AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Inquiry into The Regulatory Standards for the Approval of Medical Devices

Submission to the Senate Standing Committees on Community Affairs

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1. Executive Summary

AusBiotech Ltd (AusBiotech) welcomes the opportunity to contribute to the Inquiry into The Regulatory Standards for the Approval of Medical Devices that was announced on 15 June 2011 by the Senate Standing Committees on Community Affairs.

AusBiotech is Australia's biotechnology industry organisation, which represents over 3,000 members, covering human health, medical devices and diagnostics, bioinformatics, food technology, agricultural, environmental and industrial sectors in biotechnology.

AusBiotech consulted widely including with its medical device members and has identified four key issues that it believes should be considered by the Senate in the context of this Inquiry:

- Regulation of high risk medical devices – addressing term of reference (a)

  AusBiotech supports the important role of the TGA as the national regulator for assessing the safety, quality and efficacy of therapeutic goods and believes the TGA should establish a more open, transparent and integrated regulatory system. AusBiotech recommends to the Inquiry that it find that the TGA should:
  - Implement third party conformity assessment (CA);
  - Implement mandatory timelines for completing CA and applications;
  - Provide a mechanism for Australian medical device manufacturers to determine their application status; and
  - Generally work to improve efficiencies in processing applications to ensure the TGA operates in harmony with other regulating bodies.

  AusBiotech believes that such changes would assist Australian medical device manufacturers bring their products to market in Australia in a timely and cost-effective manner. AusBiotech also believes such changes would assist in levelling the playing field between Australian and overseas medical device manufacturers.

- Reimbursement system for medical devices – addressing terms of reference (b) and (c)

  AusBiotech recommends that the Senate Committee observe Recommendation 10 of the Health Technology Assessment (HTA) Review and the performance of the Prostheses List Advisory Committee (PLAC) to develop the procedures for assessing the cost effectiveness of subsidised medical devices. AusBiotech supports the reform to abolish the negotiation of benefits for individual listed products as well as the setting of maximum benefits to eliminate the potential gap payments for private health insurance patients in accordance with Recommendation 9 of the HTA Review. With the Prostheses List focused solely on the cost of the prostheses, AusBiotech suggests that the Senate Committee oversees an inquiry to assess the feasibility of the reimbursement system supporting treatment costs for patients over multiple admissions.

- Reuse of medical devices – addressing term of reference (e)

  AusBiotech recommends that the Senate Committee considers an inquiry to address the safety concerns associated with the reprocessing of single use medical devices in Australia.

- Evaluation of the Health Technology Assessment (HTA) Review – addressing term of reference (h)

  AusBiotech is supportive of opportunities for regulatory reform especially to improve process efficiency and reduce the regulatory burdens that can impede Australian medical device innovation. Thus, AusBiotech recommends that the Senate Committee monitor the recommendations of the HTA Review and their implementation by the Government.

2. Background

AusBiotech Ltd (AusBiotech), Australia's biotechnology industry organisation, represents over 3,000 members in the following sectors of biotechnology: human health, medical devices and diagnostics, bioinformatics, food technology, agriculture, environment and industrial.

AusBiotech represents its members by providing expertise as an industry advocate as well as by developing industry submissions to policy and other reviews panels being conducted at both government and corporate levels.

AusBiotech was closely involved in the Health Technology Assessment (HTA) Review and represented on the steering committee.

The current inquiry into The Regulatory Standards for the Approval of Medical Devices comes after an investigative report by the 4 Corners program (on 16 May 2011) which revealed the failure and subsequent recall of DePuy Orthopaedics' articular surface replacement (ASR) hip and call for legislative reform (relating to the approval process) by Senator Nick Xenophon.

3. Responses to Terms of Reference

AusBiotech has consulted widely including with its medical device members and has identified four key issues that relate to the terms of reference (ToR) listed below and will be addressed in this submission:

- Regulation of high risk medical devices

  ToR (a) The role of the Therapeutic Goods Administration (TGA) in regulating the quality of devices available in Australia

- Reimbursement system for medical devices

  ToR (b) The cost effectiveness of subsidised device

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

- Reuse of high risk medical devices

  ToR (e) The safety standards and approval processes for devices that are remanufactured for multiple use

- Evaluation of the Health Technology Assessment (HTA) Review

  ToR (h) The effectiveness of the implemented recommendations of the Health Technology Assessment.

4. Regulation of high risk medical device

The path to the Australian market for indigenous medical device manufacturers is significantly longer when compared to the path for overseas manufacturers intending to sell into Australia. This is due to the requirement on Australian medical device manufacturers who must engage with the TGA to undertake conformity assessments and who rely solely on the TGA to approve products for inclusion on the Australian Register for Therapeutic Goods (ARTG).

The major barriers Australian medical device manufacturers encounter when bringing products to market in Australia are:

a) No third party conformity assessment (CA) process – the TGA is the only body that can approve the quality systems of Australian medical device manufacturers to allow products to be sold in Australia;

b) The timeline differences involved in dealing with the TGA versus other notified bodies can be significantly longer;

    i. For example, European third party bodies appear to be cognisant of the commercial deadlines facing medical device manufacturers as evidenced by their ability to complete a conformity assessment within a few months for a small fee.

c) Limited mandatory timelines for most of the TGA processes;

    ii. For example, there is only one mandatory timeline for initial conformity assessments to be actioned by the TGA – 255 days. After this time, applications for changes to conformity assessments such as adding Global Medical Device Nomenclature (GMDN) codes to an existing certificate can take up to 12 to 18 months to be completed.

d) No provision of status information to Australian medical device manufacturers for any of the TGA processes;

e) High costs associated with initial conformity assessments and subsequent changes to certificates;

    iii. For example, the TGA fee for a Schedule 3, Part 1 – Full Quality Management System Audit as part of an Initial Conformity Assessment is listed as $24,600[1]. A minor change to quality systems will require an amendment of the certificate. This incurs a fee of $14,800[1].

    Such charges make the process of bringing products to market in Australia by Australian medical device manufacturers an expensive, and potentially a prohibitive, exercise. Further, the current legislation provides no flexibility in the structure of application fees.

f) The TGA's endeavour to increase pre-market assessment of high-risk medical devices is likely to lead to substantial increases in the time to approve medical devices as well as the costs and resources required to do so.

The above barriers, either singly or in combination, will commercially disadvantage Australian medical device manufacturers not only by delaying the release of their products on the market but also by increasing the regulatory burden for Australian manufacturers of high-risk devices without necessarily improving safety outcomes.

AusBiotech supports reform on the issue of third party conformity assessment to accelerate the path to market, allowing Australian manufacturers to engage with notable third party bodies for CA in accordance with Recommendation 8 of the HTA Review[2]. Reform on the issue of third party conformity assessment has been under discussion for at least five years. Therefore, it is important and timely that the Senate Inquiry strongly recommends the TGA, in consultation with the industry, begins to implement Recommendation 8 of the HTA Review[2] as soon as possible.

AusBiotech supports the important role of the TGA as the national regulator for assessing the safety, quality and efficacy of therapeutic goods and believes the Senate Inquiry should give consideration to the TGA establishing a more open, transparent and integrated regulatory system.

AusBiotech recommends to the Inquiry that the TGA should provide timeline data for submissions to allow Australian manufacturers to better track the progress of their applications.

AusBiotech further recommends to the Inquiry that the TGA should continue to engage and communicate with stakeholders in a transparent and timely manner to accelerate the conformity assessment process and thereby enable products developed by Australian medical device companies to reach the market in Australia in a more timely and cost-effective manner. This will provide a fair competitive advantage to indigenous medical device manufacturers who AusBiotech believes are currently disadvantaged compared to overseas manufacturers. An unintended consequence of the current system may be that it unwittingly encourages indigenous manufacturers to preferentially launch and manufacture their products off-shore thereby potentially depriving or delaying the access of Australians to potentially-life-altering products.

5. Reimbursement system for medical devices

Reimbursement of costs associated with the supply of medical devices to patients in Australia is unpredictable and problematic. The listing and setting of benefits payable by private health insurers for prostheses is decided by the Minister for Health and Ageing upon recommendations made to the Minister by the Prostheses List Advisory Committee (PLAC)[3]. The PLAC was recently established by the Minister for Health and Ageing, the Hon Nicola Roxon MP on October 2 2010 to replace the Prostheses and Devices Committee (PDC) in accordance with Recommendation 10 of the HTA Review[2]. With its revised membership and terms of reference, PLAC should assist with developing clinical evidence requirements for new Prostheses List applications as well as the development of procedures and models for assessing the cost effectiveness of medical devices in a more rigorous and transparent way[4].

AusBiotech recommends the Senate Committee monitor the ongoing implementation of Recommendation 10 of the HTA Review as well as the performance of the PLAC to develop the procedures for assessing cost effectiveness of subsidised medical devices.

Prostheses listed on the Prostheses List are categorised as 'no-gap' prostheses whereby private health insurers pay the benefit or 'gap-permitted' prostheses whereby the private health insurer pays at least the minimum benefit with the patient having to pay the gap[5]. While on the surface such a reimbursement system may seem reasonable, the size of the gap payment required to be paid by the patient can influence a medical practitioner's choice of medical device to be supplied under the private healthcare system, consequently impeding the sale of 'unselected' medical devices.

Similarly, revising the Prostheses List twice per year can affect the utilisation of products. When new medical devices are listed on the Prostheses List, benefits of established medical devices can unilaterally change due to the new products being listed, subsequently, altering the gap payment required by the patient.

AusBiotech supports the reform to abolish the negotiation of benefits for individual listed products as well as the setting of maximum benefits to eliminate the potential gap payments for private health insurance patients in accordance with Recommendation 9 of the HTA Review[2].

Although the reimbursement system for medical devices is being rationalised as part outcome of the HTA Review, the Prostheses List tends to focus on the cost of the prosthesis alone and not the impact on subsequent treatment costs. The current system provides no incentive for medical practitioners and healthcare providers to look at the entire cost of the treatment over multiple admissions.

Consequently, AusBiotech suggests that the Senate Committee oversees an inquiry to assess the feasibility of the reimbursement system not only supporting the reimbursement of prostheses' but takes into account the cost of ongoing treatment and admissions.

6. Reuse of high risk medical devices

In July 2001, the Australian Health Ministers Advisory Council (AHMAC) agreed that the reprocessing of single use medical devices for reuse would be regulated by the TGA to the same standards as the original manufacturer[6]. This is legislated in the *Therapeutic Goods Act 1989 (Cth)*[7].

Although the practice is allowed in Australian and regulated by the TGA, Australian medical device manufacturers are concerned about the reprocessing of single use medical devices for reuse for a number of reasons including:

a) Single use medical devices are designed for a single purpose not multiple uses;

b) Re-manufacturers of single use medical devices do not have access to the original design specifications which makes validating the safety and effectiveness of the reprocessed device difficult;

c) Sterilisation and cleaning can result in material degradation and mechanical failure of the medical device;

d) If sterilisation and cleaning is inadequate, the reuse of the medical device can compromise patient safety.

Re-manufacturers need to be able to provide the TGA with substantial evidence to validate and demonstrate safety and effectiveness.

AusBiotech recommends that the Senate Committee considers an inquiry to investigate the regulatory process for the remanufacture and reuse of medical devices to address the safety concerns of Australian medical device manufacturers.

7. Evaluation of the Health Technology Assessment (HTA) Review

The Inquiry by the Senate Community Affairs Committees into the regulatory standards for the approval of medical devices in Australia, with particular attention to joint replacements, coincides with the Government's implementation of reform based on a substantial and lengthy consultation known as the Health Technology Assessment (HTA) Review.

AusBiotech was closely involved in the HTA Review and represented local medical device companies on the Steering Committee. The resulting 332-page HTA Report made 16 recommendations and the Federal Government began work in March 2010 to implement 13 of them to streamline processes and reduce the cost of assessing new medical technologies in Australia and improve the way new health products, procedures and services are assessed for public funding, in line with international best practice.

AusBiotech is supportive of opportunities for regulatory reform especially to improve process efficiency and reduce the regulatory burdens that can act as impediments to Australia's medical innovation and believes reform should be achievable without compromising timely and affordable patient access to medical devices that are demonstrated to deliver improved outcomes as well as being safe, effective and value for money.

AusBiotech recommends that the Senate Committee ensures the recommendations of the HTA Review are implemented by the Government in a timely and transparent manner.

AusBiotech believes that many of the issues addressed by the terms of reference of this Inquiry are well-addressed in the recommendations of the HTA Review and in their implementation and suggests that an outcome of the Senate Inquiry be the provision of opportunity for the HTA recommendations to be fully implemented and their effectiveness and impact on the regulatory standards associated with medical devices monitored.

8. Conclusion

In this submission, AusBiotech has identified four key issues that it recommends be addressed by the Senate Inquiry as it reviews The Regulatory Standards for the Approval of Medical Devices:

- Regulation of high risk medical devices
- Reimbursement system for medical devices
- Reuse of high risk medical devices
- Evaluation of the Health Technology Assessment (HTA) Review

AusBiotech would welcome the opportunity to appear before the Senate Committee to further discuss this very important matter.

9. References

1 Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Summary of fees and charges as at 1 July 2011*, <http://www.tga.gov.au/about/fees-110701.htm>

2 Australian Government, Department of Health and Ageing, *Review of Health Technology Assessment in Australia,* <http://www.health.gov.au/internet/hta/publishing.nsf/Content/review-1#recommendations>

3 Australian Government, Department of Health and Ageing, *Prostheses List*, < http://www.health.gov.au/internet/hta/publishing.nsf/Content/prostheses-1>

4 Australian Government, Department of Health and Ageing, *Achievements since the release of the Health Technology Assessment Review,* <http://www.health.gov.au/internet/hta/publishing.nsf/Content/achievements-1>

5 Australian Government, Department of Health and Ageing, *Private Health Insurance – Prostheses List*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>

6 Government of South Australia, SA Health, *TGA Regulation of the Re-Manufacture of Single Use Medical Devices*, <www.health.sa.gov.au/FactSheet - TGA-Single-use-Advice-Q&A HCW.pdf>

7 *Therapeutic Goods Act 1989 (Cth)*, <http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/>