Designation of Australian conformity assessment bodies for medical devices – Implementation, Version 1.0, November 2016

To: Business Improvement and Support Section
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AusBiotech is pleased to provide comments on the 'Designation of Australian conformity assessment bodies for medical devices – Implementation, Version 1.0, November 2016'.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and diagnostics and 400 – 900 medical technology companies) and employs in excess of 45,000 Australians.

AusMedtech, an AusBiotech program, is dedicated to the development, growth and prosperity of the Australian medical technology (device and diagnostics) industry, by providing initiatives to facilitate success in product development, manufacturing and commercialisation, and encouraging links between industry, research and governments.

The AusMedtech Regulatory Affairs Expert Panel is an expert group from amongst AusBiotech's member organisations, who provide advice on matters including the regulation of medical devices. The Panel members have reviewed the consultation document and joined AusBiotech's membership to form the basis of this submission.

AusBiotech would like to commend the Therapeutic Goods Administration (TGA) on their continuing efforts to work with industry to reform and improve its service. AusBiotech is supportive of the TGA's intention to implement a system to designate bodies for medical devices undertake conformity assessment certification of medical devices, including in vitro diagnostic medical devices (IVDs), for the Australian market.

We acknowledge that the implementation of the Designation of Australian conformity assessment bodies for medical devices is in response to Recommendation 15 (2) and Recommendation 16 of the March 2015 report of the Medicines and Medical Devices Review (MMDR). The recommendations are reproduced below and state:

> **Recommendation Fifteen**
> The Panel recommends that: […]
> 2. In order to provide timely access to devices that are safe, high quality and fit for purpose, there be multiple pathways to seek approval for the inclusion of other classes of medical device in the ARTG. Such pathways to provide for: […]
>
> **Pathway One** Conformity Assessment to occur within Australia by either:
> A. The Australian NRA; or
> ***B. A body designated by the Australian NRA to undertake Conformity Assessments of medical devices for the Australian market.***
> *[emphasis added]*
>
> **Recommendation Sixteen**
> The Panel recommends that the Australian Government develop transparent criteria that it will utilise in order to designate suitably qualified bodies within Australia to undertake Conformity Assessments of medical devices [Recommendation Fifteen, Pathway 1B].
> Such criteria to:
> 1. Include capacity to set specific requirements for different classes of medical devices; and

2. Be developed in consultation with health care consumers, health professionals, the medical devices industry and the NRA (i.e. TGA).

In principle, AusBiotech supports the MMDR panel's Recommendation 15(2) that a body designated by the TGA be able to undertake Conformity Assessment of medical devices for the Australian market. However, it is difficult to ascertain from the Implementation Consultation Paper whether the TGA's proposed designation system will translate into real benefits to patients, industry and/or government by way of reduced review times (i.e. timely access) and/or reduced costs.

The consultation paper acknowledges that the new designation system will take the TGA a considerable amount of time and effort to establish. Currently, most listings on the Australian Register of Therapeutic Goods (ARTG) are based on EU certification without application audits, or are products that would not meet the criteria, such as those under Regulation 4.1. AusBiotech encourages the TGA to conduct research in order to estimate how often sponsors/ manufacturers are likely to utilise an Australian designated body (to avoid the time of TGA's application audits) and whether the Australian market would be willing and/or able support the cost of the proposed system. We suggest that the most pragmatic and preferable option for sponsors/manufacturers, would be to utilise a body that was able to concurrently undertake Conformity Assessments for both Europe and Australia. Therefore, it would seem prudent that the TGA expeditiously determine the level of interest of European notified bodies in obtaining the designation to review under the Australian regulations.

Responses to specific questions asked within the consultation paper follow, along with some additional comments.

Page 9 - *Should designated Australian conformity assessment bodies (subject to capability etc.) be able to provide conformity assessment certification for all medical device applications? Should some device types or classes continue to be required to hold TGA conformity assessment certification?*

The proposed designation system should have the capacity to be able to determine the ability of the Australian notified body to provide certification for the devices.

Page 9 – *Does your organisation market devices to countries relying on 'home market' regulatory approval? How would this proposal impact on this?*

AusBiotech does represent members who market devices to countries that require Country of Origin approval (also known as certificates of free sale). If the proposed designation system allows for certificates to be issued more quickly (e.g. Europe and Australian certificates issued at the same time), this would represent a real benefit as submissions in these countries could be made at an earlier stage. There would be no perceived impact as Country of Origin approvals are based on Australian approvals of medical devices i.e. ARTG entries, not the proposed designation system that was followed to obtain the approval, therefore there would be no impact.

Page 9 *- Are there other key issues which should be considered in developing this proposal?*

The key issue to consider is the availability of organisations (i.e. EU Notified Bodies (NBs)) to participate in the proposed designation system given the imminent changes to EU regulations and the impact that will have on their (NBs') capacity to undertake more work. However, it is believed that this would not have an impact on Australian public health system as the TGA would be designating trustworthy organisation as

Australian conformity assessment body (CABs), which would have a positive impact due to the creation of a potential new industry. In addition, the proposed designation system could also provide more resources (in addition to the TGA) that could perform different assessments and potentially reduce times to market.

Page 12 *- Should the costs of designation be recovered directly as fees from conformity assessment bodies, or is it appropriate that some or all costs be recovered through other mechanisms such as charge on all medical device sponsors*

As the designation process is between the TGA and the Australian CABs, the fees should be recovered from the CABs. We would suggest that Australian CABs are likely to charge a higher fee to assess for the Australian regulations in addition to the Europeans given that Australia is a significantly smaller market compared to Europe.

Page 19 *- Should the designation framework be aligned to MDSAP requirements, European requirements or a hybrid?*

The designation framework should be a hybrid of MDSAP and European requirements, as this allows market access without additional audits in Australia, as well as other jurisdictions such as Canada, EU and US.

Page 19 *- Should particular aspects of each system be adopted for a hybrid approach?*

All required aspects should be incorporated into a hybrid approach (required for the certifications to support product approvals).

Page 19 *- Are the listed criteria appropriate and comprehensive?*

The criteria as outlined are both appropriate and comprehensive. However, as noted previously the proposed designation system may be cost and resource prohibitive and therefore, we encourage the TGA to conduct research to estimate how often sponsors/manufacturers are likely to utilise an Australian designated body (to avoid the time of TGA's application audits) and whether the Australian market would be willing and/or able support the cost of the proposed system.

Page 19 *- In addition to any feedback on specific aspects of the proposed approach to designation of Australian conformity assessment bodies, we are also interested in broader comments on the proposal.*

In addition to our comments above, we have concerns as to whether Australia will have the capacity, skills and experience to establish designated CABs able to satisfy the MMDR panel's Recommendations 15(2) and 16.

In summary, AusBiotech supports the implementation of a system by the TGA to designate bodies to undertake Conformity Assessment of medical devices for the Australian market. However, prior to embarking on the implementation of this system we suggest that the TGA undertake research to determine whether such a system would be both utilised by industry and be viable in Australia given potential cost, capacity, skills and experience constraints. In addition, we believe that there would be real benefits to the utilisation of CABs able to undertake concurrent Conformity Assessments for both Europe

and Australia. Therefore, we encourage the TGA to engage with European notified bodies to gauge their interest in obtaining designation to review under the Australian regulations.