Australian Government
Department of Health

DEPUTY SECRETARY

February 2016

Tony Simovski
Deputy Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
Barton ACT 2600

Dear Mr Simovski

Independent Panel Review of Medicines and Medical Devices Regulation

This letter certifies that the Independent Panel Review of Medicines and Medical Devices Regulation (the Review) has undertaken a similar process and analysis to that required for a Regulation Impact Statement as set out in the *Australian Government Guide to Regulation*.

The Review comprises two stages. The first stage made 32 high level recommendations on the regulatory frameworks for medicines and medical devices, as well as access to unapproved therapeutic goods in special circumstances. The second stage made a further 26 recommendations on the regulatory frameworks for complementary medicines, and the advertising of therapeutic products. The Review recognises the excellent reputation of the Therapeutic Goods Administration in ensuring the timely availability of high quality, safe and efficacious therapeutic goods, whilst identifying opportunities to enhance both the regulatory framework and processes. Some of the recommendations are significant in their scale and scope, and some deregulatory opportunities are contingent on enhancing other components of the regulatory frameworks.

Both reports are available on the Department of Health website.

The regulatory burden on business, community organisations or individuals has been quantified according to the Australian Government's Regulatory Burden Measurement Framework. This costing has been agreed with your office and is provided below.

Review process

An independent expert review of medicines and medical devices regulation was announced on 24 October 2014 by the then Minister for Health, the Hon Peter Dutton MP and the then Assistant Minister for Health, Senator the Hon Fiona Nash.

The Review was undertaken by an independent expert panel led by Emeritus Professor Lloyd Sansom AO, assisted by Mr Will Delaat AM and Professor John Horvath AO. The panel was supported by a Secretariat within the Department of Health.

Under its terms of reference, the panel was tasked with identifying:

- areas of unnecessary, duplicative or ineffective regulation that could be removed or streamlined; and
- opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

Addressing the RIS questions

Questions 1 and 2 consider the policy problem and why Government action is needed.

The Government commenced this Review as part of its approach to removing ineffective regulation and encouraging greater competition and innovation in the medicines and medical devices sectors, ensuring Australians can access the latest treatments in a timely manner whilst maintaining safety, quality and efficacy.

The Panel's public discussion papers outlined concerns expressed by stakeholders about the regulation of medicines and medical devices that were drawn from:

- previous review reports;
- a summary of stakeholder views;
- options for change provided by the Therapeutic Goods Administration (TGA); and
- a review of stakeholder submissions to a range of fora, including the Australian Government National Commission of Audit and consultations on Regulatory Impact Statements conducted by the TGA from time to time.

Questions 3, 4 and 6 require consideration of options to best address the policy problem and the need for Government action.

The Australian Government regulates registration of therapeutic goods, including prescription and over-the-counter medicines, medical devices, and complementary medicines, for market access in Australia. Inclusion on the Australian Register of Therapeutic Goods is a requirement to supply therapeutic goods in Australia.

Stage one of the Review makes 32 high level recommendations on the regulatory frameworks for medicines and medical devices, recommending that Australia maintain sovereignty over market approval decisions, while proposing processes that offer potential for faster access to market for sponsors of therapeutic goods. Supporting infrastructure is proposed to ensure the national regulator has the necessary tools, flexibility, and legislative underpinning to respond effectively to future challenges while maintaining its place as a regulator that is highly regarded both nationally and internationally.

Proposals include:

- implementation of additional pathways to registration, including reducing duplication through greater use of overseas assessments;

- establishment of designating bodies in Australia to undertake conformity assessments for medical devices;
- expedited and provisional approvals in certain circumstances; and
- streamlined management of access to unapproved therapeutic and variations to medicines.

Enhanced post market monitoring is also recommended in relation to some pre-market deregulatory opportunities to ensure that public health and safety is not compromised and safety, quality and efficacy of products are maintained.

Stage two of the Review makes a further 26 recommendations on the regulatory frameworks for complementary medicines and the advertising of therapeutic products. While the Review found the TGA frameworks for complementary medicines and advertising benchmark well against comparable overseas regulators, it identified opportunities for improvement. Proposals include:

- expanding the pathways by which sponsors can seek approval of an ingredient for use in a listed medicine, and for marketing approval of a complementary medicine;
- enhancing the transparency and predictability of processes and evidence requirements associated with ingredient approvals and complementary medicine marketing approvals;
- improving and clarifying the interface and synergies between the market approval of therapeutic goods and advertising requirements that ensure consumer protections are balanced with the availability of information for consumers and health professionals to make informed spending and health decisions; and
- enhancing and streamlining the advertising framework to facilitate and maximise compliance and the management of complaints.

Question 5 asks who will be consulted and how they will be consulted.

Stakeholders were consulted by the Panel in developing their recommendations, through a written submission process (open to the public) and face to face meetings. Written submissions were received from industry, consumer, clinical and professional associations and interested individuals.

Subsequent to the release of each stage of the Review, the Department of Health held stakeholder consultation forums on:

- 5-6 August 2015 which focused on recommendations identified as offering early opportunities for potential reform from stage one of the Review;
- 8-9 December 2015 on all the recommendations of stage two of the Review.

The aim of these forums was to provide stakeholders the opportunity to feedback on the practical implications (including the benefits and challenges) of implementing the proposed recommendations to help inform the Department’s advice to Government. These forums were well attended.

The Department held a further workshop on the Scheduling Policy Framework and Schedule 3 advertising recommendations on 18 September 2015, and a medical devices-focussed workshop on 24 November 2015.

Question 7 asks how the regulatory option will be implemented and evaluated.

Some of the recommendations are significant in their scale and scope, and implementation timelines will vary between early opportunities and longer term reforms subject to further examination and stakeholder consultation. Some deregulatory opportunities are contingent on enhancing other components of the regulatory frameworks, and will be considered in context with the findings of other relevant reviews and reform work being undertaken in the Health portfolio. Implementation could involve significant changes to legislation, processes, governance arrangements and systems. The design and implementation of any such programme of reform will need to be carefully considered once the Government's position on the recommendations has been finalised. Implementation, monitoring and evaluation of the impact of the reforms would be undertaken as part of the Department's ongoing and regular responsibilities for providing advice to the Ministers, the Government, and to the public.

Yours sincerely

Mark Cormack
Strategic Policy and Innovation Group

Regulatory Burden and Cost Offset (RBCO) Estimate Table

Average Annual Reduction in Compliance Costs (from Business as usual)

Change in Costs ($m)	**Business**	**Community Organisations**	**Individuals**	**Total change in Cost**
Total by Sector	$(74,976,858)	$	$	$(74,976,858)

Cost offset ($m)	**Business**	**Community Organisations**	**Individuals**	**Total by Source**
Agency	$	$	$	$

Are all new costs offset?
Deregulatory, no offsets required

Total (Change in costs - Cost offset) ($million): $(75) million