ANZTPA
Opportunities for improvement
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Smith & Nephew, Advanced Surgical Devices
Statement of Intent

27 November 2012

On 20 June 2011, the Prime Ministers of Australia and New Zealand reaffirmed their commitment to the establishment of the Australia New Zealand Therapeutic Products Agency (ANZTPA) to administer a joint regulatory scheme for therapeutic products. This reaffirmation acknowledged that the New Zealand Government will introduce a separate scheme to regulate certain natural health products in the New Zealand market.

Prime Ministers have agreed that a three stage approach over a period of up to 5 years will be adopted to progressively achieve this goal by mid-2016. The three stages involve the two countries’ regulators, Australia’s Therapeutic Goods Administration (TGA) and New Zealand’s Medicines and Medical Devices Safety Authority (Medsafe).

1. Commencing a program of Business to Business (B2B) projects and work sharing. This will enable the separate regulatory systems of each country to be supported with single sets of data, expertise and internal administrative advisory processes. Improved regulatory practices will lead to immediate benefits including improved public health outcomes and better value for money for industry and governments with greater efficiency in regulatory processes.

2. Establishing a Single Entry Point for industry and agreeing a common trans-Tasman regulatory framework. While each country will retain its own regulator and continue to make its own regulatory decisions in this stage, business will benefit from a significant reduction in red tape with only one set of requirements to operate in two countries. The creation of the new world class regulatory framework will further increase the public health benefit for consumers, reduce the regulatory burden for industry and enhance the reputation of New Zealand and Australian therapeutic products on the world market.

3. Increasingly Integrate Business Operations, including single operational and decision making mechanisms. Following passage of implementing legislation, ratification of the Treaty and final confirmation of arrangements, the separate national regulators will be absorbed into the ANZTPA. At this time New Zealand will be able to decide whether to maintain its separate scheme to regulate certain health products, or bring those products under ANZTPA.

This statement of intent reflects a significant step in the lengthy process since the Treaty between Australia and New Zealand was signed in 2002 envisaging all therapeutic products being regulated under a joint regulatory scheme by a single regulatory agency.

The agreement to establish a single Australia New Zealand Therapeutic Products Agency is also another important step forward in the development of closer economic relations between Australia and New Zealand. In addition, deliverables from this project such as regulatory harmonisation will strengthen the broader relationship between the two countries and benefit industry in both countries.
Things that jump out....

- Improved regulatory practices
- Improved public health outcomes
- Better industry value for money
- Governments will greater regulatory efficiency
- Significant reduction in red tape
- Create a world class regulatory framework
- Reduce regulatory burden
- Enhance the reputation of Australia and NZ therapeutic products on the world market.
- Single operational and decision making mechanisms.
It all sounds GREAT!!!!
So where are we now....

- There has been little communication with industry from a medical device perspective.
- There is a common intent from both Australia and New Zealand to improve regulatory practices.
- If we are trying to achieve "the creation of a world class regulatory framework", should we not be examining lessons learnt from the current Australian framework and others around the world.
The current Australian government has a real appetite to cut regulatory red tape and ensure that Australia is open for business.

ANZTPA is an opportunity to deliver improved regulatory practices and reduce red tape.

“Openness, sharing and playing nicely together..” – Ross Blackman
With looming ANZTPA implementation on 1 July 2016

Let's not reinvent the wheel......
To examine efficiency we have to look for regulatory commonality……

<table>
<thead>
<tr>
<th>Region</th>
<th>Compliance Standard</th>
<th>Regulation</th>
<th>Submission Method</th>
<th>Adverse Event Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>Quality System Regulation (current Good Manufacturing Practice)</td>
<td>21 CFR Part 820</td>
<td>510(k) or Pre-Market Authorization (PMA)</td>
<td>Medical Device Reporting (MDR)</td>
</tr>
<tr>
<td>Canada</td>
<td>ISO 13485:2003</td>
<td>Medical Device Regulations (MDR) SOP/98–282</td>
<td>Medical Device License (MDL)</td>
<td>Mandatory Problem Reporting (MPR)</td>
</tr>
<tr>
<td>Japan</td>
<td>ISO 13485:2003</td>
<td>Pharmaceutical Affairs Law (PAL) and MHLW Ordinance #169</td>
<td>Summary Technical Documentation (STED) and Shonin</td>
<td>Similar Vigilance reporting</td>
</tr>
<tr>
<td>Australia/New Zealand</td>
<td>ISO 13485:2003</td>
<td>Therapeutics Goods Act</td>
<td>Device with existing CE Marking or Technical File/Design Dossier</td>
<td>Medical Device Incident Reporting</td>
</tr>
<tr>
<td>Rest of World</td>
<td>Some rely on ISO 13485 / some rely on Quality System Regulation and some on both</td>
<td>Some have country specific regulations or rely on other regions methods</td>
<td>Device Master Record (DMR), Technical File, or country specific submission</td>
<td>Some have processes – rely on MDR or MDV</td>
</tr>
</tbody>
</table>
Continuous improvement drives creativity and innovation.

Commonality 1 – Implementation of a quality management system

Management Responsibility
- Quality Policy and SOPs
- Quality objectives
- Management Review

QMS: ISO 13485
- Internal Audit
- Product acceptance test
- CAPA, Feedback

Product Realisation
- Design & Mfr controls
- Validation
- Clinical Evaluation
- Risk management

Customer Satisfaction
- Customer Requirements
- Management Responsibility
- Resource Management
- Product
- Measurement, Analysis, Improvement
- Measurement, Analysis & continuous improvement
- Continuous improvement drives creativity and innovation

Resource Management
- Infrastructure
- Organisation Structure
- Personnel Training

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Quality Management Systems

- Provide the road map that a medical device company needs to manage the life cycle of a device.
- Efficiencies are currently being explored by the member regulators of IMDRF through the pilot of the Medical Device Single Audit Program (MDSAP).
- It is the first step towards cross regulator confidence.
If we are confident in the assessments undertaken by EU Notified Bodies, does ANZTPA need to undertake further premarket assessment?
Commonality 3 – The requirement to report adverse events

- ANZTPA has made good progress to harmonise post market requirements
  - Joint Adverse Event Notification System (JAEN)
  - ANZTPA Recall portal
  - Trans Tasman Early Warning System
- Strengthening of post market systems makes perfect sense in monitoring the safety of medical devices.
- This echoes the proposed reforms to the EU system.
- Globally we can do better at sharing post market information from device registries (Standardisation of data sets)
ANZTPA – Can we achieve the intent?

- Manufacturers – Responsible and trustworthy application of QMS to products to demonstrate safety efficacy and performance.
- TGA and Medsafe need to work towards finding regulatory commonalities, with a system that is highly reliant on the CE mark is it appropriate that there is further premarket assessment?
- Global Regulators – Further work needs to be done towards regulatory harmonisation.
- HCPs/patients – Educated and appropriate use of medical technology to drive improved patient outcomes.
- All stakeholders – Feedback into the design of medtech to drive healthcare solutions for better patient outcomes.
Thanks for listening 😊