AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

12 May 2017

Dear Regulatory Reforms Team

Re: AusBiotech's response to the consultation on "Options for the future regulation of 'low risk' products"

AusBiotech is pleased to provide comments in response to the TGA consultation paper: "Options for the future regulation of 'low risk' products". In principle, AusBiotech supports evidence- and science-based regulation of medicines and medical devices that is commensurate with the risks posed by the products. AusBiotech agrees with the statement made by the TGA that '…by reforming the regulatory approach around certain products, it would allow sponsors and TGA to better focus on the areas of risk with these products as well as on other, higher-risk products with an approach'.

AusBiotech is providing feedback specifically with regard to the section on 'Low risk products that are currently considered medical devices'. Feedback is not provided in response to other sections of the consultation document, as majority of other products described are not relevant to AusBiotech members. AusBiotech provides the following comments on the four actions described under the heading 'Product types for consideration by MMDR' on pages 38-39.

Action 1 – Systematically review the ARTG for potential non therapeutic goods

AusBiotech agrees with proposed Action 1. However, AusBiotech suggests that measures be considered to ensure safe and effective devices are appropriately regulated. The process of removing products from Class I ARTG listings does reduce the opportunity for a regulator to receive feedback and/or monitor post-market.

Action 2 – Engage with States and Territories

AusBiotech agrees with proposed Action 2. As a mechanism to clarifying the requirements during the tender process, AusBiotech suggests that the TGA could recommend that state and territory health departments include a reference to the definition of a medical device within tendering documents.

Action 3 – Update the Excluded Goods Order (EGO)

AusBiotech recommends caution when determining the products to include or exclude from the EGO as this will reflect the requirements that manufacturers are intended to meet. AusBiotech also suggests that because products are automatically included in the ARTG this process allows monitoring of post-market

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performance by the regulator, and provides a mechanism to identify any safety concerns raised by consumers/users.

Action 4 – Review Class I medical device ARTG entry process

AusBiotech agrees with proposed Action 4.

Yours sincerely

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