AusBiotech response to the Review of Medicines and Medical Devices Regulation Stakeholder Forum

To: Medicines and Medical Devices Review Taskforce
Deregulation Branch
Best Practice Regulation and Deregulation Division
Department of Health
MMDReviewTaskforce@health.gov.au

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From: AusBiotech Ltd
ABN 87 006 509 726
Level 4, 627 Chapel St
South Yarra VIC 3141
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org

Background

The First Report of the Review of Medicines and Medical Devices Regulation (MMD) was publicly released by the Australian Department of Health on 24 June 2015. The Review examined Australia's regulatory framework and processes for medicines and medical devices to identify:

- Areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- Opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

AusBiotech participated in two days of stakeholder forums to provide feedback about the Report to the Department of Health Review Taskforce. The forums were held in Sydney on the 5-6 August 2015 and included three tailored forums to address the Medicines, Medical Devices, and Unapproved Products chapters of the Report.

AusBiotech supported the process of stakeholder engagement and the opportunity to provide the following feedback to the Review Taskforce regarding a number of aspects of the Medical Devices Forum.

The Medical Devices Forum concentrated on one of the Report's 32 recommendations (Recommendation 19) which had been identified by the Taskforce as a potential 'early opportunity' for reform based on the relative complexity and potential timeframe for implementation. Recommendation 19 focussed on the accelerated approvals for medical devices. The facilitators of the forum acknowledged that some of the other Report recommendations would be relevant to the discussion and opportunity was provided to include discussion about other relevant recommendations.

Opportunity was given to the forum participants to provide additional post-forum feedback via a participant survey. AusBiotech used the opportunity to submit the following to emphasise key points raised during forum and to include additional feedback received from members following the forum.

In summary:

1. AusBiotech gave qualified support for the expedited pathway (Recommendation 19) and cautioned that by their very nature, innovations are less well understood and therefore potentially more risky. AusBiotech made a number of suggestions during the forum and in the following submission regarding options to minimise these risks.

2. AusBiotech cautioned the Review Taskforce about implementing systems designed for a 'minor' regulatory approval pathway may have unintended impacts on the primary approval pathways.

3. AusBiotech does not support the establishment of the new Advisory Committee (Recommendation 29) on the grounds that it is:

    a. a bottleneck that will be unworkable; and

b. potentially dangerous to public health and is poor process.

4. AusBiotech reasserted it previously stated view to the TGA that the balance of pre-market and post-market regulation is not yet right and that greater emphasis and resources should be applied to the post-market assessment of medical devices.

5. AusBiotech supported the general thrust of the Report to provide flexibility and access to third party review.

Response to the MMD Review Taskforce Participant Survey Questions

1. *What did you find most useful about the session on Medical Devices?*

AusBiotech welcomed the opportunity to participate in the session – it was useful to hear from the Department and representatives of the review committee with regard to the logic and assumptions supporting the recommendations in the Report.

2. *Is there anything about Recommendation 19 that you wish to raise?*

AusBiotech and its members have expressed qualified support for the expedited pathway for assessment of novel medical devices for inclusion on the ARTG.

Expedited pathways are attractive because they provide a response to the criticism that regulation impedes innovation. Time-to-market is critical to the success of novel products and has a major impact on the commercial viability of new innovations.

AusBiotech would like to caution that:

The challenge is that by their very nature, novel products are less well understood and therefore potentially pose a greater risk to public health than that of devices that are known to the TGA. The potential risk to public health is that an expedited approval process for novel technologies is less thorough and results in release to market of unsafe innovations. The backlash could result in more onerous regulation for all.

One approach that may minimise the risk is to ensure that innovators accessing the expedited approval path are identified early and supported through the regulatory process (many innovators are small companies and are inexperienced at dealing with regulators).

A useful approach would be to implement support arrangements which provide e.g. single point of contact and higher level of advisory service for identified innovator applicants. This would facilitate reviews that are as efficient and smooth as possible without lowering standards.

In some cases it may be possible to transfer some of the regulatory oversight to the post-market domain (e.g. through post-market clinical studies and monitoring). AusBiotech is very supportive of initiatives that strengthen post-market monitoring, however cautions that such decisions should not be taken lightly for novel medical devices. There is likely to be a role for expert committee review of such decisions.

3. *What do you think would be your likely uptake of this accelerated pathway? (please provide general comments and a percentage estimate)*

Uptake of the accelerated pathway will be highly dependent on the time and effort required by sponsors to achieve ARTG listing (and whether a 'conditional' approval is what is generated from this process. If this is true, what is the process for removing the 'warning'? In some cases, the 'warning' could impede uptake and it might possibly prevent the intent of the early access). A participant at the Stakeholder Forum noted that the standard regulatory pathway in the EU is very efficient in comparison to Australian approvals. This, coupled with the TGA's current rapid assessment of EC marks, provides sponsors with an existing expedited pathway that also includes EU approval.

The proposed move to delegate the approval of devices to an 'Advisory Committee', depending on the finer detail of this aspect, may slow the process and therefore mean that the proposed 'accelerated pathway' is no better than alternate pathways. This would obviously reduce the uptake of the service.

4. *Is there anything you wish to raise in relation to approval Pathways 1 or 2 for Medical Devices that you did not have an opportunity to raise at the forum?*

AusBiotech believes that whilst the use of post-market monitoring for the approval of novel devices must be used with caution, the benefits of implementing a post-market monitoring system will advantage all three pathways.

AusBiotech has stated previously to the TGA that it believes the balance of pre-market and post-market regulation is not yet right and that greater emphasis and resources should be applied to the post-market assessment of medical devices. A post-market monitoring system would help manage the risk associated with the accelerated approval of novel devices and would provide a mechanism to shift the emphasis of assessment of products not classed as novel to post-market monitoring.

AusBiotech recommends that the Department include in the current focus on an accelerated pathway an assessment of the benefits of post-market monitoring across all three approval pathways.

5. *Do you have any comments on, or anything else you wish to raise in relation to the other Recommendations in the first Report of the Review?*

Overall, the Review's first report has been well received by industry and is viewed as positive and a welcome approach in most aspects. The focus on expedited approvals and third party conformity assessment has been especially welcome in the medical devices industry.

Third party conformity assessment

AusBiotech supports the general thrust of the report to provide as much flexibility and access to third party review as possible which is consistent with acceptable standards of rigour of review. AusBiotech is not convinced that there is a business case for the establishment of uniquely Australia third-party assessors who only provide Australian conformity assessment as manufacturers would still need to approach a Notified Body for access to the European market – which is far larger than the domestic market.

However, AusBiotech believes that there are advantages to TGA recognising specific Australian Conformity Assessment Bodies for whom there is no further TGA review of their assessment.

AusBiotech would expect that some of the larger European Notified Bodies may want to fulfil such a role and this would encourage them to establish more substantial operations in Australia. We see this as analogous to the situation in Canada where Notified Bodies also serve as CMDCAS registrars and combine both European and Canadian assessments into one audit process.

The advantage to this approach is that TGA has direct control over which assessors it accredits to provide assessments for supply in Australia. This provides a basis for greater public confidence in Australian regulatory controls. It also protects against any changes in the European regulatory system which may undermine the use of CE certificates in lieu of Australian certificates

Pathways 1 - 3

Members of AusBiotech have expressed concern regarding the focus on one particular recommendation and pathway in isolation from the others.

- Implementing systems designed for a 'minor' pathway may have unintended impacts on the primary approval pathways. For example establishing the Advisory Committee (recommendation R29) in the context of Pathway 3 without fully understanding the impact of such a decision on Pathways 1 and 2 could have unforeseen and major consequences to ARTG inclusions.
- Pathway 3 is the least likely to be used of the three pathways and is least likely to impact ARTG inclusions
- By focussing resources on Pathway 3 the Department is diverting resources away from the improvement of the more desirable improvements to Pathways 1 and 2.

Recommendation Twenty Nine

This recommendation is worthy of further discussion as it appears to address an unknown problem. While the recommendation points to the rationale of seeking to "separate the function of evaluating applications for registration/inclusion of a medicine or medical device in the ARTG from the final decision making function", it is unclear why this is required.

AusBiotech does not support the contention that it is necessary and does not believe that a conflict of interest exists between these two functions of the regulator or that it can reasonably be claimed to detract from the Regulator's ability or willingness to engage in cooperative interaction with sponsors.

Members of AusBiotech have contended that factors such as resourcing are much more likely to be responsible for any perceived 'reluctance' of the regulator to engage in dialogue with sponsors. Improving guidance documentation and developing dedicated resources would be of much greater value than establishing a new Advisory Committee on the pretext of solving a problem that is unsubstantiated.

Further AusBiotech does not believe that the interests of consumers are enhanced by consumer representation on an Advisory Committee that is tasked with approving the inclusion of a medical device on the ARTG. Again it is unclear what problem is being addressed and whether this is the right solution.

It is also uncertain what the 'expense' of this recommendation would be to approval times. It is unclear if approval times could be held or improved under this model, or if it would add time. The current ACMD process reviews some tens of device applications per year. It is our understanding that over 800 high risk (Class III and AIMD) applications are processed each year by TGA and a much larger number of Class IIa and IIb submissions are subject to TGA review. Also approximately 10% of Class I device notifications are subsequently subject to TGA post market audit. Given these numbers, it is difficult to envisage a committee based system of approvals which would be able to manage the workloads involved. Apart from the obvious logistical concerns, it may be challenging to recruit sufficient external experts to provide the meaningful level of input for each application that is implied by the recommendations of the Expert Review.

AusBiotech is unconvinced of the need for this recommendation and benefits that might be derived from it, and is concerned that it may be have unnecessary detriments.

The proposal to establish an Advisory Committee on Medical Devices ought to be given further serious consideration before proceeding.