



Medical Technology
Association of Australia



*Review of the Transparency of
Therapeutic Goods Administration
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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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1. Executive summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to respond to the review of the transparency of the Therapeutic Goods Administration (TGA) and commends TGA on opening up its current processes for comment and review.

TGA performs an integral role in ensuring the safety of Australians in using therapeutic products. This role should be communicated in more detail, with improved education on the processes that TGA employs to ensure the safety and efficacy of the therapeutic products made available to Australian citizens. Improved understanding of these processes will assist to improve public confidence in Australia's regulatory system and the therapeutic products which it regulates.

MTAA has proposed reforms which improve transparency for industry as users of the regulatory system. These include improvements to the way in which TGA communicates with companies, the consistent use of guidance to direct decision-making, and complaints handling. Industry has many similar objectives to other users of TGA's information, including healthcare professionals and the public. All have an interest in a robust regulatory system which is well understood and accessible.

2. About the medical technology industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. The medical technology industry manufactures many products that contribute to the health of Australians. These include consumable healthcare products such as wound care products and syringes, implantable products such as cardiac and orthopaedic devices, operating theatre equipment, diagnostic imaging equipment and high technology products such as robotic surgical equipment. The medical technology industry had sales in Australia of more than \$7.6 billion in 2009/10 and employs more than 17,500 people. It is strongly research-based, often working closely with healthcare professionals to design and develop products for improved patient benefit.

3. Improving the transparency of TGA – general comments

MTAA appreciates the opportunity to contribute to the review to improve transparency of TGA¹. MTAA believes that TGA has a world class reputation for the quality of the regulatory systems it has in place but that the processes that are used to ensure the quality, safety and efficacy of regulated products is often not well understood, and even more poorly communicated. This can undermine public confidence in the processes and in the regulated products.

Most products which are manufactured by the medical technology industry are highly regulated, with assessment on a risk basis. The higher the risk of the device, the greater the evidence required to support registration. Lower risk products require much lower levels of evidence and can be registered on manufacturer's declaration.

There are two focus areas of TGA activity in regulating medical devices – pre-market assessment of the evidence to support the class of registration, and post-market

¹ <http://www.tga.gov.au/consult/cons-transparency.htm>

surveillance to ensure that the product remains safe and efficacious when used on the patient population. TGA is assisted in its decision-making by reviews undertaken by the Advisory Committee on Medical Devices (ACMD). The ACMD provides independent medical and scientific advice to the Minister and TGA on safety, quality and performance of medical devices supplied in Australia including issues relating to premarket conformity assessment and post market monitoring. To this extent it plays an important role in oversight of devices.

While recently there has been a degree of increased transparency of TGA decision-making, including the release of the summary record of ACMD's recommendations for registration, there is much more than can be achieved to improve transparency of TGA processes for health consumers and industry alike. MTAA supports improved transparency for the benefit of health consumers and industry.

However improved transparency needs to be moderated by the necessity of managing commercially sensitive information in highly competitive markets. Improved transparency is not the same as full disclosure. Commercial sensitivities about the release of information advantageous to a competitor where it does not add to the public's understanding of TGA processes in a meaningful way need to be respected. This is especially the case in the pre-market environment where companies may be competing to obtain a first mover advantage. In the post-market environment it is appropriate to have disclosure of products removed from the market, either voluntarily by sponsor or as a result of an adverse event finding, provided this occurs once the process is complete. It is prejudicial to make public the process for removal before that time when additional evidence may be produced which results in a different decision.

MTAA has followed with interest the recent changes introduced by the US Food and Drug Administration (FDA) in implementing transparency reforms to the workings of that body. In June 2009, FDA Commissioner Dr Margaret Hamburg launched FDA's Transparency Initiative and formed an internal task force to develop recommendations for making useful and understandable information about FDA activities and decision-making more readily available to the public, in a timely manner and in a user-friendly format.

Among the reforms is a simplified website with readily accessible information tailored for consumers and for industry. This provides a good starting point for reforms to the range of disclosed information which TGA might implement.

4. Improving the transparency of TGA – industry specific comments

The call for submissions in response to the review seeks specific input from industry on:

- The ways that TGA could provide greater assistance to industry in the evaluation and registration, listing or marketing processes
- Any issues which industry has encountered in regards to the transparency of TGA processes and decision-making.

As part of its transparency initiative, in January 2011 FDA released its report on improving transparency to the regulated industry². This is the third report in FDA's transparency program. As the Taskforce points out in its report, in order for FDA to succeed in its mission to protect and promote public health through oversight of regulated products, FDA must clearly communicate standards and expectations to industry. These extend to the areas covered by TGA's review – evaluation and registration process.

4.1 Improving communication

Among the recommendations in FDA's Transparency Task Force Report are several which address mechanisms for improving communication between the agency and industry. Not least of these is the creation of a centralised web-based repository of information to assist industry. The result, FDA Basics for Industry³, provides a useful toolkit of information essential to support industry's understanding of FDA's processes.

In other initiatives FDA will provide regularly updated organisational charts to enable sponsors to know who they need to contact and provide a general email address for each therapeutic industry sector to submit general regulatory questions with a commitment to respond to general questions within five business days (or provide a time by which the question will be answered).

TGA may be reluctant to enable processes for direct contact between an applicant and an assessor because of the impact it may have on TGA staff resourcing, by drawing the person away from the assessment task. Another challenge for TGA is the level of staff turnover which may mean that staff are not always sufficiently up to date to answer queries. However the ability to speak directly with an assessor or to answer a specific question when it arises should smooth the registration path. These are separate queries from more general questions which can be channeled through a central contact point.

MTAA supports access to a common email address for general queries and a commitment to set times to respond to queries. In its Customer Service Charter⁴ TGA pledges to acknowledge letters and emails within five working days and ensure that its responses are timely, relevant and easy to understand. Where a full response cannot be provided within this time, TGA undertakes to when a response can be expected and keep the correspondent informed on progress if the issue is complex. TGA also publishes a general address for email queries. However the experience of many in the industry is that queries to this address go unanswered and certainly not within the time commitment set out in the Customer Service Charter. At the very least TGA should ensure that its current commitments are implemented.

Common queries can be gathered into a section on the website for frequently asked questions. While several pages on the TGA website offer FAQ sections, they are not located in one place and require expert navigation to arrive at the correct FAQ. If this

² US Department of Health and Human Services, Food and Drug Administration Transparency Task Force, *FDA Transparency Initiative: improving transparency to regulated industry* January 2011 <http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm>

³ <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm2024416.htm>

⁴ <http://www.tga.gov.au/docs/html/custserv.htm>

is challenging for experienced applicants it must be much more so for inexperienced startup companies, consumers and healthcare professionals.

4.2 Improving guidance

The publication of guidance documents is one of the most useful ways that TGA can provide standardised information for the benefit of industry. In April 2010 TGA published the Australian Regulatory Guidelines for Medical Devices (ARGMD)⁵ which for the first time created a consolidated reference document detailing the Australian regulatory requirements for medical devices. This has been a useful development although the usefulness could be improved by the publication of updates between editions. There needs to be a clear process for regular review and updating to ensure that the document continues to reflect current practice, as developed in consultation with industry.

A further action that might be taken to improve consistency of approach is for TGA to publish 'rulings' when it makes a decision following an application for a novel device. While MTAA accepts that each application must be examined on its merits, there would be significant benefit, and cost savings, for later applicants with a similar product to benefit from understanding the decision which is taken and framing the application accordingly.

One area of guidance addressed by FDA in its transparency review is that of dealing between industry and FDA officials. While there may be internal guidelines for staff members of TGA, MTAA suggests that visibility of these guidelines would benefit industry and officials and act as a brake on inappropriate communications. At the very least it would serve to educate the public, as well as industry, on the appropriateness of interaction. It would underpin the arrangements for direct contact between industry and officials who are assessing a product application.

TGA might also consider making available its internal checklists (or a version of them) to assist applicants in ensuring that their documentation is complete, thereby streamlining the assessment process.

4.3 Improving the transparency of decision-making

There are several mechanisms that could be deployed to improve the transparency to industry of TGA's decision-making. One suggestion examined by the FDA in its transparency review, and supported by MTAA, is use of an application tracking mechanism which would enable an applicant to identify the stage in the approval process that its application had reached at any given time. MTAA understands that Health Canada employs a similar tool which has the added benefit that staff are not diverted by having to answer routine inquiries on the status of progress of an application.

MTAA supports the use of statutory timeframes to provide a degree of predictability of progress with an application and the likely date by which an application will be approved. This will also enable a comparison of TGA performance against other regulators.

⁵ <http://www.tga.gov.au/devices/argmd.htm>

An issue that has been raised consistently by MTAA members and by industry more generally in the public forums during the course of the transparency review, has been the lack of consistency in decision-making by TGA. There is a widespread concern that on occasion decisions appear not to be taken by reference to published guidance, or that the relevant guidance was not made known to the company. This could be addressed through improved reasons for decision with reference to a specific guideline or prior determination or ruling as suggested in paragraph 4.2.

In a similar vein, companies need to understand the reasons for rejection of an application. MTAA has been told of circumstances where a company reapplies for registration rather than bear the cost of a review because it has inadequate information on which to base a request for review.

In general industry supports increased transparency of material which supports the registration of a product. The exception to this is material which is proprietary to the company. Material that might be made public in the medical device sphere is akin that made available in the AusPARS for prescription medicines. An AusPAR for a medical device might include information on the evaluation of the device and the considerations that led TGA to approve or not approve the application.

While companies might support the publication of a rejection of an application (together with the reasons), they do not support publication of the fact that an application has been made or withdrawn. There are commercially competitive imperatives in both these actions that could be damaging to a company without any benefit to anyone other than a competitor. An application may be withdrawn for a variety of reasons. Until such time as an application has been processed, and product registered, the information should not be disclosed.

4.4 Improving complaint handling

MTAA supports improved transparency in the proceedings of expert committees which investigate complaints about a medical device. However the content of the complaint and the product under review should not be made public until a decision has been reached and recommendation for removal of the product has been accepted. To make such commercially sensitive information available prematurely could cause unreasonable detriment. However a complaint must be dealt with expeditiously to ensure that any product which is thought to have adverse outcomes is speedily reviewed and removed.

One area of complaints handling of concern to industry is where a company identifies the illegal supply or promotion of a product. At present there is little transparency of the process by which the complaint is handled. There needs to be acknowledgement that the complaint has been received as well as visibility that the complaint is being actively investigated. The TGA Customer Service Charter has a five day commitment to respond to a complaint but in practice this is rarely observed.

4.5 Commitment to funding of transparency initiatives

TGA is funded through the fees and charges levied against industry. Many of the proposed reforms are to ensure increased transparency in the public interest, and not in the interest of industry alone. For these reasons Government should consider an appropriate level of funding for transparency initiatives.

5. Improving transparency for benefit of other users

MTAA strongly supports improved capability within TGA to manage its communications with the public, with healthcare professionals and with industry. TGA is an essential participant in the public health discourse in Australia and should have the capacity to contribute on its own behalf. While TGA may have a range of critics it must be recognised that it performs an essential role in protecting the health and well-being of Australians and should be able to communicate its own messages on how it performs this role and the processes it uses to ensure the safety and efficacy of regulated products.

All those interested in TGA's processes would benefit from improvements to the usability of its principal database, the Australian Register of Therapeutic Goods (ARTG). MTAA welcomes the recent improvements in searchability of this database and encourages ongoing improvements. One common complaint is the lack of information on products which have been removed from the ARTG. While this information is made public it is not readily accessible.
