov.au**'

Subject: "**<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*"
Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected,

within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

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.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

22/01/2020

Client ID:66834

Beiersdorf Health Care Australia Pty Ltd
4 Khartoum Road
North Ryde NSW 2113

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 22/01/2020 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
282621	Elastoplast 4.8mg Heat Plaster

As the recorded sponsor of these goods you should note the cancellation is effective from 22/01/2020.

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 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.

Cancellation Request - Completed

Confirmation Letter Generated: 22/01/2020

Cancellation Request Details	
Request Source:	22/01/2020 s22 [redacted]
Licence Info:	282621 - Elastoplast 4.8mg Heat Plaster
Type:	Medicine
Product Info:	**Products** Id: 563902 — Name: Elastoplast 4.8mg Heat Plaster
Sponsor Id:	66834
Sponsor Name:	Beiersdorf Health Care Australia Pty Ltd
User Name:	113428_66834
Location:	106392 4 Khartoum Road North Ryde NSW 2113
Contact Name:	s22 [redacted]
Contact Email:	s22 [redacted]@beiersdorf.com
Contact Phone:	s22 [redacted]
Effective Date:	22/01/2020
Approved By:	s22 [redacted] t 22/01/2020 11:46:05 AM
Oracle Write:	Successful at 22/01/2020 11:48:40 AM
Confirmation Email Sent:	22/01/2020 09:02 PM
TRIM Reference:	D20-91075
TRIM Container:	E20-11433: Therapeutic Listing - Cancellation of ARTG Entries - 2020-01-22 Sponsor: 66834 - Beiersdorf Health Care Australia Pty Ltd Contact: s22 [redacted]
Processing Notes:	Notification email attachment uploaded to TRIM (22/01/2020 9:02:10 PM) Confirmation email sent (22/01/2020 9:02:10 PM) Writing of cancellation to Oracle successful (22/01/2020 11:48:40 AM)

Cancellation Request - Completed

Confirmation Letter Generated: 28/06/2023

Cancellation Request Details

Request Source:	26/06/2023 s22 [redacted]
Licence Info:	**126550** - Elastoplast ABC Heat Plaster
Type:	Medicine
Product Info:	**Products** **Id** | **Name** 791681 | Elastoplast ABC Heat Plaster
Sponsor Id:	60
Sponsor Name:	Beiersdorf Australia Ltd
User Name:	119924_60
Location:	185 PO Box 139 (Head Office) NORTH RYDE NSW 1670
Contact Name:	s22 [redacted]
Contact Email:	s22 [redacted] @Beiersdorf.com
Contact Phone:	s22 [redacted]
Effective Date:	28/06/2023
Approved By:	s22 [redacted] at 28/06/2023 09:14:17 AM
Oracle Write:	Successful at 28/06/2023 09:39:37 AM
Confirmation Email Sent:	28/06/2023 09:12 PM
TRIM Reference:	D23-1991067
TRIM Container:	E23-169303: Therapeutic Listing - Cancellation of ARTG Entries - 2023-06-26 Sponsor: 60 - Beiersdorf Australia Ltd Contact: s22 [redacted]
Processing Notes:	Notification email attachment uploaded to TRIM (28/06/2023 9:12:01 PM) Confirmation email sent (28/06/2023 9:12:01 PM) Writing of cancellation to Oracle successful (28/06/2023 9:39:37 AM)