Document 1

Australian Government

Department of Health
Therapeutic Goods Administration

6th June 2014

Client ID: 11663

s22
Novartis Consumer Health Australasia Pty Ltd
PO Box 4499
MULGRAVE VIC 3170

Dear s22

NOTIFICATION OF THE CANCELLATION OF ENTRY ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG).

I refer to your request of 6th June 2014, in which you request the cancellation of the entry in the Australian Register of Therapeutic Goods (ARTG) of the therapeutic goods set out below.

I am a delegate of the Secretary for the purposes of Section 30(1)(c) of the *Therapeutic Goods Act 1989*.

Decision

I am writing to notify you that in response to your request, I have decided to cancel the following entry from the ARTG in accordance with Section 30(1)(c) of the *Therapeutic Goods Act 1989*.

ARTG 11053 SCOP hyoscine hydrobromide 1.5mg drug delivery system sachet

s22

As the recorded Sponsor of these goods you should note the cancellation is effective from 10th June 2014.

If you have the original Certificate of Listing/Inclusion/Registration would you please take the necessary steps to ensure it is destroyed.

You are reminded that supply of the above products following cancellation from the ARTG or without a specific exemption under the Act, is an offence under Section 19B of the Act, or incurs a civil penalty under section 19D of the Act. Accordingly, you may wish to take measures to ensure that none of the products remain in any part of the product distribution cycle for which you are responsible.

You should note that you remain liable for any outstanding annual charges relating to the entry of this therapeutic good on the ARTG during the current financial year.

Other matters

If your request is to cancel a Prescription Medicine/s 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 s22 @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 s22 .

Requesting a revocation of this decision under s 30A

If for any reason you wish to have this decision revoked, you may apply under s 30A of the Act to the Secretary to revoke the decision. You must make this application in writing within 90 days of the date of effect of the cancellation (see above). Your application should be addressed to the Secretary, to the attention of the TGA Chief Information Officer, and sent to the following address:

Office of Information Management
Therapeutic Goods Administration
PO Box 100
Woden, ACT 2606

If the cancellation is revoked, the cancellation is taken never to have occurred.

Review Rights

This decision under s 30(1)(c) is also an 'initial decision' within the meaning of section 60 of the Act. This means that you may seek reconsideration by the Minister. You should make any request in writing within 90 days after this decision first comes to your notice or to the notice of your company, to the following address:

The Assistant Minister for Health
Parliament House
CANBERRA ACT 2600

Your letter should be headed "REQUEST FOR RECONSIDERATION UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".

You should include with your request any information in support of the request that you would like the Minister to consider. Under subsection 60(3A) of the Act, the Minister is not able to consider any information that you provide after the making

of the request unless the information is provided in response to a request from the Minister.

The Minister may either personally deal with the appeal or send it to be dealt with by one of the Minister's delegates within the Department. If you are dissatisfied with the result of the decision on the reconsideration then, subject to the *Administrative Appeals Tribunal Act* 1975, you may appeal to the Tribunal for review of that decision.

However, as stated above, if you wish to have the decision revoked and the entry effectively reinstated, you may prefer to simply make a request under s 30A.

Please note that under the *Therapeutic Goods Act 1989* the TGA is required to publish in the Commonwealth Gazette or on the TGA website, particulars about all cancellations of therapeutic goods including those initiated by the sponsor.

Yours sincerely

s22 [redacted]

s22 [redacted]

Delegate of the Secretary