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PRESIDENT
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The Coordinator
Office of Device Administration
Therapeutic Goods Administration
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Email: devices@tga.gov.au

Re: Comment on Reforms in the Medical Devices Regulatory Framework

Dear Coordinator

Thank you for the opportunity to comment on the Therapeutic Goods Administration's (TGA) discussion paper on reforms in the medical devices regulatory framework.

The Australian Health Insurance Association (AHIA) represents 23 Private Health Funds, which collectively insure approximately 94 per cent of the 11.5 million Australians who hold some form of private health cover.

The AHIA is supportive of all proposals by the TGA which will result in a more rigorous assessment process, ultimately ensuring all health consumers will be protected by the highest safety and quality standards, particularly in regards to higher-risk medical devices.

The AHIA's objectives in accessing any medical devices regulation changes are to ensure devices are:

1) safe for the life of the device/patient relationship;
2) provide clinically-effective outcomes;
3) available at a reasonable cost that is comparable to other developed health economies;
4) represent a good investment vs. alternative health technologies; and
5) available in a timely-manner in the product life cycle and not restricted or slowed to market due to excessive or burdensome regulatory controls.

The AHIA understands that some of these objectives have competing interests but believes that the objective of any regulatory system should be to ensure that patient safety is of the highest priority.

Safety, Monitoring and Visibility

It is apparent from the TGA's own safety monitoring that the number of adverse incidences have been increasing steadily over the time that such data has been available. It is apparent this data has not been updated/reported since June 2009 which is of major concern as a key requirement for such a regulatory agency is transparency.

Whilst it is understood that a large number of product recalls may be actioned by the TGA they are not reported on the TGA site. Again such visibility is essential, even given the TGA's concerns over the negative impact it may have on the industry to report such failures. A system similar to the United States Food and Drug Administration's (FDA) M.A.U.D.E. Adverse Event and Recalls sites would be a suitable performance benchmark.

Risk Adjustments

The reclassification of hips, knees and shoulder joint replacement implants from Class IIb to Class III is to be commended in that it brings Australia into line with European regulatory practice and as most manufacturers operate across world markets the cost implications to industry should have been offset already. The direct costs of administration by the TGA would potentially be re-couped through system efficiencies identified by the Health Technology Assessment Review.

Interestingly, the European Directive as reported was to reclassify implanted load-bearing components that function in a similar way to the natural joint. We are unsure of the European requirements to capture data at a system level and then down to component level but this approach has a cost implication and needs to be co-ordinated with device identification rules as canvassed later.

The AHIA would recommend the inclusion of all articulating load-bearing devices such as ankles and elbows etc. Of particular concern are orthopaedic prostheses used in a spine as the potential to do harm is significantly higher in this clinical setting.

Raising the risk level classification in response to long-term patient data registers reports may result in a significant number of devices requiring reclassification when registers start

to accumulate long-term performance. Classification based on the devices capability of potentially doing harm should continue to be the key.

Device Identification and Tracking

To ensure that any system is responsive it is important to be able to correctly identify the devices of interest and more importantly their location at any particular point in time. The FDA is working towards a unique identification numbering system with appropriate descriptions. The Australian National e-Health Transition Authority (NeHTA) has been working to the same end with a commercial imperative by advocating the adoption of Global Trade Item Numbers (GTIN).

It would seem sensible not to duplicate efforts to ensure that any identification system is universal across the health system. The AHIA would welcome as such an identification system offering the type of details as evident on the National Product Catalogue (NPC) which accounts for all components of complex joint systems.

Tracking issues obviously are a key accountability of the sponsor but secondary sourcing is available through patient data registers which again should be publicly operated (by the TGA) with no vested interests driving the collection or release of results. The registers are a valuable information source and should be used to educate and inform the decision making processes of all stakeholders resulting in better clinical outcomes and system efficiencies.

With high-value, high-risk devices and the focus on e-health there is the potential for a dynamic tracking system with a post-implant opt in/out option at the universal patient data record level. A re-identification process for medical devices would be a significant investment and implementation exercise and as such should possibly look at the whole-of-health industry requirement being placed for the best e-health outcomes.

It would not be commercially appropriate for the TGA to publish device information beyond clear identifiers and what is normally captured in the approval process. Rather as advertising standards are legislated currently by the TGA it is not unrealistic to place this accountability back to the sponsor and in preventing duplication of activity assigning the repository as the NPC, which can also provided appropriate web links to sponsors where dynamic data updates may be required. Issues of device failures or near miss incidents should be visible on the TGA system but all other application issues should be sourced through the NPC.

The AHIA believes that the sponsor side of the industry would be keen to see visibility of application or review progression and the opportunity to provide feedback in a dynamic fashion. Similarly, we would be keen to have visibility of devices that have been declined to list during the transitional process, or removed from the Australian Register of Therapeutic Goods for any reason, as a number of our members deal with medical devices on an ex-gratia basis and such timely advice is crucial to them and the industry as a whole.

Clinical Effectiveness

There are mechanisms through the Commonwealth Prostheses Listing processes to access the relative clinical effectiveness of devices coming to the private health care market. This assessment should utilise best available data and be relevant to the Australian clinical setting. Such reviews should potentially be conducted at the point of market entry and shared between the public and private constituents. There are potentials to achieve efficiencies in the system as the technical and clinical resources utilised to access safety and efficacy would be suitably skilled to cover clinical assessment.

AHIA Comments on Specific Proposals

Proposal 1 - Recommend.
Note: with expanded scope of devices and ensuring a strict two year transition period.

Proposal 2A - Recommend.
Note: ensure alignment of risk stratification rules with Australia and robust implementation of proposal 2C (i).

Proposal 2B (i) – Recommend.
Note: periodic reviews should also align with private health concerns as a number of devices and procedures occur primarily in this setting. Also as per Proposal 1, we would think it appropriate that spinal prostheses are included as Class III devices.

Proposal 2B (ii) - Recommend.
Note: ensure Intra-ocular visco-elastic fluids are inclusive of liquids and gases. We would also like to see included all device accessories integral to the operation of an Intermittent Pulse Generator in either a coronary, spinal or neural setting.

Proposal 2C (i) - Recommend.

Proposal 2C (ii) - Recommend.
Note: the TGA should investigate the potential accreditation process being conducted by a third party body either locally (QA focused) or overseas.

Proposal 3 (i) - Recommend.
Note: please refer to earlier comments that the NPC should be utilised to capture device details across industry.

Proposal3 (ii) - Recommend.
Note: comments as per 3(i).

Proposal 4 - Recommend.
Note: comments as per 3(i).

The AHIA consider the proposals put forward by the TGA to be generally positive and contributing to improved health outcomes for all Australians. We encourage the TGA to continue to be more transparent in its processes to ensure greater quality and safety outcomes.

I am available on 6202 1000 to discuss these matters raised by the AHIA in further detail.

Yours sincerely

HON DR MICHAEL ARMITAGE
CHIEF EXECUTIVE OFFICER

17 December 2010