How the TGA uses MDSAP

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Process

• Approval for supply in AU; three stage process
  – EU styled Conformity Assessment (CA)
  – Submission of Manufacturer’s Evidence
  – Marketing Authorisation – ARTG inclusion (MA)

• CA has both product and QMS components
  – MDSAP is to provide evidence of a Manufacturer’s QMS for regulatory purposes
  – Manufacturer = Name on labelling
Conformity Assessment

• AU Regulations require that some products must have TGA CA certifications for product and QMS
  – Incorporate medicinal substances
  – Incorporate animal material in the design or production process
  – Incorporate material of a microbial or recombinant origin in the design or production process
  – Class IV IVDs (Blood testing, Disease screening)

• Some of these are loosely referred to as “combination” products
Manufacturer’s Evidence and Marketing Authorisation

• The Australian Sponsor submits
  – Manufacturer’s QMS Certification
  – Where relevant, Product Design Certification

• Is a pre-requisite for marketing authorisation

• MA allows the TGA to make the final decision as evidence may come from many sources;
  – EU Notified Bodies
  – Other Comparable Overseas Regulators (MDSAP)
  – Manufacturers or Critical Suppliers
# MDSAP use for TGA CA

<table>
<thead>
<tr>
<th>TGA Issued CA Certification</th>
<th>MDSAP Use by TGA</th>
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</thead>
</table>
| For Schedule 3 Part 1 for Regulation 4.1 devices;  
- Incorporating a medicine  
- Animal, microbial, recombinant origin  
- “combination” products  
- Class IV IVDs | Audit Reports for Manufacturers & Critical Suppliers used to abridge TGA’s QMS compliance verification audits for initial/surveillance/recertification.  
**Additional information / audit likely** required by TGA within the 5 year CA Certification cycle |
| For all other currently issued TGA QMS Certifications for the CA procedures | Eligible to replace TGA issued QMS Certifications for the CA procedures |
# Evidence for AU CA Procedures

<table>
<thead>
<tr>
<th>Devices</th>
<th>TGA CA QMS</th>
<th>EU CA QMS</th>
<th>MDSAP QMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation 4.1 Devices</td>
<td>✔️</td>
<td>Eligible to abridge</td>
<td>Eligible to abridge</td>
</tr>
<tr>
<td>Other currently issued TGA Certificates for QMS</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Other not requiring or without CE Certification</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>All Others</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Evidence

- **Initial and Recertification Audits**
  - Full audits cover all aspects of the QMS and Regulatory Requirements

- **Surveillance Audits**
  - Elements covered over 2 audits in a cycle.

- May require the TGA to review a number of audit reports for a cycle to determine a understanding of the extent of QMS compliance.
# MDSAP use for MA

<table>
<thead>
<tr>
<th>AU Marketing Authorisation</th>
<th>Use by TGA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products that <strong>must</strong> be selected for an “Application audit” prior to MA (Regulation 5.3)</td>
<td>MDSAP Certifications initially accepted as Manufacturer’s evidence. Audit Reports may be used to review QMS compliance prior to MA</td>
</tr>
<tr>
<td>Any other products that <strong>may</strong> be selected for an “Application audit” prior to MA</td>
<td>QMS Certifications initially accepted</td>
</tr>
<tr>
<td>Other products for which there is no EU QMS Certification</td>
<td>QMS Certifications initially accepted</td>
</tr>
<tr>
<td>Post-Market Surveillance</td>
<td>Use by TGA</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>TGA Issued CA Certificates</td>
<td>Audit Reports and status of certification used for monitoring continuing QMS compliance</td>
</tr>
<tr>
<td>Adverse Event / Recall follow-up</td>
<td>Audit Reports used for monitoring continuing QMS compliance and implementation of corrective action plans</td>
</tr>
</tbody>
</table>
Post-Market

• 5-Day Notices
  – Grade 5 or more than 2 Grade 4s
  – Fraudulent Activity
  – Public Health Threat

• Reviewed by Device Vigilance and Monitoring Section for action or referral
  – Adverse Event Investigation
  – Recall Action
  – Suspension / Cancellation of the ARTG inclusion
  – Enforcement actions
Comparable Overseas Regulator Guidance

Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices

For abridgement of TGA conformity assessments and as supporting information for applications for ARTG inclusion
Other uses

• To promote regulatory convergence
  – Format and content of Audit Report
  – Consistent requirements for 3rd parties operating on behalf of the participating RAs
  – Sharing of resources and information with Regulatory Authorities
Contact / Questions

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