

## The Case for Third Party Assessment of Medical Devices

**Australia stands alone amongst major regulatory jurisdictions in not allowing 3<sup>rd</sup> Party assessment for medical devices for domestic manufacturers.**

- **Rapid and cost effective regulatory oversight through 3<sup>rd</sup> Party assessment is available in North America, Europe and Japan for the overwhelming majority of devices.**
- **In Australia TGA recognises 3<sup>rd</sup> party certifications for imported medical devices, but requires TGA assessment of domestic manufacturers.**
- **The result is**
  - **increased costs,**
  - **delays to market access**
  - **Australian manufacturers are placed at a competitive disadvantage to importers**
  - **incentives to relocate manufacturing jobs offshore.**

The following is the text of a paper submitted to the TGA's Industry Consultation committee in November 2006 as part of a consultation on priorities for TGA's international arrangements and agreements.

For Further information about the issues raised in this paper – please contact Anna Lavelle Ausbiotech on (03) 9828 1400 or info@ausbiotech.org

## **PURPOSE:**

To present AusBiotech's priorities for international mutual recognition arrangements for medical device assessments including the role of 3<sup>rd</sup> Party assessment, particularly for Australian manufacturers.

## **SPONSOR:**

AusBiotech is the peak industry body representing the Australian biotechnology sector. AusBiotech speaks for a broad range of traditional and entrepreneurial bioscience organisations, active in human and animal health, agriculture, medical devices, bioinformatics, genomics, proteomics, manufacturing and environmental technologies. One quarter of our membership is associated with the Medical Device segment and specifically includes domestic manufacturers.

## **BACKGROUND:**

### **Australian Medical Device Manufacturers**

Australian domestic Medical Device production generates revenue of approximately A\$898 million per annum, of which 87% results from export activity\*. At current growth, the revenue is likely to be approaching A\$1 billion.

Direct discussion with senior executives of Australian medical device manufacturers indicates that, with respect to regulation and administration, their greatest areas of concern are within the control of the Therapeutic Goods Administration of the Department of Health, and Ageing and the Health Technology Assessment activities of the Medical Services Advisory Committee (MSAC).

### **Recent Reviews – MDIAA and the Banks Report**

AusBiotech strongly supports the Medical Devices Industry Action Agenda (MDIAA) launched in July 2006<sup>†</sup>, and the implementation process to address the areas of most critical need. Of particular relevance to consideration of international regulatory agreements are the following MDIAA outcomes.

#### ***MDI Action 6: Devices Regulation***

*Industry to establish a Devices Regulation Working Group with the Therapeutic Goods Administration to facilitate the successful transition of medical devices supplied in Australia to the new regulatory system by October 2007. This working group will consider international regulatory practices and lessons learned from the transition to propose desirable changes to regulatory practices that ensure safety, timeliness and transparency.*

#### ***MDI Action 9: Regulatory Cost Burden***

*Industry, in consultation with governments, to develop a proposal that would ease the regulatory cost burden on early-stage Australian medical devices companies.*

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\* IBISWorld Industry Report: *Medical and Surgical Equipment Manufacture in Australia* C2832 (2004)

† The full document can be found on the MDIAA website at [www.industry.gov.au/mdiaa](http://www.industry.gov.au/mdiaa).

The Commonwealth has also responded with recommendations, released in August 2006, to the Banks report<sup>‡</sup>, citing and supporting many of the areas in the MDIAA. Of specific relevance is:

**Recommendation 4.19: Allow choice of certification body for medical device manufacturers**

*The Australian Government should consider allowing Australian manufacturers to choose a certification body (acceptable to the Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures (having regard to the recommendations of the Medical Devices Industry Action Agenda).*

**Commonwealth Response:**

*The Australian Government agrees to the recommendation. The Medical Devices Industry Action Agenda has been considering this issue. The Action Agenda was recently announced and, as part of the implementation phase, the Action Agenda Implementation Group will consider best practice regulation for devices and will propose desirable changes to regulatory practices that also ensure safety, timeliness and transparency.*

## ISSUES:

### Current International Practices and the Effect of Device Class

In all GHTF Jurisdictions (and most other non-GHTF) regulatory assessment is risk based with the extent and type of regulatory intervention depending upon risk classification. In determining priorities for international agreements relating to regulatory recognition. It is instructive (indeed necessary) to first compare international regulatory approvals and practices by device class, while recognising that there is not exact correspondence between classifications in different jurisdictions.

Table 1 details the regulatory approvals by Class in Australia and by approval path in the USA. (510(k) and PMA categories are broadly equivalent to the Australian Medium and high Risk groups). It is clearly apparent from this table that medium risk devices constitute by far the largest proportion of assessable devices in Australia and the USA. High risk devices are only a very small proportion of approvals. It is likely that similar proportions will apply in all GHTF jurisdictions.

Class III devices are the most challenging from a regulatory point of view and are as a group tend to be subject to additional local requirements. They therefore present the greatest challenge when developing Mutual Recognition arrangements.

For low risk devices, all GHTF jurisdictions, except Australia, allow direct marketing of Class I devices with no premarket assessment. Some require a notification to the regulator within a certain time period after first supply. TGA is the only GHTF member which requires entry onto a register prior to marketing – and TGA spends significant resources in review of Class I applications, including document audit of a percentage of all Class I applications prior to the grant of marketing approval.

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<sup>‡</sup> Rethinking regulations: report of the Taskforce on reducing regulatory Burdens of Business. Australian Government response. August 2006

**Table 1: Medical Device Approvals by Class - Australian and US Data for FY 05/06**

Australia - TGA				US - FDA		
Risk Class	Number of Approvals	%	% excluding Class I	Type	Number of Approvals	%
Low: I	2100	45.1%	-	510(k) PMA	3179	99.1%
Medium: Is/Im/Ila/Ilb	2270	48.7%	88.7%			
High: III/AIMD	289	6.2%	11.3%			

**International Practices for Medium Risk Devices**

Given that the great bulk of regulatory effort is expended on medium risk devices, it is instructive to consider international practices for assessment of this group of devices. Table 2 summarises the premarket approval practices in all GHTF jurisdictions for medium risk devices.

**Table 2: Summary of Assessment Options according to region of supply and manufacture (Class II devices)**

Market	Country of Manufacture	
	Australia	Outside Australia
Australia	TGA assessment only	TGA assessment or acceptance of EC Notified Body certification (even if manufactured in non-EC country) (MRA with Canada pending for GMP)
Europe	3 <sup>rd</sup> Party assessment and audit for all assessable devices	
USA	3 <sup>rd</sup> Party 510(k) assessment and audit + expedited fee-free FDA review of 3 <sup>rd</sup> party report for a large subset of Class II devices	
Canada	3 <sup>rd</sup> Party assessment and audit for all assessable devices + Canadian license application which takes into account 3 <sup>rd</sup> Party report.	
Japan	3 <sup>rd</sup> Party assessment and audit for a large subset of Class II devices	

From Table 1, it can be seen that, with the exception of Australia, there is widespread acceptance of 3<sup>rd</sup> Party Assessment for medium risk devices. Furthermore the only GHTF agency that differentiates its regulatory practices for local rather than overseas manufacturers is TGA, which is the only GHTF agency which imposes a monopoly of assessment over domestic manufacturers for medium risk devices.

Third party assessors are in many cases accredited in all GHTF jurisdictions (except Australia). Given the existing TGA practice of accepting CE certificates of overseas manufactured devices from European Notified Bodies in lieu of TGA certification, this means that it is possible for a manufacturer to deal with a single assessor to obtain approvals in all GHTF jurisdictions, including Australia, **unless the product is made in Australia** in which case an application to TGA is required.

For manufacturers, use of such a 3<sup>rd</sup> party assessor presents a very considerable saving in costs:

- multiple reviews can be conducted as part of a single audit visit, and
- given that the document set is common (the GHTF “STED”) multiple approvals can be based upon assessment of a single Technical File.

This is reinforced in the FDA’s statement<sup>§</sup> of its third party review programme:

**“Advantages to using this program**

*During fiscal year 2002, 510(k)'s reviewed by Accredited Persons received FDA marketing clearance in an average of 77 days after initial receipt by the Accredited Person - 29% faster than comparable 510(k)'s reviewed entirely by FDA. Most Accredited Persons have specialized expertise in areas that may be helpful to 510(k) submitters, such as device testing, standards, or foreign regulatory requirements. Further, Accredited Persons have headquarters throughout the United States, in Europe, and in Taiwan, and have additional offices elsewhere, so they often can provide local service”*

### **Priorities for Future International Agreements**

From the perspective of an Australian manufacturer of medium risk devices, bilateral MRAs are almost irrelevant, as access to all the major (GHTF) markets is already available from a range of 3<sup>rd</sup> party assessors. Given the size of those markets relative to Australia and the convenience, timeliness and relative cost of third party assessors, Australian manufacturers are forced into an invidious choice of either foregoing their home market, relocating manufacturing offshore or duplicating their regulatory costs for a small increase (approximately 5%) in total market access.

Priorities for future bilateral MRAs are more pressing for importers of devices. For this group it is a straightforward question of the most likely origin of the import and its existing overseas certification. Given the current Australia-EC MRA and TGA acceptance of CE certificates for Class II devices, this essentially means devices that are not currently CE marked. Given that almost all Australian imports will have been assessed and approved in their country of origin, the priorities for future MRAs reduces to a simple matter of the most likely source of the (non-EC) import i.e.: USA, followed by Japan and Canada.

Development of the few current international agreements has been painfully slow, with considerable effort given to trial periods of confidence building. Many of the challenges surrounding the development of such agreements have centred on public health sensitivities with regard to the higher risk category devices. It is clear that the

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<sup>§</sup> US FDA - <http://www.fda.gov/cdrh/thirdparty/thirdparty-about.html#1>

most benefit is to be gained by concentrating efforts on streamlining of regulatory processes for medium risk devices. Therefore it is argued that opportunities for development of international agreements specifically for medium risk devices should be considered as this may circumvent some of the concerns attached to higher risk devices and expedite the development of MRAs. This approach may also be a more straightforward way to build confidence between jurisdictions.

In this discussion of immediate future priorities for international agreements, there is an implicit assumption that consideration of such agreements is limited to the sophisticated regulatory jurisdictions of the GHTF members. However such discussion would not be complete without acknowledgment of the emergence of very large manufacturing capabilities in non GHTF countries, especially China and India and the need for a strategic consideration of the developing regulatory regimes in these and other Asian and South American Countries and the possibilities for future cooperation.

### **Summary**

In summary, the existence of international MRAs is irrelevant for Class I devices, of lower numerical significance and greater technical difficulty for Class III devices but is of very great importance for medium risk devices, which is also the group of devices for which availability of 3<sup>rd</sup> Party Assessment is most widespread.

### **RECOMMENDATIONS:**

1. That TGA as a matter of urgency considers implementation of the use of 3<sup>rd</sup> Party conformity assessment for all Australian manufacturers, at least for medium risk devices.
2. That all negotiations of Future MRAs be conducted in the context of and allowing for 3<sup>rd</sup> Party Assessments.
3. Opportunities for development of international agreements specifically for medium risk devices should be considered.
4. That priorities for future international agreements should be focussed on mutual recognition of both product and manufacturing assessments in the order USA, Japan, Canada.
5. That longer term strategic consideration of international agreements should include significant non-GHTF markets.