Department of Innovation, Industry, Science and Research Submission to the Senate Community Affairs Committee: Inquiry into the Regulatory Standards for the Approval of Medical Devices

1. The Department of Innovation, Industry, Science and Research (DIISR) welcomes the opportunity to provide a submission to the Inquiry into The Regulatory Standards for the Approval of Medical Devices.

2. DIISR strives as a key priority to encourage the sustainable growth of Australian industries by developing a national innovation system that drives knowledge creation, cutting-edge science and research, international business competitiveness and greater productivity. DIISR is committed to developing policies and delivering programs to provide lasting economic benefits ensuring Australia's competitive future. DIISR also works to boost innovation by Australian industry and improve social and economic benefits for the Australian community.

3. DIISR notes that a number of processes in relation to Health Technology Assessment (HTA) are currently underway. They stem from the HTA review and include the Proposal for Changes to the Medical Services Advisory Committee (MSAC) Processes for Applications for Public Funding and the proposed Reforms in the Medical Devices Regulatory Framework. DIISR has made submissions to all of these processes.

4. As stated in previous submissions, DIISR supports a fundamental goal of the HTA Review to reduce regulatory costs of the current health technology assessment system while maintaining safety standards.

5. There also needs to be a balance between appropriate regulation and an efficient and sustainable industry. As stated in our previous submission, DIISR's concerns focus on the potential industry impacts of the cost (including compliance costs), speed and the regulatory burden associated with conformity assessment of medical devices and the related regulatory framework. The regulatory burden includes resourcing issues for small and medium businesses required to deal with regulatory change.'[1]

6. Regulatory reform that encourages the development and commercialisation of medical devices in Australia has the potential to increase associated Australian employment, increase competition and innovation in the Australian medical devices market and lower the cost of quality health outcomes in Australia in the long term through greater availability of safe and improved medical devices.

7. In relation to the matters to be considered under the terms of reference (TOR) of the inquiry, specific statements made in DIISR submissions are included under each matter. They merely indicate some of the issues of concern to DIISR and the submissions themselves provide more details.

[1] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 12, p.2

TOR (a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia

8. DIISR maintains the position put in previous submissions that the Therapeutic Goods Administration (TGA), 'should be the sole Commonwealth arbiter of the safety of medical devices'.[2]

9. However there is strong support from DIISR and industry for the use of accredited third party conformity assessment bodies, other than the TGA, for Australian manufacturers. As stated in its previous submission, DIISR, 'sees an opportunity to increase positive Australian health outcomes and improve the operating environment for medical devices companies through greater use of third party conformity assessment'.[3] DIISR, 'strongly supports TGA's proposed reforms for the use of third party assessment bodies for Australian manufacturers (proposal 2A) and recognition of third party assessment (proposal 2C). These measures can improve the operating environment for medical devices companies through faster and non-duplicative assessment of the safety of medical devices by more appropriate use of third party conformity assessment bodies overseen by the TGA'.[4]

10. Use of third party assessment has the potential to save considerable time and money for Australian medical devices manufacturers and their customers and could provide a choice of conformity assessment pathways as is the case in larger markets such as the European Union (EU). As stated in its previous submissions, DIISR understands, 'that assessment in larger markets, such as for a European CE mark, is often:
    a. quicker (around 90 days for the European market versus around nine months for the Australian market - 255 days plus clock stops in Australia); and
    b. cheaper (around AUD 5000 for the European market versus around AUD 100,000 for the Australian market) for identical products'.[5]

11. The TGA conducted a consultation process in 2010 about proposed reforms to the medical devices regulatory framework. DIISR has expressed concern, 'that the combined outcome of this process may be an increase in regulation. This is in contrast to the HTA Review which was conducted to streamline regulation. Any increase in regulation should relate to demonstrated safety issues relevant to the Australian context'.[6]

[2] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation l, p.3
[3] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 7, p.1
[4] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 8, p.1
[5] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraphs 16-17, pp.2-3
[6] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraphs 16-11, p.2

12. The issue of third party conformance has now been under consideration for at least five years, going back to the Taskforce on Reducing Regulatory Burdens (chaired by Gary Banks) – Recommendation 4.19.[7]

13. DIISR has also expressed concern regarding the impact of TGA's, 'cost recovery arrangements on small and medium enterprises (SMEs) taking into account the disproportionate affect of the cost and timeliness of HTA processes for SMEs'.[8]

TOR (b) the cost effectiveness of subsidised devices

14. Recommendation 2 of HTA Review, which Government accepted on 27 February 2010, was that, 'rigorous consideration of evidence be consistently applied across all Commonwealth HTA processes to ensure sustainability of the Australian Government's health financing arrangements'.[9]

15. To determine the cost effectiveness of subsidised devices, DIISR has submitted that, 'HTA committees and agencies should instigate dialogue with all stakeholders about the appropriate basis for the assessment of clinical and cost effectiveness for devices'.[10]

TOR (c) the effectiveness and accuracy of the billing code and prostheses list

16. DIISR has maintained that those responsible for HTA should consider, 'processes that allow a device or procedure to be reimbursed only for that group of patients for which it is most cost and clinically effective'.[11]

17. DIISR has recommended in previous submissions that there is a need to, 'develop a clearly articulated process, agreed by stakeholders, for collecting additional data needed to support the conversion of interim listing to permanent listing on the Medicare Benefits Schedule'.[12]

18. To encourage the research, development and supply of medical devices that address pressing health issues in the community, DIISR has also submitted that there is a need to, 'consider creating a separate regulatory and reimbursement pathway for innovative products that do not fit easily into the

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[7] Regulation Taskforce 2006, *Rethinking Regulation*, Report of the Taskforce on Reducing Regulation Burdens on Business, chaired by Gary Banks, Recommendation 4.19

[8] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation n, p.3

[9] http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/$File/hta-reviewreport.pdf at page 6, accessed on 6 December 2010

[10] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation i, p.3

[11] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation j, p.3

[12] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation k, p.3

current HTA system, with regard to mechanisms that are developed in relevant international fora'.[13]

19. Concerns were raised about the Prosthesis and Devices Committee (PDC) in the HTA review and subsequently a number of HTA review recommendations referred to the PDC.[14] It is not clear whether the PDC (now the Prostheses List Advisory Committee) is addressing all of these issues. The TGA and the Medical Services Advisory Committee (MSAC) have undertaken consultations aimed at addressing a number of HTA review recommendations.

TOR (d) the processes in place to ensure that approved products continue to meet Australian standards

20. DIISR made a number of recommendations to the HTA review in its submission regarding the improvement of assessment processes that would ensure that approved products continue to meet Australian standards.

21. DoHA has progressed streamlining the HTA system through the creation of a single entry point that integrates Commonwealth HTA in Australia. Further, as DIISR recommended in its submission to the HTA Review, 'this entry point should accept applications for all processes, allow real time application tracking for applicants and assessors, and standardise application requirements across HTA committees and agencies to reduce duplication'.[15] Implementation of this is being undertaken.

22. DIISR sought processes that, 'allow elements of the HTA system to complete assessments concurrently and to utilise international HTA assessment where this does not compromise the safety of products approved for the Australia market'.[16] Some of these elements are in the process of implementation.

23. To reduce costs to industry and to increase access to medical devices, DIISR has submitted that those responsible for HTA in Australia should, 'consider ways to make MSAC assessment faster including allowing them to rely to a greater degree on data provided by the sponsor – similar to procedures employed by the Pharmaceuticals Benefits Advisory Committee (PBAC)'.[17]

24. DIISR has also submitted that, 'Using appropriate international post-market surveillance and the alignment of Australian post-market surveillance with

[13] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation y, p.4
[14] Department of Health and Ageing 2009, *Review of Health Technology Assessment in Australia*, Recommendations 10, 11 and 12
[15] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation a, p.3
[16] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation c, p.3
[17] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation f, p.3

comparable countries (to reduce the cost of data customisation) may reduce industry cost burdens whilst maintaining appropriate assessment for safety'.[18]

25. To improve the performance of HTA committees, DIISR has submitted that it is important to, 'determine appropriate timeframes for each element of HTA and instigate performance benchmarking for all Australian committees/agencies/sub-committees over time and using appropriate international HTA processes for comparison – possibly in the form of a Client Service Charter'.[19]

26. DIISR has submitted that there is a need to, 'streamline Commonwealth HTA with the aim of eliminating any duplication of State processes and associated burdens'.[20] This would assist companies to develop approved products that meet Australian standards.

TOR (e) the safety standards and approval processes for devices that are remanufactured for multiple use

27. DIISR has submitted that the HTA Review, 'represents an opportunity to examine the HTA system so that unnecessary regulation can be removed while regulation essential for safety and accountability of public funding can be streamlined to the greatest net benefit for the community'.[21] Also that, 'a fundamental goal of the HTA Review [was] to reduce regulatory costs of the current health technology assessment system'.[22]

28. DIISR has submitted that, 'any increase in regulation should relate to demonstrated safety issues relevant to the Australian context'.[23]

TOR (f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices

29. DIISR has sought, 'greater use of and domestic alignment with, the international post-market surveillance mechanisms of comparable countries'.[24]

30. DIISR has made statements in submissions regarding the need to, 'consider implementing post-market surveillance requirements to deliver fit-for purpose

[18] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, p.13
[19] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation t, p.4
[20] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation m, p.3
[21] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, p.1
[22] DIISR 2011, *Submission from the Department of Innovation, Industry, Science and Research to the Medical Services Advisory Committee (MSAC) consultation, Proposal for Changes to the Medical Services Advisory Committee Processes for Applications for Public Funding, paragraph 7 page 2.*
[23] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 11, p.2
[24] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation p, p.3

quality control regimes, including calibration of medical devices with a measuring function, for better health outcomes'.[25]

TOR (g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified

31. The HTA review examined the effectiveness of current regimes for assessing prostheses. In its consultation paper in 2010, the TGA proposed to vary the requirements for the regulation of higher risk medical devices. The proposed reclassification of joint replacement implants, 'appears to be supported by evidence from the National Joint Replacement Register and appears to be supported on safety grounds'.[26]

TOR (h) the effectiveness of the implemented recommendations of the Health Technology Assessment

32. It is not clear that it is timely to assess the effectiveness of the implemented recommendations of the HTA review. This is because more time is needed to generate greater data regarding implementation and some of the recommendations of the HTA review are in the process of further implementation. DIISR notes that the, 'impact of the proposed changes to the HTA system approved by the Australian Government be evaluated within three years of the government response to [the HTA] review'.[27]

[25] DIISR 2009, *Submission from the Department of Innovation, Industry, Science and Research to the Health Technology Assessment (HTA) Review*, Recommendation q, p.3
[26] DIISR 2010, *Submission to Reforms in the Medical Devices Regulatory Framework*, paragraph 18, p.13
[27] Department of Health and Ageing 2009, *Review of Health Technology Assessment in Australia*, Recommendation 1, p.6