Australia TGA 2020-21 Business Plan

COVID-19, Digital Transformation, Regulatory Work-Sharing, Cell Therapy, and Diagnostic Tests

Richard Day
University of New South Wales
@osbornidayius

I recently discussed TGA's Business Plan for 2020-21 with John Skerritt, Deputy Secretary for Health Products Regulation in the Department of Health (with responsibility for the TGA), and asked a number of questions about the Plan in the following Q&A.

Global Forum: **Professor Skerritt, could you provide an "umbrella" overview of the Business Plan?**

John Skerritt: We have divided the Business Plan into an agenda and actions for our four activity streams:

- **Product regulation and safety** – through core regulatory activity and business process improvements.
- **Regulatory reform** –2020-21 will be the final year of implementation of the recommendations from the Review of Medicines and Medical Devices Regulation, the implementation of the Action Plan for Medical Devices, and a number of other reforms.
- **International engagement** –international information sharing, work sharing and regulatory convergence, as well as programs for regulatory strengthening and medicines testing in our region.
- **Regulatory education and compliance** – through education, monitoring, and targeted compliance and enforcement actions.

***GF*: In your view, does this seem to be a very ambitious programme?**

JS: Yes, it is. But we also have other ambitions. As is evident from the COVID-19 experience, we need to respond proactively to emerging public health issues as well as government policies that affect regulation. The TGA will provide advisory support to clinical trial researchers and industry developing or repurposing therapies and developing vaccines for COVID-19 and prioritise their regulatory review. We will contribute to global decision making through the International Coalition of Medical Regulatory Authorities (ICMRA) on clinical trial design and data requirements for therapies and vaccines for COVID-19. International collaboration is vital as is pretty much self-evident.

***GF*: Electronic submission and communications processes constitute a rapidly evolving domain of TGA business. Could you outline TGA progress and plans in this important area for TGA?**

JS: The TGA is also undertaking a Digital Transformation project to streamline our business systems and modernise IT infrastructure. This will benefit industry through facilitating simpler, faster interactions with the TGA while reducing our administrative effort, therefore increasing our ability to provide timely information and decisions. It will also allow for greater transparency in the regulation of medicines and medical devices, which should improve consumer confidence and benefit healthcare professionals.

***GF*: Could you outline the plans for Prescription Medicines regulation reforms?**

JS: We have a number of reforms planned for Prescription Medicines regulation:

- Continue to expand and evolve work-sharing product evaluations of new prescription medicines, extensions of indications to medicines and generic medicines with Australia-Canada-Singapore-Switzerland-UK consortium (ACCESS) partners and joint evaluations of new oncology medicines with the US and others through Project Orbis.
- Continue to improve alignment between regulatory and reimbursement evaluation.
- Implement new business processes for the provision of early scientific advice on bioequivalence data for new generic medicines.
- Implement a program of Good Clinical Practice inspections of clinical trials.
- Implement enhanced transparency measures for prescription medicines that are under evaluation.
- Continue to implement regulatory options to address prescription opioid misuse, including tightening indications, registering smaller pack sizes, and enhancing safety information. Implement a major education and communication campaign.
- Work with stakeholders to improve identification, communication, and management of medicine shortages.

***GF*: What about biological medicines?**

JS: This is a rapidly evolving area of therapeutics and regulatory reforms are needed. In the interests of patient safety in particular, we are committed to:

- Manage appropriate restrictions to the advertising and supply of autologous cell and tissue therapies that involve significant processing.
- Implement policies and regulatory changes for the regulation of faecal microbial transplant products.

***GF*: COVID-19 has raised numerous regulatory issues around medical devices. How has the pandemic impacted TGA's plans for 2021?**

JS: You're right about the impact of COVID-19 on TGA – it has been very significant, especially for medical devices such as COVID tests and facemasks, but at the same time we are continuing with other reforms. As a result, we are:

- Prioritising regulatory review of diagnostic tests and medical devices for COVID-19,
- Implementing reforms to regulatory frameworks (consultation open until 17 December 2020)
  – alignment of device classification with the EU scheme
  – new regulatory framework for personalised devices (including 3-D printed)
  – medical device software, including appropriate carve-outs from TGA oversight
  – prepare for introduction of a Unique Device Identifier system,
- Establishing a comprehensive review and testing system for face masks and other personal protective equipment currently approved in Australia, and
- Implementing the Action Plan for Medical Devices to improve how devices get on the market; strengthen monitoring and follow-up of devices already in use; and provide more information to patients about the devices they use.

***GF*: Finally, could you outline the plans TGA has for the Advertising of therapeutic goods?**

JS: TGA is looking forward to progressing recent reforms to the regulation of advertising as it remains an area of significant concern. We are looking to:

- Improve the handling of advertising complaints including a shift from individual complaints handling to identification of compliance priority areas for focused compliance and enforcement action in accordance with public health risks.
- Address regulatory compliance and enforcement priorities and advertising compliance breaches related to COVID-19.