

Indo-Pacific Regulatory Strengthening Program 2023-2027

Commenced 1 July 2023

The Therapeutic Goods Administration (TGA) has entered a strategic partnership with the Department of Foreign Affairs and Trade (DFAT) under the Partnerships for a Healthy Region (PHR) to deliver the Indo-Pacific Regulatory Strengthening Program (RSP). The Program is designed to be an extension of the previous TGA-led regulatory strengthening and support Programs (2018-23) and covers 22 countries.

In partnership with National Regulatory Authorities (NRAs), the aim of the RSP is that regulatory systems will be *strengthened*, and regulatory *support* provided, for the control of therapeutic products that support the management of communicable and noncommunicable diseases, sexual reproductive health and assistive technologies.

This will be achieved through enhanced bilateral, regional, and global reliance and cooperation mechanisms, improved regulatory tools and the design of inclusive and participatory Gender, Equality and Social Inclusion (GEDSI) regulatory systems which all will cut across the key components which make up a strong regulatory system: quality, safety, efficacy of medical products and strong risk communication.

The Regulatory Strengthening Program (RSP) 23-27 will involve:

1) Regulatory Systems Strengthening

RSP will work with countries that have an NRA to perform health systems *strengthening* and capacity building activities. This includes ensuring that the NRAs have the necessary tools to perform regulatory functions effectively, fit for purpose processes and that regulatory staff have adequate technical capability.

2) Responsive Regulatory Support

In line with good development principles, it's important that assistance is demand driven. Recognising this and the fact that many of the countries supported by RSP don't have regulatory authorities, an 'on call' *support* will be offered to address specific regulatory needs at a point in time.

The Program has been designed around the core themes of quality, safety and efficacy and risk communication, underpinned by regulatory tools and reliance and cooperation.



Program Delivery

The RSP offers tailored support to each country, as such, individual country strategies have been developed for countries with which the RSP are undertaking regulatory systems strengthening (those with an NRA).

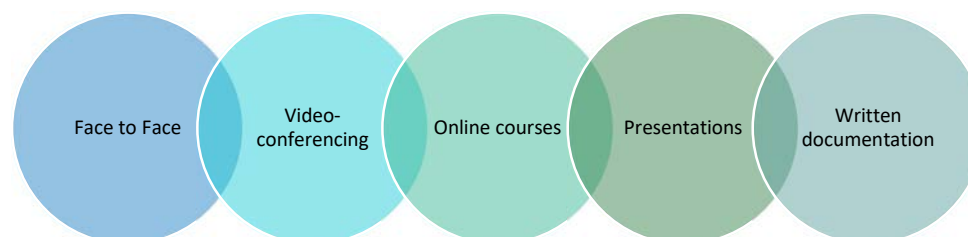
Country strategies have been designed based on the countries identified priorities, their maturity (as assessed by the World Health Organisation (WHO) [Global Benchmarking Tool \(GBT\)](#)¹, the programmatic experience over the last 5+ years and alignment to our broader MEL framework.

The country strategy design process included consultation with relevant resources, notably the WHO's [Global competency framework for regulators of medicines](#) ("the Framework") which expresses competencies and tasks for practice activities as three proficiency levels: foundational (level I), intermediate (level II), and advanced (level III). Language around proficiencies has been adopted throughout the strategies to ensure standardisation.

In addition to the approaches outlined in these country specific strategies, the RSP will work multilaterally with countries through existing forums (e.g., ASEAN Joint Assessment) and will explore new avenues for engagement identified over the course of the program. Our multi-lateral approach will be described in a complementary program strategy.

The country strategies include a description of activities under thematic areas with timeframes rather than specific points in time. These are flexible enough to accommodate evolving country priorities and few, if any, revisions should be required.

The RSP is committed to ensuring a holistic approach to capability building which includes multi-modal delivery of activities. The delivery of training will leverage the most effective elements for a given country.



Alignment with cross-cutting themes

Country strategies have been determined based on nominated priorities and alignment to the MELF. When delivering activities alignment to cross cutting themes of GEDSI, climate change and One Health will be considered. This will include promoting collaboration on and consideration of these approaches, supporting partner NRAs in implementing considered regulatory approaches and reflecting on the potential climate and environmental impacts of the Program. Where appropriate the RSP will assist with the assessment and approval of important medical products that also address the cross-cutting themes i.e. products that are important for sexual and reproductive health aspects, communicable and non-communicable disease threats.

Engagement with post

Country strategies will be shared with posts annually and be used to brief posts when RSP staff are conducting in-country activities. Country strategies can be used by post to brief partner governments and other development agencies, as required.

Posts will be informed of major activities that are being conducted and notified when there are intentions to visit the country. The RSP can be contacted at rsp@health.gov.au.

¹ The WHO's GBT assessment process also includes formulation of an institutional development plan (IDP) to build upon strengths and address identified gaps. The RSP looks for alignment with the IDPs when considering country priorities.



Siem Reap Resort

Proforma Invoice

From:

CY-SR HOTEL GRAND LION CO., LTD.

Address: #0609 Road No 6A, Phum Chongkoesu, Khum Slor Kram, Siem Reap, Cambodia.
Tell: (+855) 063 968 888/ Fax: (855) 63 96 7799, E-mail: s22@marriott.com
VAT No. B116-901700083

INV No : Profor-24029

Date Print 04-Sep-2024

Our Ref :

To:

Indo-Pacific Program

Att: s22
Address: Gulgana building, Scherger drive, Fairburn
PO Box 0000, Canberra ACT 2601, Australia
Email: s22@health.gov.au

Table with 6 columns: No, Description, No. Night, Quantity, Rate, Amount. Rows include Accommodation, Meeting Packages, Gala Dinner, and a Total row with sub-totals for 1st Deposit and Balance to be Paid.

Please pay by US Dollar.

Payment instructions:

If Payment by Cheque, please make cheque payable to CY SR HOTEL GRAND LION CO., LTD

If Payment by Telegraphic Transfer with Advanced Bank of Asia Limited (ABA)

Account Name : CY SR HOTEL GRAND LION CO., LTD
Account No : 000 694 887
Beneficiary Bank Name : Advanced Bank of Asia Limited (ABA)
Beneficiary Bank Address : No.148, Preah Sihanouk Blvd, Phnom Penh , Cambodia
Beneficiary Bank SWIFT : ABAKHPP
Intermediary Bank : JP Morgan Chase Bank
SWIFT CODE : CHASUS33

Remark: All Bank Charges are borne by Customer

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Guest Signature & Name

Authorized Signature & Name