



Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration **International Engagement Strategy**

2016-2020



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Introduction

Advancing Australia's health interests through international engagement

As part of the Department of Health, the Therapeutic Goods Administration (TGA) supports the Department's strategic priority for an affordable, accessible, efficient and high quality health system through regulation that protects the health and safety of the Australian community, while minimising unnecessary compliance burdens. The *International Engagement Strategy 2016-2020* provides an overarching framework to outline the contribution of the Australian therapeutic goods regulator, the Therapeutic Goods Administration (TGA), to international health opportunities and challenges.

This strategy sets three main goals for TGA's international work:

1. contributing to public health and safety through regulation
2. working with others to improve the regulatory system
3. participation in work sharing and convergence activities.

The strategy is intended to support the Department's vision statement *Better health and wellbeing for all Australians, now and for future generations*. It reflects content from departmental documents intended to guide the achievement of this vision, including the *2016-17 Health Portfolio Budget Statements*, the *Strategic Intent 2016-20*, and the *Corporate Plan 2016-17*.

The strategy outlines how the TGA will:

- continue to pursue Australia's global health interests through multilateral engagements and country-to-country regulatory partnerships
- keep the product regulation aspects of Australia's health system at the forefront of international best practice.

In particular, the TGA will influence international regulatory activity through continued participation in fora such as the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Medical Devices Regulators' Forum (IMDRF).

The strategy builds on the 2013-15 strategy through which the TGA advanced a number of objectives including:

- participation in international initiatives to ensure the alignment of international requirements meets acceptable Australian standards of safety, quality and effectiveness
- increased reliance on reports from international regulators used to support Australian regulatory decisions
- greater reliance on post-market signals received from international regulators to trigger appropriate early warnings for the Australian public.



Australian Government Response to the Expert Panel Review of Medicines and Medical Devices Regulation

The release of the [Australian Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation](#) (MMDR) in September 2016 sets the agenda for long-term reform of the regulation of therapeutic goods in Australia. The recommendations of the review acknowledged the benefits and efficiencies that accrue from the alignment of international regulatory frameworks as well as the advantages of the increased use of assessments from comparable regulators in reaching regulatory decisions in Australia.

The MMDR also recognised that continued work with overseas regulators to identify suitable opportunities for use of completed assessments as well as work sharing where feasible would help reduce duplication of effort and improve approval timeframes for some products.

The reform agenda for TGA includes:

- increasing the use of overseas assessments by comparable regulators, while maintaining sovereignty of regulatory decisions
- increasing flexibility in pre-market assessment processes for medicines and medical devices, including expedited evaluation of particular medicines and devices, provisional approval of certain medicines and allowing the operation of commercial assessment bodies in Australia for medical device assessments
- taking a more risk-based approach to variations to medicines and medical devices and access to products not listed on the Australian Register of Therapeutic Goods (ARTG).

It is vital the TGA is well-positioned to influence and contribute to the evolving international environment to help support the quality and safety of medicines and medical devices in Australia. This will also enhance the TGA's ability to promote best practice therapeutic goods regulation while ensuring timely and appropriate access to products to improve health outcomes.



Role of the Therapeutic Goods Administration

Evaluating the safety, quality and efficacy/ performance of therapeutic goods

In its role, the TGA safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods. This includes regulating the supply, import, export, manufacture and advertising of therapeutic goods – legal requirements set out in the *Therapeutic Goods Act 1989*. The TGA's approach to therapeutic product vigilance is to continually monitor the safety of therapeutic products and to manage their associated risks.

The international context

Internationally, the TGA is a highly regarded regulator of medicines and medical devices and works closely with the World Health Organization (WHO) and regulatory agencies in comparable health systems. Through active international engagement, the TGA builds on its reputation and expertise by contributing to policies and actions that help advance the health and wellbeing of Australians. Participating in international engagement also helps to fulfil Australia's responsibility to contribute to improving regional and global public health.

In its international work, the TGA shares information on emerging issues, actively participating in the development of standards and works to align approaches to regulation. The TGA also conducts Good Manufacturing Practice (GMP) inspections to ensure facilities that manufacture products for the Australian market do so in a manner that meets Australian standards.

The TGA regulates therapeutic goods through:

- pre-market assessment
- post-market monitoring and enforcement of standards
- licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

The Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) found that the TGA has a strong reputation as a regulator, both domestically and internationally, and that it benchmarks well against comparable overseas regulators. The MMDR noted the increasing globalisation of the pharmaceutical and medical devices industries and the rapid pace of innovation, and made recommendations as to how to position the TGA to respond to these trends in the future.

Investing in international engagement

Building and maintaining successful relationships with our international regulatory counterparts requires the investment of time and other resources. There are resource and opportunity costs related to preparation for and participation in meetings and conferences, in progressing post-meeting communications and outcomes, and in establishing mechanisms for sharing of product evaluations or safety information.

The return on this investment is progress made in addressing the TGA's international engagement goals:

1. Contributing to public health and safety through regulation
2. Working with other countries to improve the regulatory system
3. Participation in work sharing, information sharing and regulatory convergence activities.

The benefits that can be realised from increased international engagement include:

- reduced duplication of effort leading to a more efficient and effective regulatory system
- the development of a better understanding of emerging trends and innovations
- access to the latest regulatory science developments
- more informed regulatory decisions for industry
- better safeguards for the Australian community.

Case Study

How international collaboration can progress work sharing to improve generic medicines regulation

The Australia, Canada, Singapore, Switzerland (ACSS) Consortium Generics Medicines working group is advancing information sharing and work sharing arrangements in the assessment of generic drug applications. A work sharing model based on the European Union Decentralised Procedure is currently being trialed. Its goals are to harness efficiencies in the registration process, promote regulatory convergence of technical data requirements, build confidence between agencies and provide data to be used for the development of a 'business as usual' work sharing arrangement.

One of the objectives of the trial is to enable the efficient assessment of the information used in developing a preferred model for work sharing. This trial is consistent with the MMDR recommendations and is an important step in advancing mechanisms which could enable work sharing between comparable medicines regulators from other countries.



Goal 1: Contributing to public health and safety through regulation

Why is this important?

The TGA regulates the import, supply, export, manufacture and advertising of therapeutic goods including medicines, medical devices and biologicals. Since most therapeutic goods originate overseas, it is important that the TGA contributes to international efforts to support the safety, effectiveness and quality of these products.

International engagement helps the TGA maintain an effective regulatory framework that is contemporary and consistent with international best practice. It also assists with proactive post-market monitoring and management of emerging safety and performance issues with particular medicines and medical devices, and staying up-to-date with relevant international standards and conventions.

What are we doing?

The TGA contributes through active engagement in international regulatory initiatives including:

- the International Coalition of Medicines Regulatory Authorities (ICMRA)
- the Heads of Agencies (Australia, Canada, Singapore, and Switzerland (ACSS)) Consortium
- the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) at which the TGA is a formal observer
- the World Health Organization (WHO) and
- the International Medical Devices Regulators Forum (IMDRF).

A comprehensive list of TGA's engagement with international regulatory initiatives and agencies is listed in the Appendix.

Case Study

TGA's involvement in the WHO Collaborating Centre for Drug Quality Assurance

The WHO Collaborating Centre forms part of the collaborative network set up by the WHO in support of its policies and programs. In this role, the TGA:

- provides support to the WHO's program, The International Pharmacopoeia, including development and validation of test methods for medicines
- performs quality assurance testing of medicines
- provides scientific advice on quality assurance of medicines
- provides training of laboratory personnel in the validation and application of analytical procedures in the quality assurance of medicines.

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

The TGA's WHO Collaborating Centre for Drug Quality Assurance has a longstanding history of providing support to the WHO's program, The International Pharmacopoeia. The International Pharmacopoeia provides a key source of pharmaceutical standards for developing countries and regions around the world, including the Western Pacific. The International Pharmacopoeia helps protect these countries from counterfeit/adulterated/substandard medicines. The TGA's Collaborating Centre assists the WHO with the development of new monographs for medicines on the WHO Model List of Essential Medicines and other priority medicines of major public health importance by providing testing and/or scientific advice.



Case Study

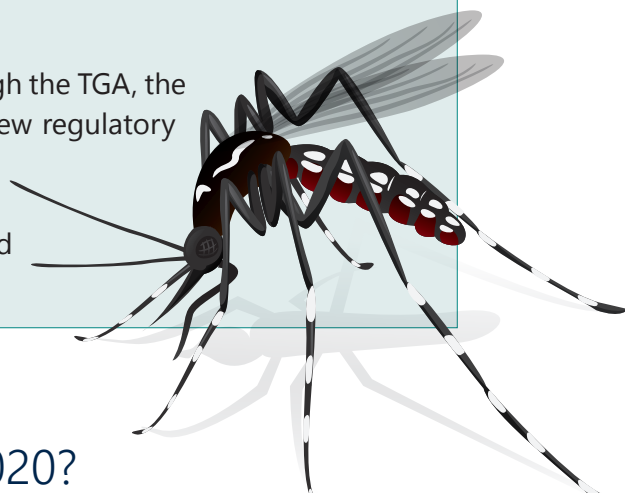
Improving access to medicines and tests used for diagnosis and treatment of malaria

Malaria continues to be a major source of morbidity and mortality in the Asia-Pacific region – in particular in South Asia, Mekong Countries, Indonesia and Papua New Guinea.

In 2014, the TGA was asked by the Asia-Pacific Leaders Malaria Alliance (APLMA) to coordinate preparatory meetings and author a detailed plan for how Asia-Pacific regulators could support better control and eradication of malaria. This plan forms part of the East Asia Leaders Malaria Elimination Roadmap which was endorsed by regional leaders, including the Australian Prime Minister at the November 2015 East Asia Summit.

The Roadmap priorities include a focus on actions to provide universal access to high quality prevention, testing and treatment commodities as well as the need to accelerate access to innovative products for malaria elimination. Delays in obtaining regulatory approval for critical medicines and diagnostic tests have been one of the biggest barriers to access. It is critical to develop ways to permit fast-track review and approval of new antimalarial medicines and diagnostic tools, without compromising on legal requirements and appropriate scrutiny of the products.

The APLMA Secretariat, the Department of Health through the TGA, the Asian Development Bank and the WHO are part of a new regulatory partnership between regulatory authorities in the Asia Pacific to improve the efficiency and quality of the regulatory review for new antimalarial treatments and diagnostic tests.



What should we be doing in 2016-2020?

1. Continue to support cooperation, engage and cooperate with the WHO and regulators in comparable health systems.
2. Continue to assist, and work with less advanced regulators in our region to strengthen their capacity.
3. Continue to participate in international regulatory fora, maximising opportunities to improve public health and safety and maintaining our leadership role.

Goal 2: Working with others to improve the regulatory system

Why is this important?

The TGA is responsible for regulating therapeutic goods to ensure they are safe, effective and of appropriate quality. By increasing efficiencies in regulatory systems and processes, including through engagement with overseas regulators, the TGA will minimise associated regulatory costs on industry.

International engagement provides opportunities for ongoing improvement of our regulatory practice. For example, through examining pre-market processes used by other leading regulators for different types of medicines and medical devices, we can ensure the TGA targets its regulatory efforts and level of regulatory oversight according to the risk of the products.

What are we doing?

The TGA works with international counterparts to improve the quality of the regulatory system. This includes:

- studying approaches and lessons learnt from international regulators for fast tracking approvals processes for certain medicines and medical devices
- exploring how risk assessments and determinations by comparable overseas regulators, as well as international standards can be used more extensively by the TGA when evaluating products.

Consistent with the recommendations of the MMDR, the TGA's international activities are helping to improve the quality of the regulatory system, including through engagement with international initiatives such as ICMRA, ACSS, IMDRF, ICH, the International Generic Drug Regulators Programme (IGDRP), the International Organisation for Standardisation (ISO), and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S).

Medical Device Single Audit Program (MDSAP)

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonisation. It is a group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory alignment.

The TGA has been actively contributing to the work of the IMDRF, to further a reliance on the output of commercial third party organisations that are capable of conducting Quality Management System (QMS) audits on behalf of regulators. The TGA was an active participant in the IMDRF working group that developed recommendations for a Medical Device Single Audit Program (MDSAP).

The MDSAP was intended to allow recognised auditing organisations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the program.

Recognising the efficiencies of a single audit that could be used to verify compliance with the regulatory requirements of multiple jurisdictions, a coalition of participating MDSAP regulatory authorities have developed and implemented a comprehensive oversight program that would allow recognised auditing organisations to undertake QMS audits on behalf of regulators in Australia, Brazil, Canada, Japan and the USA.

The program allows the TGA to make a direct contribution to the objectives, processes, competencies and outcomes of third party QMS audits through a collaborative and work sharing arrangement with comparable regulators that promotes regulatory convergence.

The TGA has provided resources for the development of this rigorous program operating under a set of documented controls and practices (MDSAP QMS), and for a contribution to an ongoing program for candidate auditing organisations. A transitional phase will commence in 2017 to align with the introduction of a new version of the relevant standard for manufacturers (ISO13485:2016) and Health Canada's planned use of the resultant MDSAP certification from 2019.

The TGA is already seeing benefits of participation in the program; for regulatory convergence and for the provision of opportunities for Australian manufacturers to access new markets. The European Union is expected to participate in the program during 2017.

This valuable international collaboration also includes:

- joint assessments of third party auditing organisations and audits of medical device manufacturers with our overseas partner regulatory authorities
- sharing of information, reports and manufacturer information
- the recognition of standards
- the convergence of regulatory practices.

What should we be doing in 2016-2020?

1. Continue to support the MDSAP Regulatory Authority Coalition in a program of ongoing assessment of third party auditing organisations. This will allow the TGA to leverage and have oversight of these audit resources and minimise the duplication of effort for both regulators and medical device manufacturers.
2. Increase flexibility in pre-market assessment/market authorisation processes for medicines and medical devices including those processes used for the recognition of existing QMS assessments that support market authorisation from recognised commercial third parties and other comparable regulatory authorities (e.g. MDSAP, Australian designated third parties).
3. Develop a more comprehensive post-market monitoring scheme for medicines and medical devices which includes enhanced collaboration and the exchange of information with overseas regulators to share information relating to quality, safety and efficacy, or information that supports market authorisation decisions (e.g. MDSAP IT portal based on the Pan American Health Organization (PAHO) Regulatory Exchange Platform).



Goal 3: Participating in work sharing, information sharing and regulatory convergence activities

Why is this important?

Participating in work sharing, information sharing and regulatory convergence activities with comparable international regulators is essential to ensure the TGA continues to make informed and internationally consistent decisions about therapeutic goods in Australia. Work sharing, information sharing and increased regulatory convergence reduce regulatory burden and contribute to provision of a wide range of therapeutic goods for the Australian consumer.

Work sharing, information sharing and regulatory convergence activities help the TGA to:

- identify opportunities to work together with comparable regulators in other jurisdictions, including the potential for work sharing assessments for products marketed in multiple countries to make more informed regulatory decisions about the safety, quality and performance of therapeutic goods available in Australia
- promote the increased use of information from comparable international regulators
- contribute to reducing the effort in pre- and post-market evaluation of therapeutic goods
- assist with timely exchange of information on products that are already on the market
- support the implementation of science-based standards that ensure the safety and quality of products throughout the supply chain.

Such activities also help the TGA build trusted relationships and stay up-to-date on emerging technologies, develop expertise to assist in regulatory decision-making and enable the enhanced use of information technology to support regulatory operations.

What are we doing?

The TGA is actively engaged in work sharing, information sharing and regulatory convergence activities through international initiatives including:

- the Australia, Canada, Singapore and Switzerland (ACSS) Consortium
- the International Coalition of Medicines Regulatory Authorities (ICMRA)
- the International Medical Devices Regulators Forum (IMDRF)

- the International Generic Drug Regulators Programme (IGDRP)
- the International Organisation for Standardisation (ISO)
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S).

Enhanced cooperation, including increased reliance on medicines evaluation and facilities inspection information from international regulators, is helping the TGA improve the efficiency of its operations.

Through the implementation of the recommendations of the MMDR, the TGA will provide greater flexibility in approval pathways for medicines and medical devices and respond to areas of regulation where the level of regulation could be more closely aligned with the risk posed by regulated products.

The Australian Government's response to the MMDR recommendations notes that, in many instances, implementation of work sharing with overseas regulators will only be achievable in the longer term.

Case Study

TGA's involvement in international standards development

Standards are an important cornerstone of good regulatory frameworks, with internationally harmonised standards helping reduce regulatory burden, enhance consumer access to innovative products and avoid technical barriers to trade.

Our microbiologists have participated in the development of international and Australian standards for nearly twenty years. This work is crucial when evaluating, for example, the sterilisation, disinfection, and microbiological aspects of therapeutic goods, with the TGA requiring manufacturer's adherence to best practices. These practices are specified in standards, which include: Australian/New Zealand standards, European Norms, International (ISO) standards, pharmacopoeial and other industry-based standards.

ISO standards are applicable to both medicines and medical devices. These standards are used by medicine manufacturers to validate and monitor the range of sterilisation processes used during the manufacturing process, and by medical device manufacturers for deeming compliance to the TGA's Essential Principles or the European Union's Essential Requirements.

Australia accesses ISO standards development through Standards Australia, and our microbiologists contribute to the technical development of all of the ISO/TC 198 standards that relate to sterilisation of products. The European Pharmacopoeia, British Pharmacopoeia, and United States Pharmacopoeia are the TGA's 'default standards' for medicines.

Our scientists contribute to the development of specific pharmacopoeial monographs and general test methods used by the industry and TGA for quality control and medicine release tests, and also hold observer status on a number of European Pharmacopoeia Groups of Experts working groups.



What should we be doing in 2016-2020?

1. Continue to actively engage with overseas regulators, as well as with regional and international organisations, to support the implementation of consistent science-based standards that underpin the safety and quality of therapeutic goods throughout the supply chain.
2. Continue to participate in international work sharing, information sharing and regulatory convergence activities to:
 - identify opportunities for Australia to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods
 - develop internationally consistent regulatory requirements
 - contribute to the development of mutual reliance frameworks that reduce regulatory burden on therapeutic goods manufacturers.
3. Provide access for Australian consumers to certain medicines and medical devices that have had evaluations either conducted in part or comprehensively by comparable overseas regulators. This will reduce duplication of effort, leading to efficiencies, while maintaining protection for Australian consumers through oversight by the TGA as the final decision-making authority.
4. Continue to leverage off alerts and pharmacovigilance data from overseas regulators to assist in post-market activities.
5. Look to international best practice to underpin emerging regulatory policy for therapeutic goods.
6. Maintain the close alignment of many areas of medical devices regulation between Australia and the European Union.

TGA's engagement with international regulatory initiatives and agencies

The TGA has active involvement in many international initiatives and working relationships with several overseas regulators. These collaborations keep TGA well-informed about post-market monitoring of therapeutic goods and ensuring the regulatory framework meets international best practice. The TGA works collaboratively with other overseas regulators on various projects and also has formal collaborative arrangements in place with a number of other regulators.

Details of some of the international regulatory initiatives and agencies with whom the TGA regularly engages include:

Name	Engagement
Australia-Canada-Singapore-Switzerland (ACSS) Consortium	<p>The ACSS Consortium comprises Australia, Health Canada, Health Sciences Authority of Singapore, and Swissmedic, the Swiss Agency for Therapeutic Products. The TGA is the Reference Regulatory Agency for the first work sharing trial underway in the Generics working group. TGA is also represented on the following working groups under the Consortium:</p> <ul style="list-style-type: none"> • Complementary Health Products • New Chemical Entity • IT • Post Market. <p>https://www.tga.gov.au/australia-canada-singapore-switzerland-acss-consortium</p>
Asia Pacific Leaders Malaria Alliance (APLMA)	<p>The Australian Department of Health, through the TGA, is a member of APLMA – which is an affiliation of Asian and Pacific heads of government formed to accelerate progress against malaria and to eliminate it in the region by 2030.</p> <p>http://aplma.org/about#sthash.wsaCcAxI.dpuf</p>
Centre for Innovation and Regulatory Science (CIRS)	<p>The CIRS is an independent regulatory science organisation conducting novel research, convening international forums for healthcare stakeholders and conducts its own research and data on comparative performance of regulators to advance global regulatory and Health Technology Assessment policies and enhance patient access to medicines. The TGA is a participating regulatory authority with the CIRS, and also sits on their Scientific Advisory Council.</p> <p>http://www.cirsci.org/</p>

<p>European Directorate for the Quality of Medicines and HealthCare (EDQM)</p>	<p>The EDQM protects public health by enabling the development, implementation and monitoring the application of quality standards for safe medicines and their safe use. The certification procedure for the European Pharmacopoeia involves assessment of the suitability of monographs to control the chemical purity, microbiological quality and transmissible spongiform encephalopathy (TSE) risk (if relevant) for any substance covered by a European Pharmacopoeia monograph.</p> <p>Australia is one of the countries (outside of European member states) that recognises the Certification Procedure for the European Pharmacopoeia in its evaluation processes for generic medicines, and provides technical reviewers each year to the certification process.</p>
<p>International Coalition of Medicines Regulatory Authorities (ICMRA)</p>	<p>The ICMRA is a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities. ICMRA aims to provide a global architecture to support enhanced communication, information sharing, crisis response and address regulatory science issues. ICMRA currently comprises over 20 of the world's major medicine regulatory authorities, as well as WHO. The TGA represents Australia as a participating regulatory authority on the ICMRA and is currently (2017-2018) a vice chair of ICMRA. ICMRA is progressing a number of strategic priority projects including Pharmacovigilance for which TGA is project lead.</p> <p>http://www.icmra.info/index.html#a_aboutus</p>
<p>International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)</p>	<p>The ICH is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. The TGA is a formal observer at the ICH.</p> <p>http://www.ich.org/home.html</p>
<p>International Generic Drug Regulators Programme (IGDRP)</p>	<p>The IGDRP was created to promote collaboration and convergence in generic drug regulatory programs in order to address the challenges posed by increasing workloads, globalisation and complexity of scientific issues. The TGA is a member of the Steering Committee of the IGDRP and participates in all the working groups. The TGA also established and maintains the IGDRP website, and currently acts as IGDRP Secretariat.</p> <p>http://www.igdrp.com/</p>

International Medical Devices Regulators Forum (IMDRF)	<p>The IMDRF is a voluntary group of medical device regulators from around the world that builds on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and works to accelerate international medical device regulatory harmonisation and convergence.</p> <p>The TGA represents Australia on the IMDRF Management Committee.</p> <p>The Medical Device Single Audit Program (MDSAP) is intended to allow MDSAP-recognised auditing organisations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of participating medical device regulatory authorities. The TGA represents Australia in the MDSAP.</p> <p>http://www.imdrf.org/index.asp; http://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/default.htm</p>
International Pharmaceutical Regulators Forum (IPRF)	<p>The IPRF creates an environment for pharmaceutical regulators to exchange information to:</p> <ul style="list-style-type: none"> • maximise potential efficiencies in addressing the increasingly complex global context of medicines regulation • facilitate the implementation of ICH and other internationally harmonised technical guidelines for pharmaceuticals for human use • contribute to the coordination of a range of international efforts related to regulation of medicines. <p>The TGA represents Australia in the IPRF working groups.</p> <p>https://www.i-p-r-f.org/index.php/en/iprf-network/mandate/</p>
International Society of Pharmacovigilance (ISOP)	<p>The ISOP is a professional, independent and non-profit society that aims to foster pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, in all countries. Australia is a member of the ISOP.</p> <p>http://isoponline.org/about-isop/</p>
International Organisation for Standardisation (ISO)	<p>The ISO is a major international standard-setting body for the manufacture and design of medical devices. The TGA uses these standards as assessment criteria and TGA officers participate in their development. Australia is a member of the ISO.</p> <p>http://www.iso.org/iso/home.html</p>

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S)	<p>PIC/S develop international standards between countries and pharmaceutical inspection authorities, to provide harmonised and constructive co-operation in the field of GMP. PIC/S' mission is: to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. The TGA is a member of the PIC/S.</p> <p>https://www.picscheme.org/</p>
Regulatory Cooperation Initiative (RCI) Between Health Canada and Australia	<p>The RCI is a work sharing project between Health Canada (Health Products and Food Branch) and Australia (TGA) in order to pursue the elimination of duplication of effort, where possible. Key areas identified as areas of focus for the project include: generic medicines; medicine manufacturing site inspections – GMP inspections; new chemical entities, over-the-counter medicines and post-market surveillance.</p>
World Health Organization (WHO)	<p>The WHO works with countries to promote affordable access to quality, safe and effective medicines, vaccines, diagnostics and other medical devices. It promotes policies and technical capacities in low-resourced health systems, develops international standards for the manufacturing and regulation of health products and provides guidance for health systems everywhere to deliver them safely and cost-effectively. Australia is a founding member of the WHO.</p>

The background features a series of overlapping, semi-transparent geometric shapes, primarily triangles and polygons, in shades of dark blue and purple. These shapes are layered to create a sense of depth and movement. A faint, glowing globe is visible in the center, partially obscured by the geometric forms. The overall aesthetic is modern and technological.

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