Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration
International Engagement Strategy

Operations Plan
2018-19

Contents

Acronyms for areas within TGA responsible for delivering work under this Plan

TGA	Therapeutic Goods Administration
MRD	Medicines Regulation Division
PSAB	Pharmacovigilance & Special Access Branch
SEB	Scientific Evaluation Branch
PMAB	Prescription Medicines Authorisation Branch
COMB	Complementary and OTC Medicines Branch
MDPQD	Medical Devices and Product Quality Division
MQB	Manufacturing Quality Branch
LB	Laboratories Branch
MDB	Medical Devices Branch
RPSD	Regulatory Practice & Support Division
RECB	Regulatory Education & Compliance Branch
REPB	Regulatory Engagement & Planning Branch
RSLB	Regulatory Legal Services Branch

Introduction

International engagement is pivotal to the work of Australia's Therapeutic Goods Administration (TGA).

To support Australian regulatory decisions we consider international reports and evaluations, monitor early warnings and other post-market signals. We participate in international initiatives to influence and align international requirements with Australian standards of safety, quality and effectiveness.

Therapeutic goods regulators have many shared priorities and international engagement provides opportunities for ongoing collaboration, shared learnings, and the alignment of policies, standards and regulatory processes. International regulatory collaboration benefits:

- **regional public health** by working towards disease elimination
- **industry** through faster market access and lower costs
- **patients** through earlier access to medicines and medical devices
- **regulators** through effective processes, less duplication and reduced workloads.

TGA's *International Engagement Strategy 2016–2020* set three main goals. Within this framework, broad themes of work to progress each goal have been identified:

1. Contribute to public health and safety through regulation

a. Strengthen the performance of regulatory authorities in our region.

b. Enhance surveillance of substandard and counterfeit medicines.

c. Participate in international regulatory forums.

2. Work with others to improve the regulatory system

a. Enable consumer access to products evaluated in part or comprehensively by comparable overseas regulators.

b. Increase flexibility in pre-market assessment/market authorisation processes.

c. Pharmacovigilance and post-market monitoring.

3. Participate in information sharing and regulatory convergence activities

a. Develop collaboration frameworks with international counterparts.

b. Support ongoing development of globally consistent science-based standards.

c. Enablers - activities to support TGA's international engagement.

This International Engagement Operations Plan is for the 2018-19 Financial Year. The plan identifies projects and activities, the benefits to be realised from those activities, and the line areas responsible for delivering on the three goals for international engagement.

1 Contribute to public health and safety through regulation

An effective regulatory framework makes a significant contribution to public health and safety in Australia and overseas.

Throughout 2018-19, the TGA will step up its involvement in the **Indo-Pacific** region to support regulatory authorities to address the capacity gaps in product registration and market authorisation. This will increase the availability of quality new and priority products to combat potential health security threats.

Strengthen the performance of regulatory authorities in our region

Project	Activities to be undertaken in 2018-19	Area
Indo-Pacific Health Security Regulatory Strengthening Program (RSP)	TGA will work to strengthen the capabilities of national regulatory authorities (NRAs) in our region, including **Cambodia**, **Laos**, **Myanmar**, **Vietnam**, **Indonesia** and **Papua New Guinea**, to increase the availability of safe and effective essential medicines and medical devices, most immediately for malaria and tuberculosis products, through improved regulatory practice and coordination. Activities include: • continue to build effective partnerships and better coordination with and between NRAs and disease control programs in the region to work towards improving regulatory systems • provide direct technical support to build regulatory capabilities in individual countries and country groupings • assist in enabling the registration of new and priority medicines and medical devices, with an initial focus on malaria and TB, in the 6 identified countries.	LB

Project	Activities to be undertaken in 2018-19	Area
Indo-Pacific Health Security Pacific Medicines Testing Program	The TGA will work with Department of Foreign Affairs and Trade (DFAT) to provide **Pacific Island** countries access to Australian laboratory testing for medicines quality assurance and discuss options for improving their quality assurance systems. Activities planned for 2018-19: • Finalise agreements with **Tonga**, **Vanuatu**, **Fiji**, **Papua New Guinea**, **Samoa**, **Palau**, **Marshall Islands**, and the **Federated States of Micronesia**. • Complete the second testing campaign under the program focussing on Insulin, Ibuprofen, Benzylpenicillin, Metformin, and Enalapril.	LB
Asian Harmonisation Working Party (AHWP)	Work with counterpart regulators to harmonise medical device regulations across the **Asia Pacific region**, including adoption of the Global Harmonisation Task Force (GHTF) / International Medical Device Regulators Forum (IMDRF) model for the regulation of medical devices, including IVDs.	MDB

Enhance surveillance of substandard and counterfeit medicines

Our commitment to public health and safety includes working to reduce the incidence and impact of substandard and counterfeit medicines through improved surveillance across our region.

Project	Activities to be undertaken in 2018-19	Area
International Laboratory Forum on Counterfeit Medicines (ILCM)	Engage, as required, with eight other major regulatory authorities to routinely share information on counterfeit medicines.	LB
Permanent Forum on International Pharmaceutical Crime (PFIPC)	The TGA's ongoing engagement with members of PFIPC assists the continuing work of Operation Pangea and allows for intelligence building, information exchange and interoperability between regulators to reduce distribution of substandard or falsified medicines.	RECB

Project	Activities to be undertaken in 2018-19	Area
Strengthen intelligence about counterfeit products	Greater interoperability between regulators will assist in combatting online trading and reduce the transit of counterfeit goods. Activities planned for 2018-19: • Enhance information exchange with **Cambodia**, **China** and **India** about illegal products entering Australia. • Leverage of the FDA's advanced online trading capabilities and working towards interoperability between countries. • In consultation with DFAT, update the **China** 2009 MoU. • Develop Priority Target Profiles through improved regulatory intelligence cooperation with **UK**, **China**, **India**, **Singapore** and **Thailand**.	RECB

Participate in international regulatory forums

Engaging in international regulatory forums aids the development of consistent regulatory processes when considering vaccines, medical devices, complementary or prescription medicines or the implementation of pharmacovigilance activities. Combined with ongoing professional development for staff, this work ensures emerging regulatory policy is aligned with international best practice.

Project	Activities to be undertaken in 2018-19	Area
Influenza Essential Regulatory Laboratories (ERLs) Laboratories are located in: Australia, Japan, UK and USA	In collaboration with the Global Influenza Surveillance and Response System (GISRS) network, the TGA contributes to the development, standardisation and regulation of influenza vaccines. Activities planned for 2018-19: • Produce, calibrate and make available reagents needed for use in the influenza vaccine potency assay. • Perform serological studies using sera from human influenza vaccines and share the results to support influenza vaccine virus selection. • Participate in the WHO vaccine composition consultations to review data generated by the GISRS and make recommendations on influenza vaccine composition for the next northern and southern hemisphere influenza seasons.	LB

Project	Activities to be undertaken in 2018-19	Area
International Coalition of Medical Regulatory Agencies (ICMRA) Further information about ICMRA is available at: http://icmra.info/drupal/	Throughout 2018-19, the TGA will continue to engage with ICMRA as Vice-Chair of the Coalition and participate with its working groups to build a global architecture to support information sharing, crisis response and address regulatory science issues. ICMRA's working groups include: • Pharmacovigilance • Communications Project • Innovation – Horizon scanning methodologies – Novel approaches to licensing. This work promotes efficient and informed, risk-based allocation of regulatory resources to avoid duplication of effort.	MRD / REPB
International Pharmaceutical Regulators Programme (IPRP) IPRP will provide an environment for exchange of information on issues of mutual concern and foster greater regulatory cooperation across member regulators.	In collaboration with IPRP members, the TGA will work to promote convergence of regulatory requirements for new chemical and biological entities and generic medicines, identify emerging regulatory issues, align activities and share learnings. Over 2018-19, the TGA will be actively engaged with and/or monitor progress of IPRP's working groups: • Quality for Generics • Bioequivalence for Generics • Information sharing for Generics • Biosimilars • Nanomedicines • Gene therapy • Cell therapy • Identification of Medicinal Products.	MRD / REPB

Project	Activities to be undertaken in 2018-19	Area
Australia, Canada, Singapore, Switzerland (ACSS) Consortium The goal of ACSS is to maximise international cooperation and reduce duplication.	The TGA's ongoing involvement with ACSS will allow us to progress the current information and work-sharing initiatives (details provided under Goal 2). ACCS working groups include: • Generic Medicines • Biosimilars • Complementary Health Products • New Chemical Entities • Information Technology • Future Strategy.	MRD / REPB
International Medical Device Regulators Forum (IMDRF) The aim of IMDRF is to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices and to accelerate international medical device regulatory harmonisation and convergence. Further information about IMDRF is available at http://www.imdrf.org/	IMDRF is an international forum to develop a globally harmonised approach to regulating medical devices, improve international standards, adverse event terminology and develop an unique device identification (UDI) system. The TGA will be actively engaged in a range of work throughout 2018-19, including: • unique device identification (UDI) application guide • personalised medical devices • improving the quality of international medical device standards for regulatory use • adverse event terminology • good regulatory review practices • regulated product submission Details for these projects provided under Goals 2 and 3.	MDB
Pharmaceutical Inspection Co-operation Scheme (PIC/S) Further information about PIC/S is available at https://www.picscheme.org/	As a foundation member, the TGA leads the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates for medicines. Throughout 2018-19 work will progressing: • quality risk management • data integrity • classification of deficiencies • automated systems • advanced therapy medicinal products (ATMPs)	MQB

Project	Activities to be undertaken in 2018-19	Area
Centre for Innovation in Regulatory Science (CIRS) CIRS is an independent research organisation providing science-based insights to advance global regulatory and Health Technology Assessment (HTA) policies. Further information about CIRS is available at: http://www.cirsci.org/	The TGA's involvement with CIRS, including as Vice Chair of Scientific Advisory Council, advances global regulatory science policies that enhance patient access to medicines. CIRS also benchmarks the performance of major regulators through its Regulatory Review Times Database. These regulators include US FDA, EMA, PMDA, Health Canada, the TGA and Swissmedic. Throughout 2018-19, theTGA will provide metrics to the CIRS database about: • the number of approved New Active Substances • types of compounds and indications approved • review types and designations • timings of approvals.	TGA
Continuing education, learning and development to maintain an effective regulatory framework	Through attendance at major international meetings, TGA staff will improve their understanding of scientific, clinical and regulatory developments. This will enhance our decision making capabilities and maintain a contemporary knowledge base to inform future policies for regulating and assessing therapeutic goods.	TGA

2 Work with others to improve the regulatory system

Faster market authorisation processes provide patients with earlier access to medicines and medical devices and minimises associated costs to industry.

Working collaboratively with international counterparts will allow us to achieve this while ensuring the TGA's strong focus on patient safety is maintained.

Enable consumer access to products evaluated in part or comprehensively by comparable overseas regulators

Project	Activities to be undertaken in 2018-19	Area
Complementary Medicines comparable overseas regulators	Establish a list of overseas regulators whose reports can be used to expedite evaluation of new listed medicine ingredients and assessed listed complementary medicines. This will reduce regulatory burden and evaluation times for sponsors and allow streamlined evaluations of new substances.	COMB
Prescription Medicines Comparable Overseas Regulators (CORs)	Engage with **Canada**, **Singapore**, **Switzerland**, **UK**, **Europe** (EMA) and **USA** (FDA) to progress the COR report-based process for prescription medicines. Planned activities include: • monitoring applications received using the new COR report-based process • further enhancing to guidance to clarify requirements and address any issues that arise for COR report-based applications.	MRD

Project	Activities to be undertaken in 2018-19	Area
European Directorate for the Quality of Medicines (EDQM) **Certificate of Suitability (CEP) Program**	The EDQM CEP program uses a centralised process to assess applications describing the manufacture and quality control of substances for pharmaceutical use. Among other benefits, issuing a CEP simplifies exchanges between regulators and industry and facilitates the assessment of marketing authorisations for medicinal products. In particular this reduces the regulatory burden of sponsors and assessment times within the TGA. Throughout 2018-19, the TGA will continue to participate in the EDQM CEP program by allowing our staff to work at the EDQM. This builds the trust of TGA evaluators in relation to the assessments performed by the EDQM, and further strengthens the international reputation of both the TGA and the EDQM CEP program.	SEB
Australia, Canada, Singapore, Switzerland (ACSS) Work-sharing Trials Generic Medicines Work Sharing Trial (GMWST) New Chemical Entities Work Sharing Trial (NCE)	In collaboration with the ACSS Consortium we will continue to focus on work-sharing initiatives to reduce regulatory burden through: • promotion of GMWST work-sharing trial with generic medicine sponsors and evaluating applications from interested sponsors • evaluation of applications for the NCE work-sharing trial.	MRD
Medical Device Single Audit Program (MDSAP) The MDSAP program promotes the use of a single program of Quality Management System Audits for medical device manufacturers performed by 3rd parties on behalf of a consortium of comparable regulators including **Brazil**, **Canada**, **Japan**, and the **USA**	Throughout 2018-19 activities will include: • working with MDSAP Auditing Organisations: Medical Device Manufacturer Witnessed audits; Surveillance Assessments; Head Office or Critical Location Re-Recognition Assessments • attending MDSAP Forums and monthly Subject Matter Experts meetings and ad hoc meetings and activities for development projects • continuing to participate in ongoing development and support for the MDSAP Regulatory Exchange Platform – secure (MDSAP REPs) and the associated Working Group. We will also support MDSAP assessments that are to be performed in the **Western Pacific Region**.	MDB

Increase flexibility in pre-market assessment / market authorisation processes

Project	Activities to be undertaken in 2018-19	Area
Early access initiatives	Through engagement with MHRA, TGA will gain a better understanding of the **UK's** early access initiative. Activities to be developed include: • Evaluator Exchange Program • Trilateral Work-sharing Model with Health Canada	PMAB, SEB
Complementary Medicines	Engage with Health Canada to investigate efficacy monographs for potential adoption or further development for complementary medicine ingredients.	COMB
Medical Devices comparable overseas regulators	Establish policies and guidelines for effective work-sharing processes with the **EU**, **Canada**, **Japan** and **USA**.	MDB
Development of joint safety and efficacy evaluation templates for new complementary medicine ingredients and products as part of the ACSS consortium	The four ACSS regulators (**Australia**, **Canada**, **Singapore** and **Switzerland**) will collaborate on joint safety and efficacy evaluation templates to reduce duplication. This will also promote mutual understanding of each agency's regulatory system and approach, and advance the TGA's commitment to use comparable overseas regulator reports as part of its evaluations.	COMB
Regulated Product Submission (IMDRF Working Group)	We will work with counterpart regulators within the IMDRF to develop a common 'Table of Contents' for medical device regulatory submissions. This format standardisation also supports electronic transmission of regulatory submissions.	MDB
Personalised Medical Devices (IMDRF Working Group)	This IMDRF working group is developing guidance that establishes definitions and regulatory pathways for Regulatory Authorities to consider in the regulation of medical devices that are intended for individual patients. This work will promote global harmonisation in terminology and premarket requirements for such devices.	MDB

Project	Activities to be undertaken in 2018-19	Area
Good Regulatory Practice (IMDRF Working Group)	Ongoing work with IMDRF to develop a common set of competency, training and conduct requirements for regulatory reviewers to build confidence in the consistency of regulatory reviews across jurisdictions.	MDB
Global Medical Device Nomenclature (GMDN) Agency	We will be participating in a project to exchange information and develop a consistent approach for nomenclature of medical devices.	MDB

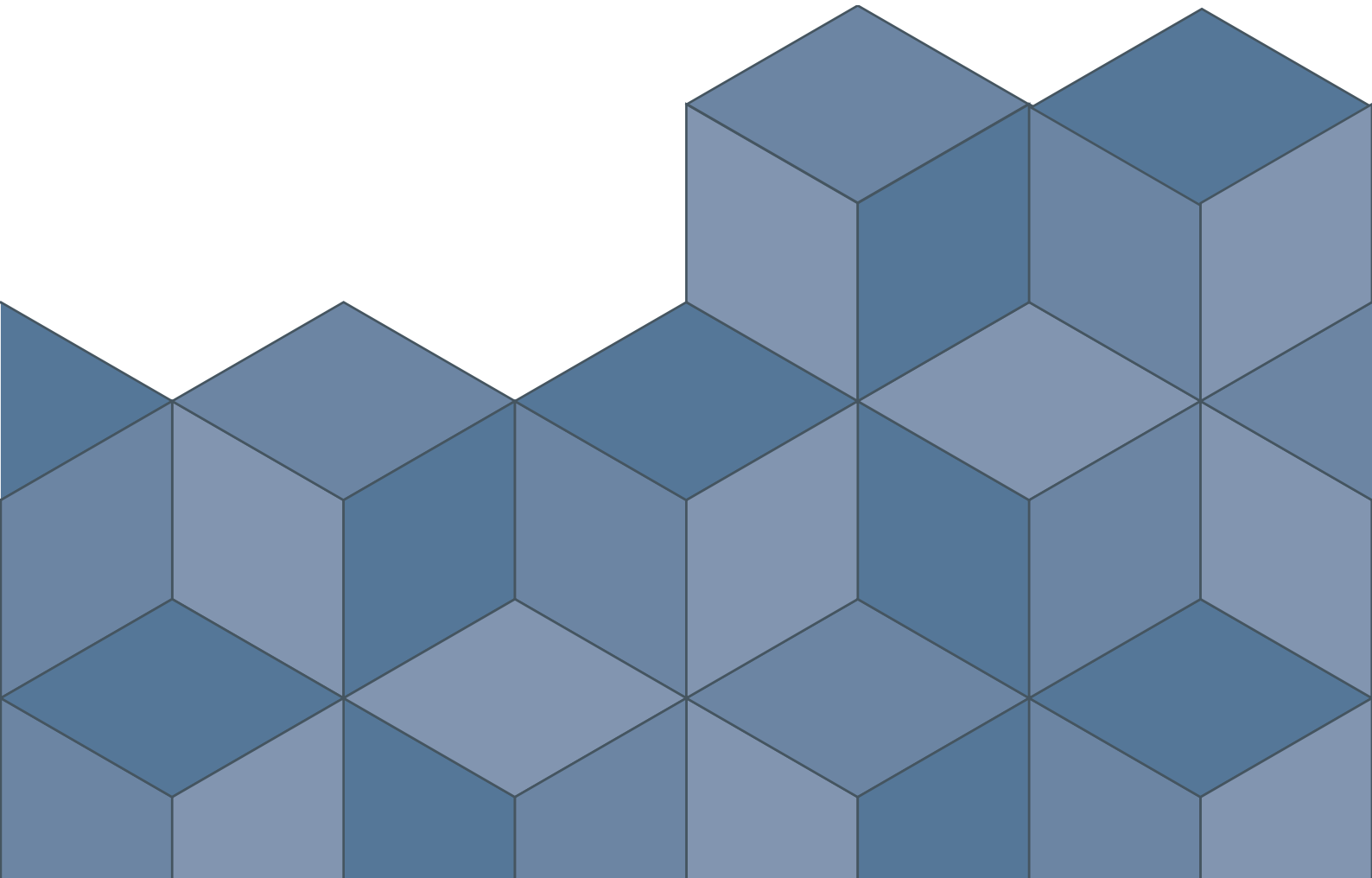
Pharmacovigilance and post-market monitoring

The TGA's international engagement on pharmacovigilance and post-market monitoring activities will focus on enhanced information sharing relating to quality, safety, efficacy and market authorisation decisions.

Project	Activities to be undertaken in 2018-19	Area
Medicines shortages	The TGA will engage with international counterparts on a regular basis to identify medicine shortages. This includes regular contact with the EMA (**EU**), FDA (**USA**), Health Canada (**Canada**), HSA (**Singapore**), Medsafe (**NZ**), SwissMedic (**Switzerland**) and MHRA (**UK**).	PSAB
Quality Management System (QMS) audits	Quality system audits of manufacturing facilities will include: • ongoing QMS audits of High Risk Class III combination and other medical device manufacturers • compliance verification/desktop assessment of audit reports from comparable regulators • assessment of MDSAP conducted audit reports.	MDB
International post-marketing surveillance	Ongoing information sharing of pharmacovigilance and signal investigation activities to strengthen TGA's regulatory intelligence with respect to provisionally approved medicines and biological medicines. Engagement includes: • regular contact with FDA (**USA**), Health Canada (**Canada**), HSA (**Singapore**), Medsafe (**NZ**), SwissMedic (**Switzerland**) and MHRA (**UK**) • International Society of Pharmacovigilance • WHO Representatives of National Pharmacovigilance Centres.	PSAB

Project	Activities to be undertaken in 2018-19	Area
International Medical Device Regulators Forum (IMDRF) Working Groups	**Adverse Event Terminology Working Group** Consistency helps when sharing information between participating regulators, industry and others. TGA will work with this IMDRF group to progress harmonisation of terms relating to the event type, evaluation, patient injury and device component. Broad consultations are planned prior to publishing documents on patient injury and device component terms. **National Competent Authority Report (NCAR) Exchange Program** Throughout 2018-19 TGA will continue to participate in this program to facilitate the exchange of information about medical device problems between participating regulators.	MDB
Good Manufacturing Practice (GMP) Inspections	Over the year, we will continue developing processes for joint inspections with partner Regulators to reduce regulatory burden to industry. Activities will include: • continuation of the collaboration program with Health Canada, including operationalisation of GMP inspections for Active Pharmaceutical Ingredients (API) manufacturers • continued participation in the PIC/S Programme to rationalise international GMP Inspections of Active Pharmaceutical Ingredient (API) manufacturers with **Australia**, **Canada**, **Denmark**, **France**, **Ireland**, **Italy**, **Japan**, **UK**, **USA**, **European Medicines Agency** (EMA), and **World Health Organization** (WHO) • continuing to upload of TGA inspection schedules into the planning module of the EudraGMDP database to facilitate joint inspection activities with other Regulators.	MQB

3 Participate in information sharing and convergence activities



Throughout 2018-19, the TGA will continue to work with our international counterparts to make informed and internationally consistent decisions about therapeutic goods in Australia.

This will be facilitated by developing frameworks for sharing information and supporting the development of globally consistent science-based standards.

Develop collaboration frameworks with international counterparts

We will develop and maintain up-to-date memoranda of understanding (MOUs) or Mutual Recognition Agreements (MRAs) with regulatory counterparts and make these readily available to our staff. This will increase awareness of existing international arrangements, promote their use and reduce unnecessary duplication of effort across regulators.

Project	Activities to be undertaken in 2018-19	Area
Over-the-counter (OTC) medicines	Engage with Medsafe (**NZ**) to progress opportunities for closer collaboration and develop improved framework for assessment and post-market monitoring of OTC medicines.	COMB
Long term rotations of evaluators with counterpart agencies	Develop an activity that builds mutual confidence in greater use of international evaluations from regulators in **UK**, **Japan**, **Singapore** and **Switzerland**.	PMAB
Senior Australia - New Zealand Evaluator's meetings	The TGA and Medsafe plan on continuing to meet monthly via teleconference. Outcomes inform evaluators and progress alignment efforts through: • identifying issues of mutual concern • sharing information on candidates entry to the new evaluation pathways • continuing to share policy initiatives.	PMAB

Project	Activities to be undertaken in 2018-19	Area
Mutual Recognition Agreements	Review and update, where necessary, MRAs with other regulatory authorities to ensure manufacturing quality through: • continued recognition of GMP Inspections performed and GMP Certificates issued by MRA authorities, in lieu of TGA physical on-site inspections for overseas sites manufacturing medicines and/or Active Pharmaceutical Ingredients (API) • development of processes which allow the use of Health Canada inspections performed outside **Canada** for the TGA GMP clearance process, in lieu of physical on-site inspections under the current Mutual Recognition Agreement with Health Canada • inclusion of Active Pharmaceutical Ingredients in the **Australia-Canada** Mutual Recognition Agreement.	MQB
Paul Ehrlich Institute (PEI)	Engagement with the **German** regulator will progress harmonisation of requirements in regard to plasma master files (PMF) and vaccines and use of the annual PMF certification in Germany as a surrogate for TGA evaluation, in accordance with the MOU between the PEI and TGA. Activities planned include: • discussing the testing requirements for viral safety of vaccines, and specifically requirements for egg-derived inactivated Influenza vaccines • discussing the mechanisms available for obtaining and using PEI assessments of viral safety for vaccines to improve the effectiveness of the TGA assessment process.	SEB
MHLW/PMDA	Invite **Japanese** regulators to discuss opportunities for formal confidence building and possible staff exchanges. TGA will gain familiarisation with Japanese assessment reports and processes which will enhance potential for staff exchanges, formal confidence-building arrangements and report-sharing.	PMAB

Project	Activities to be undertaken in 2018-19	Area
Australia-Indonesia MoU on health cooperation	Work with **Indonesia** as required and in accordance with the established framework for collaboration, to exchange information in relation to: • regulation of prescription, over-the-counter (OTC), complementary medicines and traditional medicines • regulatory frameworks and processes for medicines classification/scheduling • developent of on-the-job and short-term training • evaluation of medicines of priority for public health.	TGA

Support ongoing development of globally consistent science-based standards

Complying with ISO and other international standards demonstrates manufacturers compliance with Australian Regulations (the Essential Principles) for medical devices. Involvement in the development of these standards ensures they set high benchmarks for safety and performance and reflect our requirements as a regulator.

Project	Activities to be undertaken in 2018-19	Area
Participate in the development of relevant ISO Standards and other relevant International Standards	Throughout 2018-19, the TGA will participate in the work of **ISO's** technical committees to develop standards for medical devices, including standards that underpin: • quality management • biological and clinical evaluation • sterilization of health care products (see TC198 below) • administration of medicinal products and catheters • transfusion, infusion and injection, and blood processing • non-systemic contraceptives and STI barrier prophylactics • lung ventilators and related equipment. Participate in **Standards Australia's (SA)** local standardisation committees. SA is Australia's nominating body to ISO and the local committees serve to ensure that ISO standards are suitable for use in Australia before they are adopted here. This work will influence standards for: • medical electrical equipment • surgical implants • medical gas systems • medical device quality systems • diagnostics clinical laboratory testing and in vitro diagnostic test systems. Participate on **American Society for Testing and Materials (ASTM)** committees and standards. ASTM standards are used to demonstrate compliance with Australian regulations.	MDB

Project	Activities to be undertaken in 2018-19	Area
ISO Technical Committee 198 (TC198) Sterilisation of health care products	Standards and guidance documents developed by ISO TC198 are used internationally and within Australia by industry and regulators as an adjunct to *Annex 1 Manufacture of sterile medicinal products to the PIC/S Code of GMP* and as a basis for manufacturing standards for cell-based health care products. Throughout 2018-19, the TGA will represent Australia at the ISO TC198 plenary meeting and technical meetings, as well as continue development of a range of ISO TC198 standards for: • ethylene oxide sterilisation • radiation sterilisation • moist heat sterilisation • packaging • microbiological methods • aseptic processing • reprocessing of resterilisable medical devices • washer-disinfectors • assurance of sterility.	LB
International Council on the Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	The TGA will participate in meetings with ICH Expert Working Groups to provide guidance on data requirements for BCS based biowaivers, including work on: • an electronic common technical document • a biopharmaceutics classification system • the detection of toxicity to reproduction for human pharmaceuticals.	SEB & PMAB

Project	Activities to be undertaken in 2018-19	Area
World Health Organisation (WHO) • WHO Collaborating Centre for Drug Quality Assurance • WHO Collaborating Centre for Quality Assurance of Vaccines and other Biologicals • WHO Consultation of Quality Control Laboratory Tools and Specifications for Medicines • International Non-proprietary Names (INN) Consultations	WHO's *International Pharmacopoeia* is a key source of pharmaceutical standards for developing countries and regions. Planned activities for 2018-19: • Successful re-designation of the Collaborating Centre for Drug Quality Assurance for the period 2019-2022. • Successful re-designation of the Collaborating Centre for Quality Assurance of Vaccines and other Biologicals for the period 2019-2022. • Finalise drafting monographs for moxifloxacin hydrochloride and moxifloxacin tablets. • Ongoing work to contribute to the harmonisation of prescription medicine names. This reduces prescription errors, improves pharmacovigilance and provides savings for the PBS.	LB, SEB, PSAB

Project	Activities to be undertaken in 2018-19	Area
International Medical Device Regulators Forum (IMDRF) Working Groups	Work to progress identification of commonly recognised standards and analyse differences on adoption/recognition between members. **Standards Working Group** • Progress the new project to update the list of international standards recognised by IMDRF members. • Review and launch the guidance document "Optimizing Standards for Regulatory Use". **Personalised Medical Devices Working Group** • Develop guidance that establishes definitions and regulatory pathways for regulators to consider in the regulation of medical devices that are intended for individual patients. • Promote global harmonisation in the terminology and premarket requirements for such devices.	MDB

Enablers - activities to support TGA's international engagement

Project	Activities to be undertaken in 2018-19	Area
Horizon Scanning Model	Develop a model to facilitate the timely capture and communication of global issues and opportunities affecting the regulation of medicines and medical devices.	REPB
Regulatory Intelligence Standard Operating Procedures for international engagement	Develop a consistent and coordinated approach, including an inter-agency template, to track intelligence activities about regulatory intelligence matters.	RECB
Directory of contacts with comparable regulators	Develop a resource that allows TGA staff to engage at level with international regulators, reducing the loss of corporate knowledge if and when staff change positions.	REPB
Technology resource support strategy	Given Australia's geographic location, time and cost of travel, we will enhance the TGA's capacity to engage in international regulatory forums by identifying resources required and consistent protocols to take advantage of video and phone technology.	REPB
Communications portal	Collect, compile, edit or write information about international activities, resources and protocols for use by TGA staff and make available from the TGA's intranet and internet sites, as appropriate.	REPB
Hosting international delegations and training	Coordinate resources as required to facilitate international visitors coming to the TGA.	REPB
Coordinate training	Coordinate and develop, in collaboration with international counterparts, training for staff from other regulatory authorities wishing to visit Australia, specifically those from the Western Pacific Region.	REPB

Therapeutic Goods Administration

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