Submission to *Reforms in the Medical Devices Regulatory Framework*

1. This submission is from the **Department of Innovation, Industry, Science and Research** (Innovation) to the Therapeutic Goods Administration (TGA) consultation, *Reforms in the Medical Devices Regulatory Framework*. Innovation thanks the TGA for this opportunity to put forward its views.

2. Innovation strives to encourage the sustainable growth of Australian industries by developing a national innovation system that drives knowledge creation, cutting edge science and research, international competitiveness and greater productivity. Innovation is committed to developing policies and delivering programs, in partnership with stakeholders, to provide lasting economic benefits ensuring Australia's competitive future.

3. Innovation provided a submission to the 2008 consultation, *Use of Third Party Conformity Assessment Bodies for Medical Devices Manufactured in Australia*, a precursor to these proposed reforms. Innovation also made a submission to, and participated extensively in, the Health Technology Assessment Review (HTA Review). The HTA Review was conducted as a Better Regulation Ministerial Partnership between the Minister for Health and Ageing and the Minister for Finance and Deregulation.

4. Innovation understands that as the TGA's own processes for assessment of medical devices prior to market entry were within the scope of the HTA Review, the TGA considered it premature to proceed with a number of the issues raised within the originally proposed timeframes. The HTA Review final report was released in February 2010. Recommendation 8b of the report was for the TGA to, 'Respond to issues raised in the consultations regarding third party conformity assessments by July 2010', which is being undertaken through this process.

5. Innovation notes that the TGA has undertaken many recent initiatives to improve the medical business environment such as its business process reform project.

6. In October 2010 the TGA proposed reforms for the medical device regulatory framework in a consultation paper (**Attachment A**) and this submission is in relation to those proposals.

Summary

7. Assessment for conformity with regulation conducted by a body other than the TGA is called third party conformity assessment. As stated in its previous submission, Innovation 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.

8. Innovation 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.

9. The consequent incentive to medical device manufacturers and distributors to introduce safe new medical devices into the Australian market could increase associated Australian employment. Both importers and local Australian and overseas based manufacturers make investment decisions that take into account the compliance costs of Australian medical devices regulation, often in comparison with potential operation(s) overseas. Any incentive to invest in Australian medical device businesses could also increase competition and innovation in the Australian medical devices

market, which may lower the cost of quality health outcomes in Australia in the long term through a greater availability of safe and improved medical devices.

10. Innovation has concerns relating to the implementation of the TGA's other proposed reforms.

11. Innovation's concerns on implementation of reforms to the framework for medical devices regulation as a whole are 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. The Australian medical devices market is a small proportion of the global market and an industry association has estimated that about 90 per cent of medical devices in Australia are imported. In order to ensure that the overall regulatory burden on industry is not increased we recommend that industry is consulted regarding costs and that the TGA use the business regulation costing tool at http://www.finance.gov.au/obpr/bcc/index.html as an indication of the level of cost to industry of detailed implementation of proposals for medical device regulation.

12. There needs to be a balance between appropriate regulation and an efficient and sustainable industry. These 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. Innovation proposes strategies in this submission to ameliorate these concerns while being mindful of the TGA's responsibility to ensure medical device safety.

13. Further public detail on the proposed implementation process should be provided by the TGA to reduce industry confusion and counter the belief that the proposed reforms will create additional regulatory burdens and costs, particularly for overseas companies and importers making investment decisions in a global context.

Current regulatory issues

14. The previous Innovation submission to the TGA detailed that the streamlining of regulatory requirements for medical devices has been considered, to our knowledge at that time, on six occasions since 2004[1].

15. Current regulation stipulates that the TGA is the only body that can assess Australian manufactured medical devices for safety for Australian market entry. Some overseas assessors can assess imported medical devices for conformity with Australian safety regulatory requirements for medical device market entry. This effectively creates a disincentive to manufacture medical devices in Australia as importing them can provide medical device businesses access to cheaper and faster assessment.

16. The previous Innovation submission gave an example of the difficulty with current Australian assessment arrangements, '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

[1] The August 2008 Productivity Commission (PC) Research Report stated that streamlining of regulatory requirements for medical devices has been considered by a number of previous reviews, including:
'a [Department of Health and Ageing] administrative review of the Medical Services Advisory Committee (2004-5); the [Productivity] Commission's Research Study on Impacts of Advances in Medical Technology (2005); the Regulation Taskforce [chaired by Garry Banks] (2006); during the development of the Medical Devices Industry Action Agenda (DITR 2006); and the recent Doyle Review of Prostheses Listing (2007).'

b. cheaper (around AUD 5000 for the European market versus around AUD 100,000 for the Australian market) for identical products'.[2]

17. The TGA has agreed with some countries that it will accept safety assessment by certain bodies for imported medical devices or their manufacturing processes for Australian market entry. These agreements are with multiple countries such as those in Europe or directly with single countries such as Canada.

Detailed comments on proposals

Reclassification of joint replacement implants (proposal 1)

18. To our knowledge, this proposal appears to be supported by evidence from the National Joint Replacement Register and appears to be supported on safety grounds. Innovation's concerns on implementation have been previously stated in paragraphs 11 and 12.

Use of third party assessment bodies for Australian manufacturers (proposal 2A)

19. Innovation strongly supports the TGA's proposed reform for the use of third party conformity assessment bodies for Australian manufacturers (proposal 2A). While the approach may have positive impacts, much will depend on:

    a. **the coverage of the proposed change** – how many extra medical devices are able to be assessed by third party conformity assessment bodies after reclassification; and

    b. **the effect of the proposed change** – whether the TGA will accept certificates for all classes of device rather than adding a further step in medical device assessment.

20. As we have previously suggested, for higher risk devices, the appropriate risk management approach could be that the assessment body issues a certificate which operates in Australia as a conditional certificate, which would take effect as a full certificate if the TGA does not raise objections within a defined time period. The guiding principle for certificates issued by assessment bodies could be that the higher the risk of the device, the longer the period that the TGA could have to object to a certificate. This would allow a longer period to address high risk devices while providing a certain timeframe for assessment for the medical devices industry. The TGA would also have the power to revoke a certificate in appropriate circumstances.

21. Innovation believes that full acceptance of certificates from third party conformity assessment bodies will reduce the demands on TGA resources. We understand that the use of third party conformity assessment bodies has been adopted in the United States because it is a means of creating efficiencies in the regulatory environment. Whereas feedback from industry has been that various third party conformity assessment mechanisms currently in place for Australia have not been effective to date. Also the proposed approach may assist the TGA as increased use of appropriate third party conformity assessment could reduce the TGA's requirements for assessment expertise, especially for novel medical devices.

Having a transparent and streamlined process for designation of appropriate third party conformity bodies for use in Australian assessment.

22. Innovation recommends that the TGA develop criteria (that are made publicly available) and establish a well-resourced process as soon as possible for the TGA to assess and designate appropriate third party conformity assessment bodies for Australian regulation. The TGA should publish on their website a list of authorised assessment bodies to facilitate their use. Ongoing monitoring of these bodies by the TGA would also be required to ensure that these assessment bodies remain appropriate.

[2] Data supplied by industry.

23. Adoption of this approach is likely to minimise: a) the barriers to appropriate third party conformity assessment for Australian regulation; b) the issues with the current assessment system for Australian manufacturers; c) TGA resources by standardising the approach to examining appropriate assessment bodies; and d) the time taken for the system to be established by using a standard well-resourced approach.

24. This approach is also likely to:

    a. maximise the use of appropriate third party conformity assessment for Australian medical device regulation; and

    b. assist Australian medical device exporters to simultaneously obtain assessments for both Australian and overseas markets, thereby improving the medical device manufacturing environment in Australia.

That contingent proposed reforms are expedited to establish the use of third party assessment bodies for Australian manufacturers.

25. While further resources may be required to expedite all the elements of proposal 2 we note that this short term investment should deliver longer term savings.

Increasing pre-market scrutiny for implantable medical devices (proposal 2B)

26. This proposal appears to be to increase medical device safety. Innovation's concerns on implementation have been previously stated at paragraphs 11 and 12.

Recognition of third party assessment bodies (proposal 2C)

27. While proposed confidence building for notified bodies (third party conformity assessors) designated under the Mutual Recognition Agreement with the European Union (proposal 2Ci) is strongly supported as it is activity aimed at increased use of appropriate third party conformity assessment, we have implementation concerns that may be addressed through further information.

28. Innovation has had some industry feedback that the TGA has varying degrees of confidence in assessments of notified bodies and that previous confidence building has not been effective. It is not clear if these are widespread views.

29. In any event if, as part of confidence building implementation, the TGA develops and publishes criteria:

    a. for appropriate third party conformity assessment for use in future bilateral agreements; and

    b. to be used for recognising Australian third party assessment bodies (proposal 2Cii);

    this is likely to increase the confidence in notified bodies that conform with the criteria.

30. It is crucial that these criteria are used by the TGA to assess and authorise third party conformity assessment bodies and that such assessments are accepted by the TGA (using appropriate risk management) unless there is significant evidence to the contrary. This would demonstrate full TGA recognition of third party assessment bodies through ongoing action.

31. While proposal 2Cii of recognising Australian third party assessment bodies is strongly supported to improve the operating environment for Australian medical device companies, Innovation has concerns that such reform is needed urgently and the proposal does not appear to be an urgent area of reform. The TGA October 2010 proposal is that, 'further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers'.

32. However this idea was proposed some time ago. The January 2006 report *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business* (the Banks review) recommended that the, 'Australian Government should consider allowing 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'[3].

33. Innovation is of the view that this reform is urgent as it would provide faster and non-duplicative assessment of the safety of medical devices by greater appropriate use of third party conformity assessment bodies overseen by the TGA.

34. The TGA consultation paper shows that there is strong industry support for amending the regulatory framework to allow third party assessment for Australian manufacturers[4].

35. The paper also states that the majority of stakeholders believe that the TGA should be responsible for assessment, designation and monitoring of conformity assessment bodies providing services to Australian manufacturers[5]. For input of a wide range of views in designation, TGA designation could be on advice from national medical device representation bodies, the National Prescribing Service, relevant professional colleges and/or consumers.

Amending the way in which a medical device is included in the Australian register of therapeutic goods and enhancing identification of approved devices (proposal 3)

36. Not enough information is provided on how this proposal is to be implemented to fully assess it.

37. The increased capacity to identify medical devices that have been approved would enhance regulatory safety action, such as a recall of specified medical devices. However there has been broad industry adverse reaction to the implications of specific Australian regulation-based requirements on individual medical devices, particularly in the context of global markets. Any adverse impacts on the medical devices industry could be minimised through the development of a well publicised flexible approach in consultation with industry and by being cognisant of international medical device tracking mechanisms.

38. Some of these issues appear to arise because existing flexible options acceptable to the TGA are not apparent to all businesses involved in the medical device industry.

39. Effective implementation could include a draft document that is developed by the TGA in conjunction with medical device representation organisations to inform industry of available options. The document could include:

    a. the information sought by the TGA;

    b. the options for sponsors to identify different types of medical devices (e.g. stickers on packaging and information on invoices and leaflets);

    c. the obligation on companies to justify their approach with examples of the types of justifications that have been deemed appropriate by the TGA; and

    d. revised implementation timelines as small companies have a limited capacity to implement such changes.

[3] http://www.regulationtaskforce.gov.au/__data/assets/pdf_file/0007/69721/regulationtaskforce.pdf at Recommendation 4.19 at page 31, accessed on 3 December 2010.
[4] http://www.tga.gov.au/devices/consult/cons-devices-reforms.pdf at page 49, accessed on 6 December 2010.
[5] http://www.tga.gov.au/devices/consult/cons-devices-reforms.pdf at page 49, accessed on 6 December 2010.

40. Also, we note that Recommendation 2 of HTA Review[6], which Government accepted on 27 February 2010[7], 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'. To better facilitate such rigorous consideration, the TGA could improve the clarity of its evidence requirements and publish reasons for all decisions. This is to increase industry understanding of the basis of decisions (Innovation has had industry feedback that there is currently uncertainty regarding the basis of some decisions) thereby resulting in submissions that better support rigorous consideration.

Publication of device product information on the TGA Website (proposal 4)

41. This proposal appears to be to ensure medical device safety through an increase in information, but insufficient detail is provided to fully assess the proposal. Some parts of industry have suggested that this could be done by notification only so that there is no cost associated with variations. They have also supported continuing supply by declaration as the TGA can undertake an audit at any time. Innovation's concerns on implementation have been previously stated at paragraph 11.

42. Innovation understands that some industry claims relating to the use of product information, which the TGA effectively requires be the same for the same products produced by different businesses on safety grounds, may operate as a barrier to competition in some areas. Innovation supports the immediate legislative removal of this barrier.

Conclusion

43. While the TGA's proposed approach may have positive impacts, much will depend on:

    a. how many further devices are able to be assessed by third parties;

    b. whether the TGA will accept third party conformity assessment certificates as final once appropriate risk management mechanisms are in place, such as when a time period for TGA objection has expired;

    c. the TGA's willingness to introduce a strategy for the new requirements with flexible compliance options for business and communicating these effectively to business;

    d. the TGA's willingness to allow all interested organisations to assess medical devices for safety for entry into the Australian market provided that they meet appropriate TGA developed criteria for conformity assessment;

    e. lengthening transition times (12 months was proposed) in response to industry feedback on resourcing issues associated with changed regulation requirements; and

    f. how long the proposed reforms take, and whether the reforms as a whole reduce the costs, time and regulatory burden of assessment of medical devices for industry.

[6] http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/$File/hta-review-report.pdf at page 6, accessed on 6 December 2010.
[7] http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr10-nr-nr036.htm, accessed on 6 December 2010.

Devices Regulatory Reform Proposals

Proposal Summary

Proposal 1	**1**	**Reclassification of joint replacement implants** A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.
Proposal 2	**2A**	**Use of third party assessment bodies for Australian manufacturers** That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.
	2B	**Increasing pre-market scrutiny for implantable medical devices**
	(i)	**Devices requiring a TGA Conformity Assessment Certificate to be issued** Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.
	(ii)	**Applications to be selected for auditing** Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.
	2C	**Recognition of third party assessment bodies**
	(i)	**Confidence building for EU Notified Bodies designated under the MRA** That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.
	(ii)	**Recognising Australian third party assessment bodies** That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.
Proposal 3	**3**	**Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices**
	(i)	**amend the way in which a kind of device is included on the ARTG; and**
	(ii)	**enhance the ability to identify devices that have been approved by the TGA for supply in Australia.**
Proposal 4	**4**	**Publication of device product information on the TGA Website**