The TGA's Processes for Review and Decision Making for Medical Devices

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November 2012

Today's Overview

1. The TGA's regulatory system
2. The assessment process
3. Good decision making

TGA's Regulatory System

The Framework

- TGA adopted a new regulatory framework for medical devices in 2002 (5 year transition)
- New regulatory framework for IVDs commenced in July 2010 (4 year transition)
- Both implement the recommendations of the Global Harmonisation Task Force

The Framework

- classification based on risk to the patient, user or the environment
- manufacturer must demonstrate compliance with “essential principles” that describe the safety & performance of a medical device
- proof of compliance is demonstrated through a conformity assessment procedure

Classification - MDs

- Class III and Active Implantable (AIMD) – highest risk
- Class IIb – high to moderate risk
- Class IIa – moderate to low risk
- Class Is and Im – low risk, but special requirements
- Class I – lowest risk

Classification - IVDs

- Class 4 – high public health risk, high personal risk
- Class 3 – moderate public health risk, high personal risk
- Class 2 – low public health risk, moderate personal risk
- Class I – low personal risk
- Risk defined in terms of risk of an erroneous result

Conformity Assessment Procedures

- Conformity Assessment procedures set down the activities to be undertaken by a manufacturer to demonstrate conformity with regulatory requirements
- Range of procedures available that are appropriate to the risk classification and type of the medical device
- Regulatory authority assesses manufacturer's application of the conformity assessment procedures, in accordance with risk classification of the device

Implementation

- Manufacturer must comply with EPs and CAPs
- Australia imports ~85% of its medical devices
- Require system that recognises overseas certification, but gives assurance of performance in accordance with Australian requirements

Implementation

- Conformity assessment by the TGA required for
  - Australian manufacturers
  - Devices of animal/microbial/recombinant origin
  - Devices incorporating a medicine
  - Class 4 IVDs
- CE certification generally accepted for other devices
  - Document review for Class III and AIMD and some IVDs (Application Audit)
- Must have DoC to Australian requirements

Conformity Assessment

- Requirements aligned with GHTF recommendations
- Similar to European system
- Manufacturer requires QMS in accordance with ISO 13485
- Manufacturer must generate evidence of compliance with the Essential Principles for each device manufactured – STED, Design Dossier

The Assessment Process

Assessment Resources

- Conformity assessment section within ODA
- Team leaders
  - Engineering
  - Biocompatibility/toxicology
  - IVDs
- Clinical section within ODA
- Other areas of TGA
  - Sterility
  - Biological safety
  - OMQ auditors
  - TGA Laboratory staff
  - Medicines evaluators if required
- External resources
  - Contractors

Review Process

- Application received, sent to Stream Leader – co-ordinator appointed
- Initial screening – identifies
  - Any major deficiencies
  - Type and depth of assessment required
  - Expertise required
  - Need for on-site audit
- Assessment plan developed
  - Need for referral to Advisory Committee?

Review Process – Assessment Components

- Engineering/electrical safety
- Biocompatibility/toxicology/stability
- Clinical evidence/risk assessment
- Sterility/preservative efficacy/disinfectant efficacy
- Biological safety
- Evaluation of ancillary medicine
- IVDs – in accordance with GHTF STED requirements/performance testing
- QMS audit – either on-site or desk-top

Review Process – Depth of Review

- Dependent upon class of device
- For Class III MDs and Class 4 IVDs, equivalent to the review of a prescription medicine
  - Test protocols
  - Reports etc
- For Class IIb MDs and Class 3 IVDs – review of critical aspects and check that technical file is complete
- For lower risk classes, just a check that the technical file exists and a sampling of reports for critical aspects

Review Process

- Co-ordinator initiates review
- Sends requests for assessment to relevant team leaders
- Receives assessment reports
- Sends requests for further information to sponsor, where necessary
- Refers responses back to individual assessors
- Collates assessor's reports, prepares final assessment report, with recommendations
- Stream leader reviews report and recommendations

Review Process - ACMD

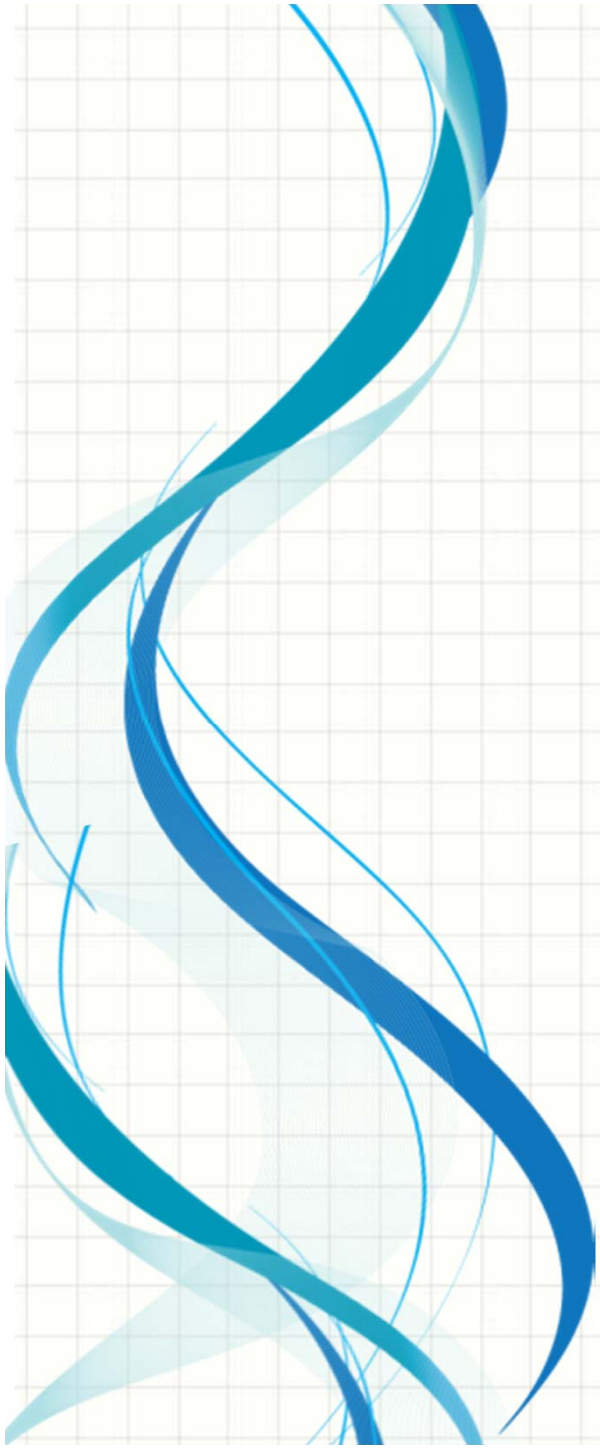
- If application goes to Advisory Committee, Stream Leader or Section Head summarises assessment reports and prepares submission to ACMD (Delegate's Overview)
- Assessment reports (all components) sent to sponsor and Committee
- Sponsor has right of response to address issues raised – no new data allowed

Review Process - ACMD

- ACMD appoints rapporteurs, to address committee
- Committee makes recommendation on approval, approval with conditions, or rejection
- TGA makes final decision

Post-review Process

- Team leader reviews assessment report and ACMD recommendations, if relevant, and if satisfied, prepares conformity assessment certificates or letter of rejection
- Section Head approves report and authorises issue of conformity assessment certificates if relevant



Good Decision Making

Documentation of Decisions

- Appeals processes
  - Appeal to Minister - Internal Review
  - Administrative Appeals Tribunal
  - Court action
- Need to justify and support decision
  - Transparency
  - Consistency
  - Fairness
- FOI processes
  - File keeping, records

Documentation of Decisions

- Understanding of legislative framework
  - Ensure the decision is in accordance with regulatory powers
  - Made by a person with the relevant authority
- Clear Statement of Reasons
  - Related to the clauses of the regulations/guidelines etc
  - Addresses compliance with Essential Principles
  - Takes into account information supplied

QUESTIONS?