R15/504026

NATERA, Julian

From: Phillip Cooley <Phillip.Cooley@tga.gov.au>
Sent: Monday, 4 May 2015 12:18 PM
Subject: RE: Draft consultation description [DLM=Sensitive:Legal]
Attachments: Ministerial Submission - ACE Amendment Regulations.DOCX; Ministerial Submission - ACE Amendment Regulations.tr5

The draft is forwarded for review/comment.

Phillip Cooley
Assistant Director
Regulatory Decision Review
Regulatory Business Services Branch

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Email: phillip.cooley@tga.gov.au

Therapeutic Goods Administration
Department of Health
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www.tga.gov.au

From: Vinod Mahajan
Sent: Monday, 4 May 2015 12:00 PM
To: Phillip Cooley
Subject: RE: Draft consultation description [DLM=Sensitive:Legal]

Thanks. Let me know when this is ready. It needs to go to the AMO this week

Vinod Mahajan B.Com, CPA, FCA (ICAI)
Director
Regulatory Decision Review

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From: Phillip Cooley
Sent: Monday, 4 May 2015 11:56 AM
To: Vinod Mahajan
Subject: RE: Draft consultation description [DLM=Sensitive:Legal]

Working on it... Am picking up Will's informationas I go as most is pertinent for the MinSub Minute

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From: Vinod Mahajan
Sent: Monday, 4 May 2015 11:46 AM
To: Phillip Cooley
Subject: FW: Draft consultation description [DLM=Sensitive:Legal]

HI Phill,

Any chance of seeing the draft Minsub this A/n.

Regards

Vinod

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From: Will Freebairn
Sent: Monday, 4 May 2015 11:21 AM
To: Philippa Horner; Nicole McLay; Vinod Mahajan; Phillip Cooley; Vimala Srinivasan
Cc: Terry Lee
Subject: Draft consultation description [DLM=Sensitive:Legal]

Dear All

Please find attached above a suggested consultation description (to be included in the ES), for your review – grateful for comments and changes.

I couldn't recall where we ended up in terms of timing of publication of the RIS – but I have drafted the last sentence on the assumption that it would have happened by the time the package goes to the ExCo meeting.

Regards

Will

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Australian Government
Department of Health

Ministerial Submission
Standard

<PDR Number>
Version: (0)

To: **Assistant Minister Nash**

cc: **Minister Ley**
Martin Bowles PSM
Deborah Chan
Fay Holden
Kirsty Faichney

Subject: **Regulation amendments to implement an Annual Charge Exemption (ACE) Scheme**

Purpose: **To seek your final approval for amendments to the Therapeutic Goods Regulations 1990 (the Regulations) to implement an annual charge exemption scheme to replace the current low value turnover exemption scheme.**

Critical Date: TBC May 2015

Reason: Documents (if approved) must be returned to the Department by 20 May 2015 for delivery to the ExCo Secretariat for the ExCo meeting of 28 May 2015.

Recommendations: That you:	
1. That you APPROVE the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations* (Attachment C);	**1. Approved / Not approved**
2. That you SIGN (but not date) the Executive Council Minute for the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations* (Attachment B);	**2. Signed / Not signed**
3. That you SIGN (but not date) the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations* (Attachment C);	**3. Signed / Not signed**
4. That you INITIAL each page of the Explanatory Memorandum for the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations* (Attachment D);	**4. Initialled / Not initialled**
5. That you NOTE the Explanatory Statement for the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations* (Attachment E).	**5. Noted/ Not noted**
Signature: ..../...../2015	

Contact Officer:	Ms Samantha Palmer	First Assistant Secretary, Regulatory Support Division,	Ph: (02) 6232 8240

		TGA	
Clearance Officer:	Adjunct Professor John Skerritt	National Manager, TGA	_____ *Clearance Officer Signature* ...../...../2015

Issues:

1. The current low value turnover (LVT) exemption scheme was reviewed as part of the government's red tape reduction program to identify any unnecessary regulatory (including administrative) burden arising in relation to the scheme.
2. A new exemption scheme has been designed in response to the review findings which, if implemented, will replace the existing LVT scheme with a scheme based on $0 turnover of an entry on the Australian Register of Therapeutic Goods (the Register). The replacement scheme would apply to all new entries in the Register from 1 July 2015, as well as pre-qualified existing entries in the Register prior to 1 July 2015. An entry subject to an annual charge exemption would not incur an annual charge until the entry commences turnover.
3. The change in the low value turnover threshold, currently '15 times the applicable annual charge' to a $0 turnover threshold will mean that certain low value turnover entries (not $0 turnover entries) will incur annual charges for the first time.
4. The impact of the changes will be off-set by general reductions (between 5% and 23%) to the annual charges for most classes of therapeutic goods.

Background:

On 22 January 2015, you approved a Submission (**MS14-001805**) which provided you with two options for the replacement of the current LVT exemption scheme with a new scheme. The first option was an exemption scheme based on 'No Supply' of a product which would have required changes to the *Therapeutic Good Act 1989* (the Act); the second option was an exemption scheme based on $0 turnover of a product which could be implemented by amendments to the *Therapeutic Goods Regulations 1990* (the TG Regulations). You advised that changes to the LVT exemption scheme should be by amendments to the Regulations, not by changes to the Act.

On 20 April 2015, you approved a subsequent Submission (**MS15-000733**) for the Regulation Impact Statement (RIS) for the review of the LVT exemption scheme; and the creation of a separate annual charge category for non-biologic generic prescription medicines and introduction of an annual charge for them which is 23% lower than the current annual charge for non-biologic prescription medicines; and approved a reductions of 5% in annual charges for prescription medicines (non-biologics) other than generic prescription medicines, and medical devices class IIa and above (including the preparation of drafting instructions for amendments to the *Therapeutic Goods (Charges) Regulations 1990* which will be submitted to you for approval for consideration by the Federal Executive Council (ExCo) in May 2015.

The *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulation 2015* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). Under the Act, therapeutic goods must be entered on the Register before being supplied in, or exported from, Australia, unless exempt or otherwise approved. Sponsors of goods (other than export only goods) must pay an annual charge to maintain their entries on the Register. The Therapeutic Goods Administration (TGA), which is part of the Department of Health and administers the Act, operates on a full cost recovery basis. Annual charges funds important post-market monitoring and compliance activities under the Act. Under the TG Regulations sponsors with a turnover in a financial year of not more than 15 times the amount of the annual charge for that year will be exempt if they make an

application to the Secretary within the specified time period and provide evidence that is validated by an independent accountant.

The Amendment Regulation amends the TG Regulations to replace that scheme (from 1 July 2015) with revised exemption arrangements. Sponsors of goods coming onto the Register will be exempt from annual charges until they commence turnover of their goods if the sponsor submits a declaration to the TGA for each financial year confirming that that was the case. The declaration must be given by 22 July in the next financial year, but sponsors who miss this deadline may submit a late declaration by 15 September in that next year. There are also transitional arrangements for sponsors of goods already on the Register on 1 July 2015 –such sponsors must not have had turnover for financial years 2013-14 or 2014-15 (or, in the case of new entries in 2014-15, for that year) as well as 2015-16 in order to qualify for an exemption in 2015-16.

The Amendment Regulation also allows the sponsor of a registered medicine, biological or higher risk medical device not eligible for an exemption to apply to the Secretary for a waiver of the annual charge for a financial year. The Secretary may grant a waiver if satisfied it is in the interests of public health for the goods to stay on the Register, and that it would not be financially viable for the goods to stay on the Register if the change has to be paid. This decision is subject to review by the Minister and by the Administrative Appeals Tribunal.

Relevance to Election Commitments/Budget Measures:
The proposed annual charge exemption scheme is directly relevant to the Governments red tape reduction program.

The objective of the Review of the Low Value Turnover Exemption Scheme was to identify issues in the current scheme with an objective of the scheme and eliminating any unnecessary regulatory burden.

Sensitivity:
The Australian Dental Industry Association (ADIA) advised on 20 February 2015 that it does not support the proposed annual charge exemption scheme because while the scheme would reduce red tape, ADIA believes that the benefit [of the red tape reduction] would be off-set by a significant increase in the annual charges paid by businesses in the dental area.

Financial Implications:
The proposed changes will result in deregulatory savings of $3.0 million per year. Sponsors of therapeutic goods will also save an additional $2.4 million per year in LVT exemption application fees (as no application fee will be payable for an exemption under the new scheme.

Regulatory Burden Implications and/or Deregulation Opportunities:
The Office of Best Practice Regulation (OBPR) was consulted in the development of this proposal and determined that a Regulation Impact Statement (RIS) was required for the proposed amendments.

A RIS was developed and provided for two pass assessment by the OBPR. The RIS was subsequently assessed by OBPR as meeting best practice regulation requirements on 26 March 2015. You approved the OBPR certified RIS on 20 April 2015 (**MS15-000733**).

Timing/Handling (including legislative changes):
Subject to your approval, it is intended to lodge the proposed amendment regulation with the Executive Council in time (i.e. by 20 May 2015 deadline) for its 28 May 2015 meeting. The amendments would commence on 1 July 2015

Consultations:
The TGA released a consultation paper in April 2014 seeking feedback on the current LVT scheme and on a number of possible options for replacing it, including an option of only applying annual charges

when therapeutic goods are supplied to the market. Feedback noted that the current LVT scheme was complex and burdensome to navigate. Most submissions supported either changes to that scheme or its replacement with one that applied charges when goods are supplied to the market.

The TGA met with peak bodies in October and November 2014, and with consumer health advocacy groups in December 2014, to discuss proposed changes to exemption arrangements in more detail, and follow-up communications were done in writing. Subsequent sectoral meetings were held with these groups to discuss the likely impact of the proposed changes, and a targeted industry information session in late March 2015 modelled the effects of the proposed changes. The design of the new scheme, consistent with that set out in the Regulation, was also outlined with peak bodies at bilateral meetings in early March 2015. Overall, industry is supportive of the new arrangements, with only the Australian Dental Industry Association expressing reservations. A regulation impact statement has also been prepared, and is available from the TGA's website (www.tga.gov.au)".

Communication Activities:
There are no community awareness opportunities relating to this item

Attachments:
A: MS14-001805 and MS15-000733;
B: The Executive Council Minute for the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations 2015*;
C: The proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations 2015*;
D: The Explanatory Memorandum for the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations 2015*; and
E: The Explanatory Statement for the proposed *Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulations 2015.*

MINISTERIAL SUBMISSION – REFERENCE GUIDE

The following pages are for reference only. Please remove before submitting to MaPS.

GENERAL INFORMATION	
Executive Advice to Assistant Secretaries	Ensure the Submission: • sets out clear, logical exposition of the facts • has been discussed with all relevant areas of the branch/department • has been discussed with the relevant First Assistant Secretary • has clear and complete coverage of the pros and cons • uses subheadings if required • has clear recommendations that are self-standing and tailored to accurately reflect requirements of the Submission • uses attachments for further detailed analysis and summarises the relevant analysis rathe than requiring the Minister to rely on the attachments.
Who should clear the Submission?	• the Secretary must clear Submissions with whole of department or portfolio impacts or where there are identified significant risk factors for the portfolio • the Secretary should be consulted on Submissions relating to the business of the Cabinet • Deputy Secretaries must clear Submissions on significant policy issues impacting multiple divisions • First Assistant Secretaries should clear Submissions relating to significant new policy matters or those with high level division specific sensitivities • the Secretary will clear most Submissions to appoint agency CEOs and equivalent officers as well as other appointments the Secretary has an interest in • the Secretary should be consulted on Submissions relating to other significant or sensitive appointments to boards or committees • Assistant Secretaries may clear all other Submissions. First Assistant Secretaries shoulc be consulted on Submissions that address issues of particular sensitivity or risk.
Other Consultation/ Clearance Requirements	Ministerial Submissions relating to departmental submissions to a Parliamentary inquiry OR Government Responses to Parliamentary Inquiry Reports can be cleared as appropriate as indicated above, however: • The Secretary must clear a departmental submission to a Parliamentary Inquiry before the submission is provided to a Minister's office for noting • The Secretary should be consulted on Government Responses to Parliamentary Inquiry Reports before the Government Response is directed to a Minister's office for clearance
Length of Submission	Ministerial Submissions should be no more than three pages in length. Additional information may be included as attachments if necessary.
Critical Date and Reason for Critical Date	A critical date must reflect an actual legitimate deadline. It should not be arbitrarily chosen as a method of ensuring urgent consideration by the Ministerial office for administrative convenience. Reason for Critical Date: Explain the reason for the critical date, including (if relevant) implications if the date is not met.
5 Day Rule	Where a critical date is specified, it should allow the Minister not less than 5 working days to consider. Where the Submission breaches the 5 day rule at the request of a Minister's office, the date and the name of the requesting Adviser must be provided to the Ministerial Submissions officer for reporting purposes.

<table>
<tr><td colspan="2">TEMPLATE HEADINGS (All template headings are mandatory. Use N/A if not applicable.)</td></tr>
<tr><td>Issue</td><td>This section should headline, in numbered points, the key issues that are being presented for the Minister's consideration.</td></tr>
<tr><td>Background</td><td>Provide only the background necessary to understand the issues to be discussed.</td></tr>
<tr><td>Relevance to Election Commitments</td><td>Identify links between the issues raised in the Submission and the specific election commitments of the Government, ensuring that careful consideration is given to whether an issue is consistent with the policy directions of the Government.

If the Submission relates to National Partnership Agreements or Implementation Plans under the Intergovernmental Agreement on Federal Financial Relations, the Commonwealth-State Section must be consulted during the production of the Submission. Phone (02) 6289 3307 or email COAG.Framework@health.gov.au</td></tr>
<tr><td>Sensitivity</td><td>Address any specific community sensitivities or handling issues of which the Minister should be aware.</td></tr>
<tr><td>Financial Implications</td><td>If there are financial implications, including new and varied expenditure, savings and underspends, letters to the Minister for Finance and/or Treasurer for signature, and/or Regulation 10 implications, Budget Branch must be consulted and will advise whether a co-signatory is required.

Address any financial implications relating to the matter being considered by a table indicating 4 year costs, if applicable (refer below for example).

This [activity/grant/procurement] would commit a total of $xx.x million of existing funding, over the forward estimates:

<table>
<tr><th></th><th>2014-15 ($m)</th><th>2015-16 ($m)</th><th>2016-17 ($m)</th><th>2017-18 ($m)</th><th>Total ($m)</th></tr>
<tr><td>Cost of [activity/ grant/ procurement]</td><td>x.x</td><td>x.x</td><td>x.x</td><td>x.x</td><td>x.x</td></tr>
<tr><td>Funding available</td><td>x.x</td><td>x.x</td><td>x.x</td><td>x.x</td><td>x.x</td></tr>
</table>

OR

The proposal would cost/save a total of $xx.x million, over the forward estimates:
<table>
<tr><th></th><th>2014-15 ($m)</th><th>2015-16 ($m)</th><th>2016-17 ($m)</th><th>2017-18 ($m)</th><th>Total ($m)</th></tr>
<tr><td>[name of proposal]</td><td>x.x</td><td>x.x</td><td>x.x</td><td>x.x</td><td>x.x</td></tr>
</table>

If there are changes to program funding, a statement must be included that Budget Branch has been consulted and cleared the financial implications. Where a Submission seeks approval of continuing expenditure under an existing program (ia not new funding), the Submission must clearly show the current year budgeted funding and the expenditure to date.

Where a Submission indicates that funding for a new proposal could be sourced from an existing program, the Submission should explain the impact of the utilisation of these funds for this purpose. That is, what will be the impact on the program losing the funds and what are possible alternative uses of these funds - what is the 'opportunity cost'. If there are other possible sources, say so – give options. Provide big picture spending details on similar or related activities.

Where a Submission relates to new policy, indicate if costs have been agreed by the</td></tr>
</table>

	DoFD or not, and ensure consistency with any relevant Cabinet decisions.
Regulatory burden implications and/or deregulation opportunities	What regulatory or administrative arrangements are related to this proposal? What is this proposal's impact on regulatory or compliance burden for businesses, community organisations and/or individuals? Does it offer opportunity for deregulation &/or reduction in red tape or impose additional requirements? If non-regulatory, does it propose changes to administrative arrangements that may increase or decrease costs for businesses, community organisations and/or individuals? Where any of these implications are identified, you MUST contact the Deregulation Unit through dereg@health.gov.au. An example of increasing regulation would be requiring businesses to purchase additional equipment or provide specified training for all employees. An example of deregulation might include a proposal to move from regular mandatory independent inspections of all businesses to risk based audits. An example of reducing red tape would be a proposal that requires no legislative change but which reduces costs to business, community organisations or individuals. For example moving from paper based applications to simpler, more timely on-line methods, or reducing the frequency and/or complexity of reporting.
Timing / Handling (including legislative changes)	If appropriate, include information on urgency and proposed next steps or timeframes. If legislation is needed, a statement must be included that Legal Services Branch confirms that this is the case. If the action proposed requires any changes to portfolio legislation, state the proposed timing of those changes.
Consultations	Indicate all internal and external consultation undertaken. For liaison between divisions to constitute 'consultation' it must occur at the Assistant Secretary level or higher. Consultations must include PSD if there are any financial implications. Any initiatives relating to cancer, including listing of cancer related drugs on the PBS, must be discussed with Cancer Australia.
Communication Activities (including Community Awareness and Public Announcements)	Describe any community/stakeholder awareness implications, such as the opportunity of announcing new funding availability, a new policy or initiative, or other items of community interest. If you believe there are potential communication activities, the PDR should be assigned to Communications Branch for consideration during the drafting or clearing stage of the Ministerial Submission.