AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AusBiotech submission to the Senate Inquiry regarding the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

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AusBiotech is pleased to provide the Senate Inquiry with perspectives from the life sciences industry in regard to the *Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016* (the Bill), and urge that the Bill be supported to enable regulatory reform measures stemming from the review of Medicines and Medical Devices Regulation (MMDR).

For more than 30 years, AusBiotech has been working to represent the view of the life sciences industry, so as to advance its development in Australia and globally, and to deliver the benefits of biotechnology to patients, communities and consumers by translating world-class research into real solutions.

AusBiotech is a well-connected network of over 3,000 members from across the life sciences ecosystem, 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.

AusBiotech supports the MMDR's regulatory reforms and efforts to reduce costs and administrative burden for industry, making the assessment process shorter and simpler, while maintaining the safety and quality of medicines and medical devices.

The Review's recommendations that won Government support were sensible and supported by stakeholders – from consumers to industry - and are expected to provide industry with annual savings of around $75 million through the reduction in unnecessary red tape and regulation on the pharmaceutical and medical device industries, while maintaining safety and integrity of the regulatory process.

AusBiotech's initial submission to the Review was made in January 2015, however the Industry has been advocating for many of these improvements for a decade.

New pathways for the priority approval

The Bill contains provisions for a "regulation-making power to set out the details of new pathways for the priority approval of medicines and medical devices and biologicals that are fully-evaluated for safety-quality and efficacy or performance" in order to facilitate quicker patient access to new medicines and devices that have significant advantages over existing treatments.

The new framework for allowing some breakthrough medicines and medical devices to be evaluated more quickly is intended to provide faster access to market (and care of patients) without lowering the standard of scrutiny. This is attractive to consumers, health professionals and industry and for example could reduce the evaluation time for some medicines from a maximum of 255 working days to 150 working days.

The details of the new pathway arrangements are yet to be determined and are the subject of extensive and proper consultation, prior to the specific regulations being finalised.

Conformity assessment of medical devices

The Bill also supports the recommendation for the conformity assessment of medical devices to occur in Australia by private bodies designated by the TGA. It provides a regulation-making power to allow the Secretary to designate bodies in Australia to appraise the suitability of the manufacturing process for devices manufactured in Australia, and to assess whether such devices meet minimum standards of safety and performance.

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.

Currently conformity assessment certification is undertaken by the TGA for just under 10 per cent of devices sold in Australia. The remaining 90 per cent are certified through European bodies that perform medical device regulatory activities, with the oversight of national governments. Having Australian organisations other than the TGA, which are able to carry out conformity assessment certification in Australia will enable manufacturers to choose between the TGA and organisations either in Australia or Europe certified, to carry out this process for low-medium risk devices. The organisations based in Australia will have the direct legal oversight by the TGA, while the European organisations already have oversight from a comparable European government regulator.

Other sections of the Bill

There are a number of other provisions in the Bill that will enable sensible reforms to the regulatory process, and which AusBiotech also supports. These include:

- The ability to reduce wait time and fees for minor variations in cases where the safety, quality and efficacy of a medicine are not affected by the variation, via a notification process. In financial year 2015 - 16 there were 1285 prescription medicine minor variation applications submitted to TGA. If 80 per cent of these could be instead notified that would mean that for over 1,000 products the approval times would be reduced by up to 45 working days (9 weeks).

- Enabling practitioners, under the Special Access Scheme (SAS), to notify the TGA that they are prescribing particular medicines, without first having to seek the TGA's approval. In the financial year 2015 - 16 there were 20,113 SAS approvals for medicines, 3,231 for biologicals and 2,233 for devices. The reforms would apply to about 13,000 applications a year, which will allow quicker access by patients to goods not approved in Australia but which have a history of safe use in Australia or in other countries.

- Reducing the number of statutory committees that advise the TGA, from 11 to seven.

In conclusion

The Bill forms an important step in the realisation of regulatory reform for the approval of medicines and medical devices in Australia and long-awaited improvements to the environment for the development of new health technologies. These reforms, which are supported by stakeholders, have been more than a decade in discussions, two years in review and AusBiotech urges the Senate Inquiry to support these much-needed reforms.

AusBiotech's extensive advocacy, especially in regard to third party conformity assessment and expedited pathways for approval, will benefit the industry with less confusion and red tape, speed, education, and efficiency, and get products to patients more quickly without comprising safety.