



Media release

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AusBiotech to submit to Inquiry on medical device regulation

AusBiotech is preparing a submission to a Senate inquiry into medical devices that will include a call for the full implementation of reforms to the regulatory standards currently being rolled out by the Government for the approval of medical devices in Australia.

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 biotechnology on the Steering Committee. The resulting 338-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.

As a key industry stakeholder, 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.

In a separate submission to Australia's Therapeutic Goods Administration (TGA) on the reforms to the Medical Devices Regulatory Framework (Dec 2010) AusBiotech responded to four proposals in an October discussion paper, including "Increasing pre-market scrutiny for implantable medical devices," based on the HTA Review recommendation 8c.

The recommendation concluded that the TGA should re-assess its current requirements for pre-market assessment of higher risk devices for entry into the market, with a view to addressing perceived shortcomings. However, neither the TGA discussion paper or the HTA Report provide evidence of regulatory failure in higher risk devices – apart from anecdotal reports – and AusBiotech is concerned this recommendation will likely lead to a substantial increase in resources and costs, thus increasing the regulatory burden for manufacturers of higher risk devices without necessarily resulting in improved safety outcomes.

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Recommendation 1 of the HTA Report was: "That the impact of the proposed changes to the HTA system be evaluated within three years of the government response to this review." AusBiotech would like to see this and other HTA recommendations fully implemented before conclusions are drawn.

AusBiotech will be working with its members in the coming weeks to prepare a submission to the Senate Inquiry, with comments due by 15 July to AusBiotech and the submission due on 29 July 2011. The Senate Inquiry is scheduled to report on 12 October 2011.

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Further information about the Senate Inquiry can be found at:

http://www.aph.gov.au/senate/committee/clac_ctte/medical_devices/index.htm

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About AusBiotech

AusBiotech is Australia's voice on biotechnology, and represents more than 3,000 members, encompassing medicines, medical diagnostics and devices, agriculture, alternative fuels and climate change.