

Independent program evaluation and forward scoping (PEFS): Joint TGA and DFAT Management Response

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Date Approved: 15 February 2023

SUMMARY

Regulatory Strengthening Program (RSP)

Focus	Details
AidWorks initiative numbers	INM657
Commencement date	01 October 2018
Completion date	30 June 2023
Total Australian \$	11 million
Delivery organisations	Therapeutic Goods Administration (TGA), Duke-NUS Centre of Regulatory Excellence (CoRE), United States Pharmacopeia (USP)
Region	South-East Asia and Papua New Guinea

Focus	Details
Initiative objective/s	The Indo-Pacific Regulatory Strengthening Program (RSP) was jointly developed by the Department of Foreign Affairs and Trade and the Department of Health (DoH), through the Therapeutic Goods Administration (TGA). Funded by the Health Security Initiative for the Indo-Pacific, the Program aims to improve marketing authorisation systems for medicines and medical devices and to promote regional collaboration on regulatory practice. The TGA will establish people -to -people and institutional links with counterpart regulatory authorities in Cambodia, Indonesia, Laos PDR, Myanmar, Papua New Guinea, Vietnam, and Thailand. The high-level objective is to strengthen health security in the Indo-Pacific by improving access to quality medical products for the diagnosis, treatment, and prevention of priority diseases. The Program complements DFAT's \$75 million Product Development Partnerships Fund, which aims to bring new treatments and diagnostics to market for malaria and tuberculosis.

Australian Expert Technical Assistance Program Regulatory Support and Safety Monitoring (AETAP-RSSM)

Focus	Details
AidWorks initiative numbers	INN668, 21A116, 14488/30
Commencement date	30 Apr 2021
Completion date	30 June 2023
Total Australian \$	9 million
Delivery organisation	TGA
Region	South-East Asia and the Pacific
Initiative objectives	The Australian Expert Technical Assistance Program for Regional COVID-19 Vaccine Access: Regulatory Support and Safety Monitoring (RSSM) will support Pacific and Southeast Asian countries' efforts to deliver safe, effective and accessible COVID-19 immunisation programs, based on a health and regulatory systems strengthening approach and in line with best practice standards. The Therapeutic Goods Administration (TGA) will provide technical regulatory input to support evaluation of COVID19 vaccines, marketing authorisation/product registration of COVID19 vaccines, ensuring the quality of vaccines procured, and pharmacovigilance and vaccine safety activities.

EVALUATION SUMMARY

Evaluation Objective: The purpose of the Program Evaluation and Forward Scoping Program (PEFS) was to evaluate DFAT-funded work of TGA (2018-present) and to also scope a future TGA-DFAT partnership. The evaluation component of the report aimed to determine whether the RSP and RSSM had met, or were on track to meet, their end of program outcomes (EOPOs), associated enablers and barriers to EOPOs as well as suggested program modifications to increase the ability to achieve intended outcomes. The scoping section of the report intended to propose country specific approaches and regional cooperation mechanisms for a future phase of work.

Evaluation Completion Date: 31 December 2022

Evaluation Team: Dr Barry Walker and Dr Kathryn Dinh

MANAGEMENT RESPONSE

The TGA and DFAT welcome the independent Program Evaluation and Forward Scoping Program (PEFS). The TGA and DFAT consider that the broad selection and participation of evaluation participants has resulted in robust program-wide evaluative findings and illustrative country-specific achievements and challenges. The realist evaluation section of the PEFS usefully identifies and articulates program-wide strengths, detractors and opportunities for improvement. DFAT and the TGA find it valuable to review informative evaluative findings across both programs of work in one coherent report and to triangulate findings from the external evaluation team with our own assessments and feedback from partners. The scoping report, and its recommendation for DFAT to enter into another partnership with the TGA, aligns with DFAT's favourable view of the program. The TGA and DFAT welcome broad recommendations in the report, and the TGA will lead work to review technical sections of this report and will include elements that add value to the program and meet partner country needs.

Individual management response to the recommendations

#	Recommendation	Response	Explanation	Action plan	Timeframe
1	<p>Strategy: TGA and DFAT to develop a five-year strategy for a new TGA-DFAT partnership funded by DFAT, incorporating elements that will continue from both RSP and AETAP-RSSM. The strategy could include:</p> <ul style="list-style-type: none"> • Clear vision, goal and anticipated end of program outcomes in regulatory strengthening that align with the goal and objectives of DFAT's next phase of health security programming and takes into account pandemic preparedness • 10-year stretch objectives • Sections for strategic planning with Duke-NUS Centre of Regulatory Excellence (CoRE), United States Pharmacopeia (USP), mSupply and National Centre for Immunisation Research & Surveillance (NCIRS) <p>The strategy could also incorporate recommendations 2a to 5 below.</p>	Agree	<p>TGA and DFAT agree that a five-year strategy, that combines the RSP and AETAP-RSSM programs is desirable.</p> <p>DFAT will continue to manage delivery of outcomes for partner organisations, which will complement the regulatory strengthening activities of the TGA.</p>	Recommendation 1 will be addressed as part of the strategic design process.	30 Jun 2023
2a	<p>Scope of work</p> <p>Technical areas: TGA to continue to provide country-level technical assistance in the core areas of Market Authorisation (MA), Good Manufacturing Practice (GMP) and pharmacovigilance (PV).</p> <p>: Merge activities provided under RSP and AETAP-RSSM.</p> <p>: Consider limited technical assistance (TA) in advanced therapeutics, substandard and falsified medicines</p>	Agree	<p>The TGA and DFAT broadly agree with the recommendations on technical areas of focus, program merging recommendations and agree that GEDSI should be integrated into the long-term planning of the program, with specific goals identified.</p> <p>DFAT and the TGA will remain committed to working with global partners to address substandard and falsified medicines on the</p>	Recommendation 2a will be addressed as part of the strategic design process.	30 Jun 2023

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	: Include a long-term planned approach to Gender equality, disability and social inclusion (GEDSI).		market, namely supporting the WHO's Member State Mechanism for Substandard and Falsified Medical Products through active participation and encouraging the involvement of partner NRAs. The TGA agrees that technical assistance and support in relation to the regulation of advanced therapies should be incorporated into the program. In particular, the TGA will support partner countries in their assessment of whether adequate safety monitoring systems are in place for these products.		
2b	Types of programming: TGA to maintain a tiered, country-specific technical assistance framework taking into account the existing maturity level of the NRA or regulatory capacity of the MoH, along with due regard to regional public health priorities. : Establishing autonomous manufacturing capability is becoming a priority for many countries in the region.	Partially agree	DFAT and the TGA agree that a focus on country--specific needs, capabilities and capacities is important. Establishing autonomous manufacturing capability is a priority for many countries in the region, but is not the focus of a regulatory strengthening program nor something which the TGA is best placed to deliver. NRAs can be supported to build capacity in the areas of technology transfer assessment (quality assessment) and Good Manufacturing Practice (GMP) inspections. Building capability in these areas will allow NRAs to adequately assess new domestic manufacturing facilities for registration.	The TGA will work closely with NRAs to update country-specific workplans in line with new program goals and updated country needs, aimed at increasing the maturity level of the NRA, in line with the WHO GBT.	30 Jun 2024
2c	Regulatory cooperation (convergence, reliance, harmonisation etc): TGA to support existing processes	Partially agree	The TGA currently supports the WHO CRP, ASEAN JACG and WHO Pacific sub-regional platform. The	The TGA will continue to support the WHO CRP, ASEAN JACG and the	Ongoing

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	<p>for regional regulatory cooperation, including the ASEAN JACG and the WHO Pacific Sub-Regional Platform.</p> <p>: TGA, with DFAT’s support, to work towards supporting other NRAs in the region as a more sustainable model of regulatory strengthening.</p> <p>: TGA to work with DFAT in providing input on any proposed regulatory legislative changes in partner countries that support convergence.</p> <p>: DFAT to collaborate with other donors to strengthen regulatory cooperation through the regulatory providers’ forum (see below).</p> <p>: TGA to assess how to support the ASEAN Common Technical Document process.</p> <p>: TGA to support building of common capacity and understanding on risk management and assessments for MA of new products and PV planning.</p>		<p>TGA has supported a number of ASEAN JA processes to date as the reference agency, through the provision of technical assistance to the RSP countries involved.</p> <p>The TGA agrees that support can be given to other NRAs in the region to take on a lead role in the provision of technical assistance and regulatory strengthening, where appropriate.</p> <p>Upon request, the TGA currently provides support for legislative changes in partner countries and agrees that this should be continued to be offered as part of a regulatory strengthening program with due consideration to key stakeholders and policy settings.</p> <p>Refer to recommendation 4 for the TGA and DFAT’s views on donor collaboration.</p> <p>The ASEAN CTD (ACTD) and associated guidance documents are well established and adopted by all ASEAN countries. The TGA is able to offer support for the implementation of ASEAN and ICH guidelines and their interpretation by NRAs, where this is identified as a priority in country--specific work plans.</p> <p>The TGA and DFAT agree that support should be given to build an understanding of risk</p>	<p>development of the WHO Pacific sub-regional platform.</p> <p>The TGA will work with DFAT and other regional partners (especially the WHO and other regulators engaged in regulatory strengthening activities in the region) to consider how other NRAs in the region can be engaged to take on a lead role in the provision of technical assistance.</p>	<p>30 Jun 2025</p>

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			<p>management and assessments for MA of new products and pharmacovigilance (PV) planning. All technical assistance provided through the program has a focus on risk-based decision making and mitigating risks for all products in the interests of public health and safety. PV continues to be a focus of the program with PV systems strengthening a key item for future programming.</p>		
2d	<p>Information technology: TGA to support and advise on the implementation of IT systems used to facilitate compatible regulatory processes where possible. This could include continued work with mSupply and contributing to early steps for a joined-up data base on regulatory decision making. Early steps could include TGA agreements for sharing documents bilaterally or between sub-regional groups of countries.</p>	Partially agree	<p>The TGA supports the implementation of IT systems to facilitate electronic dossier submission and assessment. There are multiple IT system providers currently working in the region. The TGA will support NRAs to implement regulatory IT systems of their choosing, irrespective of the system provider.</p> <p>The TGA and DFAT do not believe that a joined-up data base for regulatory decision making should be a priority for the next phase of programming. The TGA currently works bilaterally with countries to share documents under MoUs as well as multilaterally through the ASEAN JA and the WHO CRP, both of which have platforms for the secure sharing of documents and are conducted with the full knowledge and support of the relevant pharmaceutical company.</p> <p>In the policy and legal settings of many countries in the region, information relating to the receipt of a regulatory application is itself considered to be commercial-in-confidence information, in addition</p>	<p>The strategic decision and country plans for the partnership for the next five years will include:</p> <ul style="list-style-type: none"> • The TGA to provide support to NRAs with the implementation of IT systems regardless of the technology platform. • The TGA to provide requested support and advice to regulatory IT systems partners working in the region • The TGA to continue supporting bilateral sharing of documents under MoUs and multilaterally through already existing platforms (such as ASEAN JA, CRP). • The TGA to provide product specific technical support to Market Authorisation activities to one or more NRAs at the request of the Market Authorisation Holder (MAH). 	Ongoing

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			<p>to the accompanying data and supportive documentation. Such challenges need to be considered in relation to operationalising 'common applications' and resource sharing initiatives.</p> <p>The TGA will continue to provide support for the development of the WHO Pacific sub-regional platform, which will be a useful resource for countries involved.</p>	The TGA to encourage MAH support of document sharing through secure means.	
4	Regulatory providers' forum: TGA and DFAT to initiate a regulatory providers' forum, together with other actors such as WHO, Bill & Melinda Gates Foundation (BMGF) and USP. This forum will coordinate regulatory strengthening activities, including training and support and cooperative regulatory processes such as reliance, in the Indo Pacific. Such a forum would include MFDS (South Korea), NIID (Japan), NZ MedSafe and others funding and conducting activities in the region.	Partially agree	The TGA and DFAT agree that there would be benefit in establishing closer relationships with other donors, associated NRAs and complementary providers of regulatory strengthening (such as WHO headquarters, country and regional offices, USAID, MFDS South Korea, NIID Japan, NZ MedSafe, BMGF, USP). The modality for how to engage these partners will be determined following further consultation.	Recommendation 4 will be addressed as part of the strategic design process.	30 Jun 2023/Ongoing
5	Partnership between TGA and DFAT: Strengthen the partnership approach between DFAT and TGA, including the allocation of greater resourcing from DFAT (Global Health Division (GHD) program management and time spent by posts) by: <ul style="list-style-type: none"> - GHD engaging posts in country-level planning of a new TGA-DFAT partnership and brokering meetings with MoHs/partners; and GHD providing background information to posts on how to support the work of TGA. 	Partially agree	<p>The TGA and DFAT agree there is considerable merit in maintaining a strong and productive partnership.</p> <p>The TGA and DFAT GHD agree that further efforts can be made to engage posts with strategic forward country planning and program implementation, while remaining mindful of resource constraints and competing priorities in broad bilateral relationships.</p>	<p>Actions and working arrangements to promote a strengthened partnership approach will be reflected in the strategic design for the next 5 years, and reviewed during regular partnership discussions between the TGA and DFAT.</p> <p>The strategic partnership design will acknowledge and complement the existing DFAT-funded TGA-led Pacific</p>	30 Jun 2023/Ongoing

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	<ul style="list-style-type: none"> - DFAT specifically engaging with PICs for ongoing TGA TA and facilitating cross program learning with Pacific Medicines Testing Program (PMTTP). - DFAT facilitating TGA support for ASEAN JACG and the WHO-coordinated Pacific Sub-Regional Platform. - DFAT conducting diplomatic meetings (Japan, Korea, NZ, US etc.) to optimise regulatory inputs and coordination in the region. - DFAT to enhance coordination (where appropriate) with other relevant DFAT-funded programs – e.g. PDP (Product Development Partnerships) Fund, mSupply, NCIRS so that there is increased visibility of planned activities and where each partner can add value to the other. 		<p>The TGA’s technical expertise and existing relationships mean it is well placed to lead the Australian Government’s engagement on certain issues without requiring or benefitting from DFAT support. DFAT will remain central coordination point for all DFAT funded program partners. The TGA and DFAT engagement with Japan, Korea, NZ and US will be considered in recommendation 4.</p>	<p>Medicines Testing Program and the programs will be strongly coordinated.</p>	
6	<p>TGA organisational management: Increase the knowledge and experience of development and culturally responsive practice within the TGA team in order to strengthen work with country partners.</p> <p>: Explore organising the secondment or placement of a TGA member of staff into DFAT’s Global Health Division or having a DFAT member of staff seconded/placed in TGA for a limited period/regularly to improve mutual understanding of activities and ways of working, as well as in development practice through closer work with DFAT.</p>	Partially agree	<p>The TGA and DFAT agree that further increasing knowledge and experience of development and culturally responsive practise should be a priority in the next phase. Secondments are one possible approach.</p>	<p>The TGA and DFAT to explore a secondment plan and/or shared working arrangements to facilitate knowledge sharing.</p> <p>The TGA and DFAT to explore available developmental and cultural awareness training for TGA staff on DFAT’s Lumi training platform and through external providers.</p>	<p>31 Jan 2024</p> <p>31 Jan 2024</p>

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7	<p>Measuring outcomes: Use the robust monitoring systems established by TGA to increase focus on measuring and reporting on interim and end of program outcomes for the remainder of this phase of activity and ensure that MEL (Monitoring, Evaluation and Learning) systems for a future TGA-DFAT partnership continue to emphasise the monitoring of outcomes.</p> <p>: In the MELF (Monitoring, Evaluation and Learning Framework) for a future partnership with DFAT, include an indicator to measure the value of TGA's partnerships with regional stakeholders.</p>	Agree	The TGA and DFAT agree that a strong focus on robust monitoring, evaluation and learning systems is important. Improved indicators to measure the value of TGA's partnerships will be explored.	Recommendation 7 will be addressed as part of the strategic design process.	30 Jun 2023