ashm
Supporting the HIV, Viral Hepatitis and Sexual Health Workforce

24 February 2017

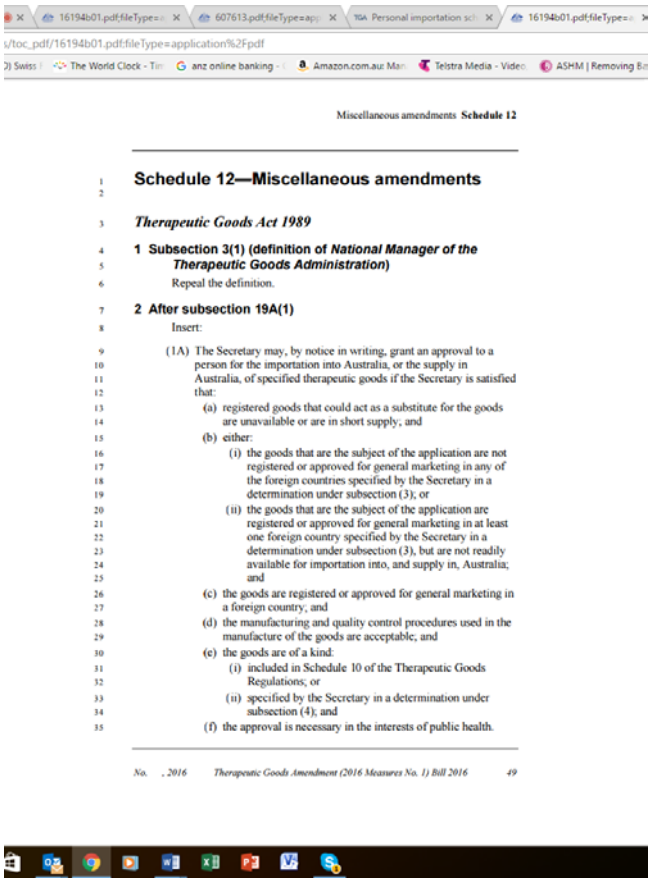
Attention:
The Senate
Standing Committee on Community Affairs
Legislation Committee
PO Box 6100, Parliament House
Canberra ACT 2600
Email: community.affairs.sen@aph.gov.au

Dear Secretary Jeanette Radcliffe,

It is unclear from the text below or the explanatory memorandum as to whether the intention of Schedule 12 19A (1) would in any way replace, impede or otherwise interfere with the TGA Personal Importation Scheme https://www.tga.gov.au/personal-importation-scheme .

I have contacted the committee and it could not be clarified if this was a replacement or additional provision.

ASHM would find it very problematic to introduce the additional requirement for the secretary to sign off on the PIS. This is not a current requirement, though a number the condition set out in the PIS are also in 19(a) 1 below.



Miscellaneous amendments **Schedule 12**

Schedule 12—Miscellaneous amendments

Therapeutic Goods Act 1989

1 Subsection 3(1) (definition of *National Manager of the Therapeutic Goods Administration*)

Repeal the definition.

2 After subsection 19A(1)

Insert:

(1A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods are unavailable or are in short supply; and

(b) either:

(i) the goods that are the subject of the application are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3); or

(ii) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3), but are not readily available for importation into, and supply in, Australia; and

(c) the goods are registered or approved for general marketing in a foreign country; and

(d) the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and

(e) the goods are of a kind:

(i) included in Schedule 10 of the Therapeutic Goods Regulations; or

(ii) specified by the Secretary in a determination under subsection (4); and

(f) the approval is necessary in the interests of public health.

No. , 2016 Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 49

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All other aspects of the Bill seem sound, and thank you for the opportunity to comment on the Bill.

Yours sincerely,

Adj A/Prof Levinia Crooks AM
Chief Executive Officer

On behalf of the ASHM Board
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