Australian Government
Department of the Prime Minister and Cabinet
Office of Best Practice Regulation

Reference: 16228
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Victor Portelli
Acting Deputy Director General
IP Australia

Dear Mr Portelli

Final Details stage Regulation Impact Statement – Export of Patented Pharmaceuticals to Countries Experiencing a Health Crisis

Thank you for forwarding the details-stage Regulation Impact Statement (RIS) for the above proposal for final assessment on Wednesday, 4 December 2013. I note that you have formally certified the details-stage RIS as required by the best practice regulation requirements.

The OBPR assesses details-stage RISs for consistency and adequacy – consistency relates to following the prescribed process and adequacy relates to the quality of the analysis. I note our comments of Tuesday, 3 December 2013 on the initial draft have been appropriately addressed, as you confirmed in your letter certifying the final version of the RIS.

I note the agency has been consistent with the RIS guidelines, having twice provided a certified details-stage RIS (addressing all seven elements) to the OBPR for the two-pass assessment before the decision-maker considers the RIS.

I note that the details-stage RIS is adequate as it does not contain obvious errors and has a degree of detail and depth of analysis that is commensurate with the magnitude of the problem and the size of the potential impact of the proposal – the Office of Best Practice Regulation (OBPR) considers that the RIS is a category 'C' RIS, reflecting that the issue is of relatively minor significance in the broader economy with minor competition impacts.

I note that the regulatory costs and cost offsets have been agreed with the OBPR. I note that an options-stage RIS was not required, and that this was flagged in the RIS.

I note that the RIS identifies that:

- the problem being addressed relates to the difficulties for developing countries in getting timely and affordable access to medicines under patent, such as South Africa;
- the objective of the Government's action was to assist developing countries access medicines under patent, while still maintaining incentives for innovation and investment in medicine;

- the preferred option to address this problem and objective was the implementation of the TRIPS protocol, which would enable the Federal Court to grant the right to export medicines under patent without the permission of the patent owner where the importing country is experiencing a health crisis;
- a benefit of implementing the TRIPS protocol was that it may have health benefits for countries experiencing a health crisis;
- a cost of implementing the TRIPS protocol is that it may influence the commercial negotiations of patent owners as well as have some minor costs associated with resolving matters through the Federal Court;
- the experience from other countries was that the number of medicines under patent supplied under the TRIPS protocol has been small; and
- consultation was undertaken with organisations representing patent owners and suppliers of medicines and that their comments have shaped the proposed implementation model for the TRIPS protocol in Australia.

The Government's Best Practice Regulation Handbook (June 2013), at paragraph 6.4, requires that for legislation which is tabled in the Parliament, a copy of the details stage RIS must be included in the explanatory memorandum (for primary legislation) or the explanatory statement (for legislative instruments). Please ensure that your officers provide the OBPR with a copy of (or link to) the explanatory memorandum or explanatory statement when these are made public.

Additionally, the Office of Best Practice Regulation (OBPR) maintains a RIS website and the Government requires that details stage RISs be posted within 5 business days of a regulatory decision being publicly announced. We would appreciate you advising us when a decision on this proposal is announced, and forwarding a final copy of the details stage RIS in *Microsoft Word .doc* format in a form meeting the Australian Government's *Web Content Accessibility Guidelines*. We suggest liaising with your web services team to ensure these guidelines are met. The OBPR should be consulted if the details stage RIS is amended. It is the agency preparing the RIS, not the OBPR, which is responsible for the content of the published details stage RIS.

The website provides a public comment facility on RISs posted on the site. The OBPR moderates this facility for offensive content but does not moderate debate.

Please retain this letter as a record of the OBPR's advice. Our reference number for this issue is 16228. If you have any further queries, please do not hesitate to contact me.

Yours sincerely

Jason McNamara
Executive Director
Office of Best Practice Regulation
December 2013