DEPARTMENT OF HEALTH AND AGEING
RESPONSE TO PRODUCTIVITY COMMISSION REPORT ON
REGULATORY BURDENS ON BUSINESS - MANUFACTURING AND DISTRIBUTIVE TRADES

FOOD REGULATION

PC Recommendation	DoHA Response to PC Recommendation
PC Concern: Inconsistency in food regulation.	
Draft Response 3.1 The Australian Government should publicly announce what reforms are to be implemented, and their timing, as a result of the analysis undertaken as part of the Bethwaite review. In finalising its report on regulatory burdens for this year, the Commission will consider, having regard to any announced reforms, the need for a further limited review to improve the national consistency of food regulation.	The Australian Government has identified food regulation as a priority for consideration through the COAG Business De-regulation and Competition Working Group (BRCWG). The important information collected through the reviews including the Bethwaite Review will be provided to the COAG BRCWG to inform the broader policy debate. A further decision about a public release of the Bethwaite Review will be made by Government.
PC Concern: Improving the operations of the Australia New Zealand Food Regulation Ministerial Council.	
Draft Response 3.2 The changes made to the *Food Standards Australia New Zealand Act 1991*to improve the timeliness and stakeholder consultation in the amendment and development of food standards should be independently reviewed two years after their implementation.	It is agreed that timely review of changes is appropriate. However, the timing of the reviews needs to be determined in the context of the broader considerations as per draft response 3.1.
PC Concern: Improving the operations of the Australia New Zealand Food Regulation Ministerial Council.	
Draft Response 3.3 The Ministerial Council should amend the Food Regulation Agreement to reflect the general practices for decision-making by other Ministerial Councils established to oversight, coordinate and integrate policy, such as the	The arrangements for the Food Regulation Ministerial Council are consistent with other Ministerial Councils where appropriate, recognising the differing roles and responsibilities in legislation of the various Ministerial Councils.

Australian Transport Council, the Gene Technology Ministerial Council and the Ministerial Council on Energy. In particular, the Ministerial Council should require a majority vote to initiate a review of a draft amendment of the Food Standards Code prepared by Food Standards Australia New Zealand. The Ministerial Council should incorporate, in managing its business, an explicit process step of ensuring that all requests from members of the Ministerial Council to initiate a review provide a justification in terms of the criteria that are specified in Part III of the Food Standards Agreement. The justification for any review should be published.	The Department of Health and Ageing will request the COAG BRCWG to consider the issue of majority voting to initiate a review of a draft amendment of the Food Standards Code prepared by Food Standards Australia New Zealand. Reviews may only be requested against criteria identified in the Food Regulation Agreement and these are published when a review is requested.
Draft Response 3.4 The agreed-to COAG guidelines for the development of regulation should be incorporated into the Food Regulation Agreement. The Australia New Zealand Food Regulation Ministerial Council should publish a regular report of its regulatory actions against the COAG regulatory guidelines. Compliance could be further improved by having the Chair of the Ministerial Council manage the regulatory business of the Council so as to comply with these guidelines.	The arrangements for the Food Regulation Ministerial Council are consistent with other Ministerial Councils where appropriate, recognising the differing roles and responsibilities in legislation of the various Ministerial Councils.
PC Concern: Food regulation and public health.	
Draft Response 3.5 The Australia and New Zealand Food Regulation Ministerial Council should not consider making decisions on matters of public health through food regulation until such time as the Australian Health Ministers' Conference has considered all policy responses and referred the relevant matters to the Australia New Zealand Food Regulation Ministerial Council for a food regulation response.	The arrangements for the Food Regulation Ministerial Council are consistent with other Ministerial Councils where appropriate, recognising the differing roles and responsibilities in legislation of the various Ministerial Councils. The Government agrees that further clarity between decisions on matters of public health policy and decisions of regulation would be beneficial to the operation of the Ministerial Council. These will be considered in the context of the broader considerations as per draft response 3.1.

THERAPEUTIC GOODS REGULATION

- **Medicines regulation**

PC Recommendation	DoHA Response to PC Recommendation
PC Concern: Timeliness and cost of Therapeutic Goods Administration manufacturing audits/Good Manufacturing assessment processes, including insufficient recognition of overseas assessment.	
Draft response 4.1 The current reviews by the Therapeutic Goods Administration need to achieve the following outcomes: ▪ a stronger commitment by TGA to timely audits/clearance processes, including by incorporating explicit timeframes into publicly available guidelines; ▪ improved transparency of the risk-based criteria used to determine expiry dates for Good Manufacturing Practice certificates; ▪ wider recognition of international processes and acceptance of GMP certificates where conducted by bodies assessed as suitably competent, for example those acceptable by the US Food and Drug Administration.	Good manufacturing practice (GMP) inspections are a critical component of the Therapeutic Goods Administration (TGA) regulatory framework and any initiatives aimed at reducing regulatory burden on industry need to be balanced with maintaining appropriate standards of public health and safety. The TGA is committed to completing timely inspections and desk-top audits both through improvements to administrative processes and through recruitment of suitable staff. A commitment to specific GMP clearance timeframes would require additional resources and these costs would need to be recovered from industry. Pharmaceutical industry peak body associations have not indicated that this is a proposal that they wish to pursue (and pay for). Information for sponsors and manufacturers on the acceptable form of evidence of GMP compliance for overseas manufacturers is included in Guidance on the GMP clearance of overseas medicines manufacturers, 16th Edition, March 2008, which is published on the TGA website at: http://www.tga.gov.au/manuf/gmpsom.htm. Increased transparency could be achieved through publishing some details of the risk-based approach used by the TGA in its GMP processes, on the TGA website. The TGA will undertake to publish such information. In addition to the

	TGA led initiatives to improve the international approach to GMP identified in the draft PC report, the TGA has recently joined with the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMEA) in a pilot project designed to facilitate collaboration on inspections of active pharmaceutical ingredients (API) manufacturers in third countries. The pilot project provides for sharing of information on inspections between the TGA, US FDA and the EMEA and rationalisation of international GMP inspection activities. Should the pilot project demonstrate that it is an effective mechanism for improving the efficiency of GMP inspections, further international collaborative inspection programs are likely to be developed. To manufacture therapeutic goods in Australia, a manufacturer must demonstrate compliance with manufacturing principles which include relevant Codes of GMP and Quality Systems. Overseas manufacturers of therapeutic goods supplied to Australia are also required to meet an acceptable standard of GMP.
PC Concern: PBS Reference pricing methods impose excessive compliance costs.	
Draft response 4.2 The Department of Health and Ageing should examine ways to reduce compliance costs for business associated with the Weighted Average Monthly Treatment Cost methodology for reference pricing, consistent with ensuring tax payers continue to get the best value from PBS listed medicines.	The current process for Weighted Average Monthly Treatment Cost (WAMTC) reviews already minimises compliance costs while ensuring due process is followed. To date WAMTC reviews have yielded $500 million in savings to PBS expenses. WAMTC reviews result in price decreases where there is strong statistical evidence that drug sponsors have been paid by the Australian Government at levels greater than what demonstrated health outcomes would justify. Individual sponsors are able to quickly assess their situation using a WAMTC calculator and submit a suitable price response in keeping with company strategy.

PC Concern: Delays in achieving PBS listing due	
Draft response 4.3 The Pharmaceutical Benefits Advisory Committee should be allowed, when requested by applicants, to conduct its assessment of a medicine for PBS listing in parallel with the TGA's assessment of the application to register the medicine.	Current TGA and Pharmaceutical Benefits Advisory Committee (PBAC) processes allow PBAC to commence its assessment of a medicine when it is around two-thirds of the way through the TGA process. The current PBAC is flexible and allows its assessments to commence earlier in the TGA process when a new medicine provides a real advance in the treatment or prevention of a disease. The Access to Medicines Working Group (AWMG), a joint Department of Health and Ageing – Medicines Australia working group, is charged with exploring the capacity to further streamline and coordinate TGA and PBAC processes. The AMWG recently delivered its Interim Report to Government and it is under consideration. Further streamlining current TGA and PBAC processes is not without risk. The most significant risk is that the subsidy recommendation (PBAC) is not aligned with the approved uses of the product (TGA). As medicines cannot be subsidised for non-approved uses, PBAC may need to reassess its recommendation which would result in significant delays in achieving PBS listing and additional costs to both Government and industry.
PC Concern: Confusing and inconsistent advertising restrictions and associated complaints mechanism for pharmaceuticals.	
Draft response 4.4 The Australian Government should implement the Australia New Zealand Therapeutic Products Authority-related reforms which streamline and clarify advertising rules and work with state and territory governments to ensure reforms also address the need	The need to reform the regulation of the advertising of therapeutic goods was raised as part of the stakeholder consultations arising from the Australia New Zealand Therapeutic Products Authority (ANZTPA) process. The Government has given consideration to the way forward for regulatory reforms proposed under ANZTPA and has agreed

for a simplified system for complaints about national advertising.	that the TGA consult with stakeholders on these reforms so that they can move forward in an Australia only context. The TGA is planning to consult with stakeholders on possible changes to the advertising regulatory arrangements which would streamline requirements and simplify the complaints system. This will include consideration of implementing a centralised mailbox for all complaints about therapeutic goods advertisements.

THERAPEUTIC GOODS REGULATION

- **Medical devices**

PC Recommendation	DoHA Response to PC Recommendation
PC Concern: TGA monopoly on conformity assessment for Australian manufacturers.	
Draft response 4.5 The *Therapeutic Goods Act 1989,* and regulations as necessary, should be amended to allow Australian manufacturers to choose a certification body (acceptable to the Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures.	The use of external assessment bodies was raised as part of the stakeholder consultations arising from the Australia New Zealand Therapeutic Products Authority (ANZTPA) process. The Government has given consideration to the way forward for regulatory reforms proposed under ANZTPA and has agreed that the TGA consult with stakeholders on these reforms so that they can move forward in an Australia only context. The TGA has conducted initial consultations with stakeholders on a possible model to enable the use of external assessment bodies in conformity assessment. Further consultations will be required acknowledging changing international experience.
PC Concern: Efficiency of TGA registration process.	
Draft response 4.6 For lower risk devices, the TGA should more widely accept prior overseas registrations of medical devices from jurisdictions with competent authorities and suitably rigorous assessment processes.	For lower risk devices, the TGA currently accepts evidence of prior overseas registrations as part of its decision making processes. This position is consistent with that adopted by other major regulatory jurisdictions.

PC Concern: Multiple and overlapping processes.	
Draft response 4.7 A comprehensive and independent public review of Health Technology Assessment processes for medical devices should proceed as soon as possible. Outcomes should include: ▪ a streamlined regulatory framework for medical devices to remove duplication and overlap in the current arrangements; ▪ improved efficiency and timeliness of processes for assessing the safety and performance of devices and the suitability of procedures/devices for public funding and reimbursement by health funds.	A review of Health Technology Assessment Arrangements is under active consideration.