TGA RELEASED REGULATION IMPACT STATEMENT (RIS) EXPOSURE DRAFT OUTLINING PROPOSED TIGHTER CONTROLS FOR CONFORMITY ASSESSMENT

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UL’s Medical Regulatory Advisory services team provides the support needed to help you and your organization understand each country’s unique requirements. This article provides a summary of the recently proposed tighter control for conformity assessment by the Australian Therapeutic Goods Administration for high risk medical device.

Background

The Therapeutic Goods Administration (TGA) released a proposal paper, Changes to premarket assessment requirements for medical devices. This paper focused on two elements of the premarket assessment process:

1. Conformity assessment
2. Approval for marketing through inclusion on the Australian Register of Therapeutic Goods (ARTG).

It was released on January 2013 followed by extensive industry and stakeholder consultation that closed on March 15, 2013. The proposed changes to legislation will be implemented by TGA and could affect all companies entering the Australia market, particularly new medical devices which are high risk. Upon the consultation closing, TGA released the Regulation Impact Statement (RIS) which examines the impacts of the proposed regulation and a range of alternative options while meeting the government’s policy objectives.

The exposure draft RIS document provides details on the proposed changes and was released for comment from all parties affected by these reforms. The intention of this exposure draft RIS is to maximize transparency by circulating the draft to the industry before a final document will be provided to the government. Some topics, such as the analysis of costs, will require industry input to be completed, and so the document is expected to be edited substantially before it is finalized.

Proposal

The proposal paper released in January outlined three proposed regulatory reforms for premarket assessment of higher risk medical devices:

— Proposal A: Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion, through:
  • Targeting of mandatory audits for a wider range of high risk medical (but not IVDs); and
  • Increased assessment of additional evidence of conformity (but not IVDs);
— Proposal B: Publication of medical device regulatory decision (including IVDs);
— Proposal C: Abolition of requirements for TGA conformity assessment for Australian manufactures of lower Class medical devices (including IVDs).

Objective

The RIS exposure draft examined the reform proposals to provide assurance that higher risk medical devices approved do not compromise public health and safety while at the same time:

1. Support timely availability of medical devices to the Australian public;
2. Minimize unnecessary regulatory burden and costs on the medical device industry;
3. Improve the ability for TGA to target emerging risks in a timely manner;
4. Continue Australia’s commitment to promoting alignment of international medical device regulation.

Assessment of Proposal

Based on the feedback from the consultation process, the RIS amends the earlier proposals and outlined the following changes under the new proposal:
1. TGA would expand the range of products subject to mandatory audits prior to ARTG inclusion (excluding IVDs at this stage given the IVD transition is continuing).

The two elements of this proposal are:

— Expand the requirement for a mandatory audit to cover specific implantable and long term surgically invasive Class IIb medical device. This is in addition to applications for the kinds of devices currently referred to in Regulation 5.3.

— Introduction of the new Level 3 audit for AIMD and Class III implantable and surgically invasive medical devices.

• May include review of the Design Examination report, desk audit of the manufacturer QMS, and raw clinical data underpinning the conformity assessment report rather than the expert clinical report as in Level 2 audit.

• The estimated cost of the new Level 3 audit would be AUD $16,382, which would be experienced by approximately 261 applications each year in Australia, costing AUD $4,275,609 per annum to the industry. (Full cost of a Level 3 audit would cost AUD $22,974 as published by the AusPAR style document)

2. TGA would publish the medical device regulatory decisions (including IVD) in a format similar to the current AusPAR (Australian Public Assessment Report for prescription medicines). The final format would need to be further consulted with stakeholders before finalizing. This is to ensure TGA can protect and meet industry confidentiality requirements while providing appropriate information to the Australian public about the decision making.

3. Abolishes the requirement for Australian manufacturers of medical devices to have TGA conformity assessment for all medical devices except for Class 4 IVDs. Therefore, an Australian manufacturer could have a European notified body issue their conformity assessment certificates rather than being limited to going to TGA. At the present, since the differences in regulation for Class 4 IVDs are too significant to allow TGA to accept European certification, all Class 4 IVDs will be excluded from this proposal until the European reforms to adopt the GHTF model.

Summary

Based on the TGA assessment, the proposed reforms fulfill the objectives of the RIS. It will help ensure that high risk medical devices approved do not compromise public health and safety with greater scrutiny of a wider range of medical devices. At the same time with the minimizing of unnecessary regulatory burden and associated costs, it balances the increased scrutiny against retaining the timely availability of medical devices to the Australian public. Lastly, the improved transparency from the reform is in line with international regulators and contributes to Australia government’s international harmonization agenda for medical device regulation.

Once the RIS is finalized with comments and feedback from industry and stakeholders, it will be provided to the Australian Government to inform decision making on the reform proposal.

UL Medical Device Regulatory Support (MDRS) Services

UL’s MDRS team provides the support needed to help you and your organization understand each country’s unique requirements and receive global
regulatory approvals for your medical and IVD devices. This support includes aspects of clinical, non-clinical, technical file submission, quality system inspections, radiation registration, FDA remediation, risk management and the steps involved to submit registrations.

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1Australian Government Therapeutic Goods Administration - Changes to premarket assessment requirements for medical devices: Proposal paper

2Australian Government Therapeutic Goods Administration - Consultation: Regulation Impact Statement: Changes to premarket assessment for medical devices