Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

TGA International Engagement Strategy 2013-2015

TGA Health Safety Regulation

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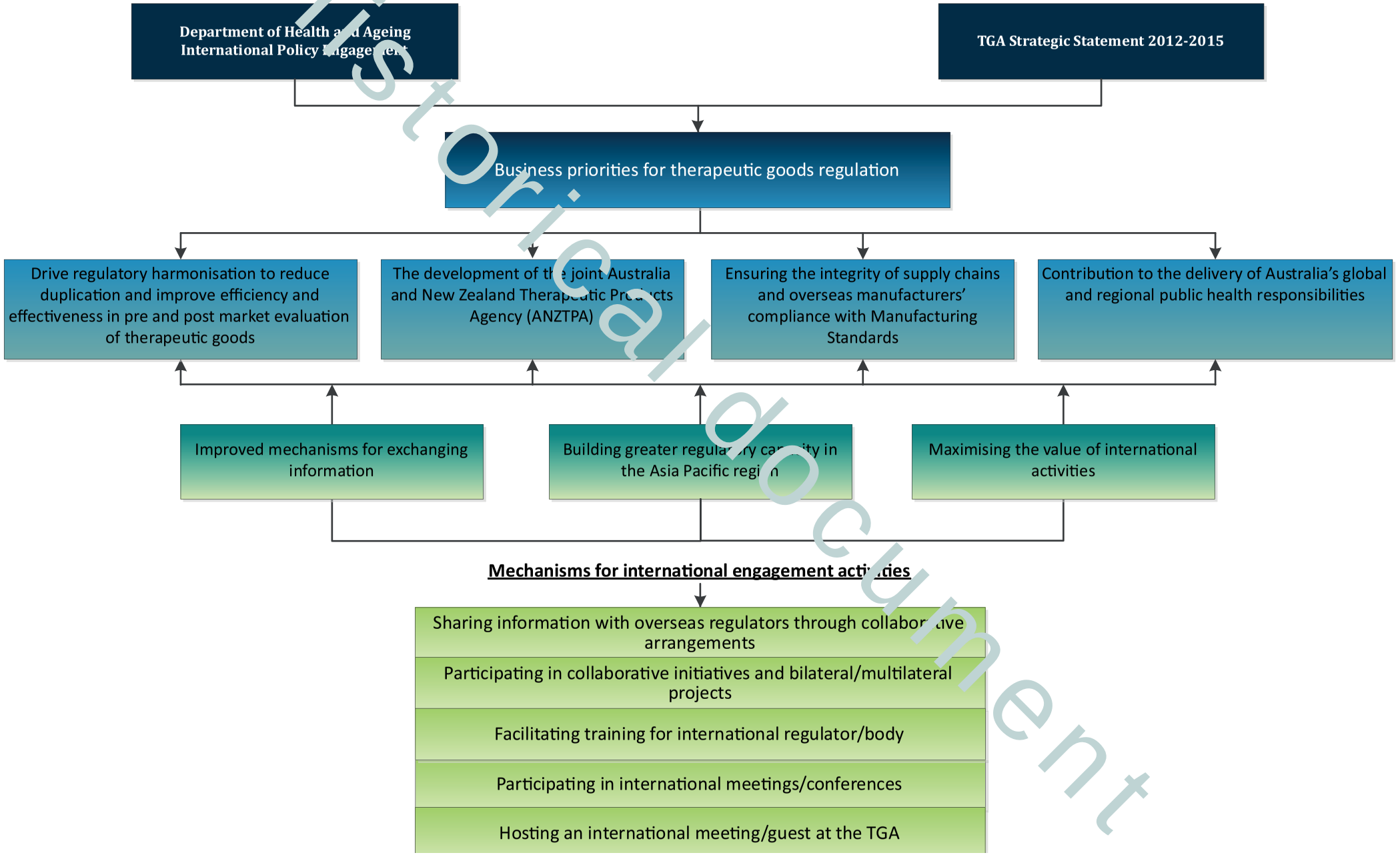
TGA INTERNATIONAL ENGAGEMENT FRAMEWORK



The Therapeutic Goods Administration (TGA), part of the Department of Health and Ageing, safeguards and enhances the health of the Australian community through the effective and timely administration of the Therapeutic Goods Act 1989*. Working collaboratively with major international counterparts to achieve greater regulatory convergence, and assist our regional partners to build greater regulatory capacity can assist us to fulfil this mandate.*

Introduction

The therapeutic goods industry is becoming increasingly globalised and the TGA must be able to assure public confidence in products no matter where they are produced. As this is occurring, international regulators are demonstrating a greater willingness to develop partnerships and share information, skills and experience to ensure more informed and consistent decisions about the quality, safety and efficacy of therapeutic products.

Successful relationships with our international regulatory counterparts require investment of time and other resources. The major return on this investment is a reduction in duplication of effort in pre and post market evaluation of therapeutic goods, leading to a more efficient and effective regulatory system. Other benefits include a better understanding of emerging trends, more informed and consistent regulatory decisions for industry and better safeguards for the Australian public.

Purpose

The *TGA International Engagement Strategy 2013-2015* provides the overarching direction for international engagement for the TGA for this three year period. It links current Australian Government priorities for international engagement that are necessary to support effective therapeutic goods regulation with the TGA's business-as-usual activities and sets clear goals for international engagement activities.

The strategy will be reviewed periodically and amended as necessary in response to the changing international environment to ensure that it continues to reflect government priorities as they change over time. Indicators of performance will be internally monitored to ensure that the strategy continues to assist the TGA in reaching its goals.

Priorities for therapeutic goods regulation in an international context

Drive regulatory harmonisation to reduce duplication and improve efficiency and effectiveness in pre and post market evaluation of therapeutic goods

There are many direct benefits to industry and consumers that are derived from international regulatory harmonisation. Where regulators in different jurisdictions can agree common standards, guidelines and regulatory requirements, the time to market for therapeutic products can be shortened. Regulators can work together to share information (including confidential and non-public data) for product registration and pre market evaluation reports. In the post market space, regulators can share product signals (or potential adverse events), adverse events information, manufacturing compliance reports and recall activities to ensure greater responsiveness and improve protections for consumers.

Through actively participating in global and regional activities that influence the setting of international standards and the regulatory harmonisation agenda, as part of the Health portfolio the TGA can work to ensure that the international framework meets Australia's high regulatory standards. Furthermore, as the TGA is required by Government to fully recover its operating costs for all activities that fall within the scope of the *Therapeutic Goods Act*, including the TGA's public health responsibilities, building greater efficiencies into business processes is an important consideration.

The development of the joint Australia and New Zealand Therapeutic Products Agency (ANZTPA)

The Australian and New Zealand Governments have committed to establish the Australia New Zealand Therapeutic Products Agency (ANZTPA) to safeguard public health and safety, further economic integration and benefit industry in both countries. It will be the first fully joint trans-Tasman regulator and will provide for the efficient and cost-effective regulation of medicines and medical devices and become a centre for excellence for Australian and New Zealand therapeutic products in the regional and global market place.

In the lead up to commencement of the joint regulator by July 2016, the TGA and the New Zealand therapeutic goods regulator, Medsafe, will engage in activities to progressively harmonise business processes between the two regulators and the development of a common regulatory framework. More information is available at www.tga.gov.au.

Ensuring the integrity of supply chains and overseas manufacturers' compliance with Manufacturing Standards

Ensuring that overseas manufacturers comply with Manufacturing Standards is a TGA core business activity. However, as global therapeutic goods manufacturing continues to diversify and move into lower cost developing countries, the challenges of ensuring supply chain integrity and compliance with manufacturing standards are not ones that can be managed by any one regulator. The TGA will work closely with partner

regulators through the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the International Medical Devices Regulators Forum (IMDRF) to progress international harmonisation. The IMDRF Medical Devices Single Audit Program is a particularly important platform that has the potential for early and concrete benefits to be achieved through closer collaboration.

In partnership with the United States Food and Drug Administration, the Brazilian Health Surveillance Agency and the Health Canada's Health Products Food Branch, the TGA will commence work under the Medical Devices Single Audit Program which will enable the parties to strengthen cooperation in the scientific and regulatory area of medical devices with the intention of a single audit being undertaken to satisfy the regulatory requirements of all four participants.

Contributing to the delivery of Australia's global and regional public health responsibilities

Medicines regulators around the world are seeking coordination of global harmonisation and work sharing activities in order to maximise their benefit and eliminate duplication and wasted effort. Australia will play a strong role in facilitating further international collaboration between medicines regulatory agencies.

As part of Australia's Health portfolio the TGA will also actively engage in international therapeutic goods policy development and discussions regarding the harmonisation of regulatory requirements and standards for therapeutic goods, as well as issues such as access to medicines by developing countries, rational and quality use of medicines, microbial resistance, pandemic preparedness, substandard and counterfeit medicines. The TGA can also assist Australia's neighbours to meet the challenges of emerging communicable diseases, ensuring the integrity of supply chains and providing advice and assistance against other health threats.

TGA goals for international engagement

Improved mechanisms for exchanging information

Sharing information with international regulators is critical to ensuring the safety and efficacy of therapeutic goods. In premarket activities information sharing enables the TGA to make regulatory decisions about new chemical entities and generic products cognisant of the decisions of overseas regulators and data relating to use of these products by other populations. In addition, where the TGA has productive working relationships with international regulators, early warnings about signals and recall activities is more forthcoming and enables timely regulatory action in Australia. The TGA will continue to build and maintain relationships with our regulatory colleagues both bilaterally and through international networks and actively seek opportunities for information exchange at relevant international forums.

Building greater regulatory capacity in the Asia Pacific region

Australia is regularly called upon to provide training and share expertise with other regulators, particularly those with developing regulatory systems in the Asia Pacific region. This arrangement strengthens Australia's relationship with the Western Pacific Regional Office (WPRO) of the World Health Organization (WHO), which coordinates efforts to build regulatory capacity in the region.

Fulfilling the TGA's obligations to the WHO as a Collaborating Centre for Drug Quality Assurance and a Collaborating Centre for Quality Assurance for Vaccines and other biologicals is also a core ongoing regional activity. The two WHO Collaborating Centres form part of the collaborative network set up by WHO in support of its policies and programs. Designation is based on the TGA Office of Laboratories and Scientific Services' activities and expertise that align with WHO aims and objectives.

Maximising the value of international activities

Highly selective participation in international meetings and workshops is critical to ensuring the TGA's performance as an effective regulator. The TGA will take a strategic and better coordinated approach to planning and managing international activities, including international travel for inspection and other activities. Greater emphasis will be placed on using teleconference and video conference facilities, desk top assessment, building relationships with international regulators to improve information sharing and initiating side meetings with key stakeholders during international travel opportunities to maximise the value of every trip.

Risks

Reluctance or inability to engage in international activities (due to lack of resources, or competing priorities) generates risks. It can result in reduced currency of regulatory knowledge and skills at the TGA, an inability to readily and quickly access information from international counterparts about the safety, quality and efficacy of therapeutic products, and prevents efficiencies being built into reducing the time to market for new therapeutic products. To reduce these risks, strategic and coordinated investment is required, both in dedicating resources to work sharing and harmonisation projects and attending international meetings as well as a greater reliance on whole of Government expertise and resourcing opportunities. The resulting benefit will be significant, but will take time to achieve.

Other risks to the effective delivery and implementation of activities under this International Engagement Strategy include differences in international regulatory approach, failure to agree common international standards, inability to share unredacted information between regulators and limited access to information on post-market monitoring. The significant TGA Blueprint reform agenda and the workload for the establishment of ANZTPA may also impact on the TGA's ability to participate in international forums and to allocate resources to regional capacity building initiatives.

Indicators of performance

The TGA will internally review its performance against this strategy in order to ensure it is responsive to the changing environment and continued alignment with government priorities.

By end 2015, the TGA will have:

- **Participated in international harmonisation initiatives that can be demonstrated to have ensured the international regulatory framework meets acceptable Australian standards of safety, quality and efficacy. These may be through participation in both global and regional forums and work sharing initiatives.**
- **Demonstrated an increased reliance on the number of reports from international regulators that have been used to support Australian regulatory decisions.**
- **Demonstrated a greater reliance on post-market signals received from international regulators to trigger appropriate early warnings for the Australian public.**
- **Developed targets and completed work to progress a Common Regulatory Framework between the TGA and Medsafe.**
- **Commenced work sharing and single inspections under the Medical Devices Single Audit Program.**
- **Completed the planned review of the TGA collaborative arrangements to ensure alignment with TGA strategic objectives.**

Annex 1 – International regulatory harmonisation activities in which TGA participates (as of 2013)

The TGA has been involved in the following international activities for some time. These are key activities in progressing international harmonisation and the TGA will continue to participate as much as possible.

International Conference of Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

ICH (www.ich.org) brings together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Its mission is to make recommendations towards achieving greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines.

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S)

The PIC/S (www.picscheme.org) are two international instruments between governments and pharmaceutical inspection authorities which provide an active and constructive co-operation in ensuring Good Manufacturing Practice (GMP). The schemes' objective is to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products. PIC/S assists Australian efforts to regulate overseas manufacturers and assists the TGA to build confidence in the practices and standards followed by overseas regulators with a view to mutual recognition of decisions around GMP inspections.

International Generic Drug Regulators' Pilot (IGDRP)

The TGA and regulators from Brazil, Canada, China, Chinese Taipei, European Union, Japan, Korea, Mexico, Singapore, Switzerland and United States are participating in an International Generic Drug Regulators Pilot (IGDRP). This project builds on the work of the bilateral and quadrilateral generic medicines work sharing projects. The IGDRP aims to maximise international cooperation, reduce duplication and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic goods.

International Medical Devices Regulators' Forum (IMDRF)

The TGA will continue its active participation in the International Medical Device Regulators' Forum (IMDRF – www.imdrf.org) and engage in activities to discuss the future directions and accelerate medical device regulatory harmonisation and convergence. Key priorities include: a review of the National Competent Authority Report Exchange Program; a roadmap for the implementation of the uniform device identification system; implementation of the Medical Devices Single Audit Program; the development of IMDRF recognised standards; and establishment of arrangements for regulated product (electronic) submission.

Medical Devices Single Audit Program (MDSAP)

(www.imdrf.org/workitems/wi-mdsap.asp)

With the United States Food and Drug Administration, the Brazilian Health Surveillance Agency and the Health Canada Health Products and Food Branch, the TGA is developing MDSAP for implementation from 2015. Through this platform the parties will strengthen cooperation in the scientific and regulatory area of medical devices. The implementation of the program should allow for a single audit to satisfy the regulatory requirements of participants.

Centre for Innovation in Regulatory Science (CIRS)

CIRS (www.cirsci.org) is a not-for-profit international body that brings together the pharmaceutical industry, regulatory authorities and academia to explore issues that underpin regulatory policy. The TGA National Manager is a member of the CIRS Scientific Advisory Council and the TGA participates with other regulators in projects on the assessment of benefit and risk in the evaluation of medicines and in benchmarking the TGA's pre-market approval processes.

International Regulatory Cooperation for Herbal Medicines (IRCH) Working Group

The WHO International Regulatory Cooperation for Herbal Medicines (IRCH – www.who.int/medicines/areas/traditional/geninfo/en/) is a global network of regulatory authorities responsible for herbal medicines. Current members include Australia, Brazil, Canada, China, India, Indonesia, Japan, Malaysia, Mexico, Pakistan, Republic of Korea, Saudi Arabia, Singapore, United Kingdom, and United States of America. Australia and Canada are co-chairs of an IRCH working group that aims to develop consistent approaches towards the assessment of evidence for complementary medicines. The intent of the working groups is to identify how regulatory agencies can work more closely together and leverage resources and expertise.

International Conference of Drug Regulatory Authorities (ICDRA)

ICDRA (www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/) provides regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. It is instrumental in guiding regulatory authorities, WHO and interested stakeholders in determining priorities for action in national and international regulation of medicines, vaccines, biomedicines and complementary medicines through its recommendations for regulatory capacity building, strengthening partnerships and networks, education and training, reporting arrangements and promotion.

Annex 2 – TGA participation in cross-organisational international projects, as of 2013

Quadrilateral cooperation

The TGA is a partner in the Heads of Agencies Quadrilateral Consortium which also involves Health Canada, Swissmedic, and the Health Sciences Authority of Singapore. Together the parties work collaboratively on work sharing initiatives to enhance regulatory convergence, adopt common standards and to ensure the timely and enhanced global market access to high quality generic medicines. Work sharing projects include: generic medicines, New Chemical Entities, Compliance and Enforcement (for manufacturing), Information Technology Architecture, Risk Communications.

A new activity will be to develop a secure portal for information exchange using "Cloud" technology. The goal for the Consortium is to consider, and ultimately rely on evaluations undertaken by partner agencies and achieve 'real time' work sharing for simultaneous activities.

Bilateral cooperation with Health Canada

The TGA and Health Canada also continue to undertake bilateral work sharing activities such as generic medicines, manufacturing clearances through desk-top assessments, over the counter medicines monograph development. Under this arrangement the TGA also undertakes commercial assessment activities under the provisions of the Canadian medical device legislation. Learnings from the first (2011-12) phase of the cooperation program will be applied as the projects are increasingly embedded as business-as-usual in each regulator.

European Community – Australia Mutual Recognition Agreement (MRA)

The amended MRA came into force on 1 January 2013. Under this agreement, the TGA will act as a commercial body in conducting assessment work under the provisions of the European Community legislation. A number of confidence building activities will be undertaken between the two parties regarding high risk medical devices. The confidence building activities will be reviewed after two years of the MRA coming into effect.

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