Australian Government
Department of Foreign Affairs and Trade

Product Development and Access Partnerships Guidelines and Templates

Contents

Section 1: Background and Introduction

1.1 The Australian Government, through the Indo-Pacific Centre for Health Security (CHS or Centre) which sits within the Department of Foreign Affairs and Trade's Global Health Division, is seeking proposals for the Product Development and Access Partnerships under the Partnerships for a Healthy Region initiative (PHR) (2022-23 to 2026-27).

1.2 The predecessor to the PHR, the $300 million Health Security Initiative for the Indo-Pacific Region (HSI), 2017-2022, aimed to reduce risks associated with emerging and endemic infectious diseases with the potential to cause social or economic harm on a national, regional or global scale. The HSI supported four Product Development Partnerships (**PDPs**). Additional PDP investments were made by DFAT to support partner governments' COVID-19 prevention and response strategies.

1.3 PDPs are publicly-funded global research and development organisations that bring together public, private, academic and philanthropic actors to drive the development of life-saving medical products for use in developing country settings. PDPs aim to develop and deliver new diagnostics, medicines, vaccines and vector control tools, with a focus on neglected diseases such as tuberculosis (TB) and malaria. Neglected diseases are those for which there are no, ineffective or incomplete tools to respond to the disease coupled with an insufficient commercial market to drive companies to develop new products.

1.4 Since June 2012 the Australian Government has supported four main **PDPs**: the Medicines for Malaria Venture (MMV), TB Alliance, the Innovative Vector Control Consortium (IVCC), and FIND. Australia's current funding for these **PDPs** concludes in June 2023. Over this time the product pipeline of these **PDPs** has advanced with a number of key products introduced, or on the cusp of being introduced, into the Indo-Pacific region. This includes TB and malaria drugs and diagnostics, vector control toolkits and COVID diagnostics. In addition, the Australian Government has supported the Coalition for Epidemic Preparedness Innovations (CEPI).

1.5 Up to AUD75 million will be made available over five years (2022-23 to 2026-27) for activities supported through the Product Development and Access Partnerships program under PHR. In addition to funding for core research and development activities, this competitive process will also encourage PDPs to address product access barriers. This could include working with a range of partners such as international and local NGOs, specialists in the development of treatment guidelines, or agencies specialising in de-risking the procurement of medicines or health technologies by developing countries to reduce product prices and facilitate supply.

1.6 These Guidelines explain the competitive application process for selection of organisations or consortiums that will be supported by DFAT through the Product Development and Access Partnerships program.

Section 2: Operational objectives

2.1. The **Partnerships for a Healthy Region initiative's** goal is *to help build resilient and equitable health systems in the Indo-Pacific region, capable of progressively reducing disease burdens and responding effectively to health emergencies* (see Annex 1 for the Partnerships for a Healthy Region initiative's provisional program logic). The strategic objective of the **PHR** is that *Australia is a trusted health partner in the Pacific and Southeast Asia, with stronger institutional linkages and high value placed on our public health expertise*. The Competitive Application process for **Product Development and Access Partnerships** seeks to meet this goal through a focus on research and product development and to further drive access to these new products in the Pacific and Southeast Asia region.

2.2. **Intermediate outcomes** (provisional) specific to **Product Development and Access Partnerships** that are to be achieved are as follows:

Intermediate Outcome 1: New products targeting diseases in scope are trialled in partner countries.
Intermediate Outcome 2: New products targeting diseases in scope receive marketing authorisation at global level and in partner countries.
Intermediate Outcome 3: Guidelines and policy documents are updated stating acceptability of new products at global level and in partner countries.
Intermediate Outcome 4: New products are included in the Global Fund Procurement Database and/or similar procurement tools or instruments.
Intermediate Outcome 5: Volume of product distributed in the partner countries increases.

2.3. **End of Program Outcomes (EOPOs)** (provisional) specific to **Product Development and Access Partnerships** that are to be achieved by 2027 are as follows:

EOPO 1: Increased development, trialling, registration of, access to and take up of new or modified drugs, diagnostics, vaccines and vector control tools for use in partner countries.
EOPO 2: More effective engagement with national Governments, relevant donors, multilaterals and global institutions.
EOPO 3: Demonstrated prioritisation of GEDSI within product design, target audience, trial design, purpose and characteristics as relevant to disease burden.

2.4. Applicants will be asked to outline how their proposed activities align with the above goals, objectives and outcomes.

Section 3: Eligibility criteria

3.1 Organisation eligibility

3.1.1 **Eligible Organisations** are PDPs, other Not-for-Profit Organisations and incorporated entities. Only PDPs may receive standalone funding. Other organisations may participate in or lead consortiums, provided such consortiums include at least one PDP.

3.1.2 **Eligible Organisations** may be involved in multiple consortiums and proposals.

3.1.3 Should two or more **Eligible Organisations** wish to enter a consortium together, one partner must be nominated as a **Lead Organisation**.

3.1.4 If successful, the **Lead Organisation** will be accountable for all funds. A DFAT Funding Agreement will be signed with the **Lead Organisation**, and the **Lead Organisation** will be responsible to DFAT for the performance of the consortium under the Agreement to achieve the objectives as required.

3.1.5 Consortium proposals must be accompanied by a separate letter from each participating organisation providing information about itself, noting the relationship between the **Lead Organisation** and participating organisation(s) and expressing the intent to collaborate.

3.1.6 DFAT reserves the right to reassess any proposal if, following submission, the membership of a successful consortium proposal changes, including withdrawing consortium organisation member(s).

3.1.7 Organisations submitting proposals must not have any reason preventing them from operating in Southeast Asia, the Pacific or Australia.

3.1.8 For the purposes of clauses 9 and 10 below, **'Former DFAT Employee'** means a person who was previously employed by DFAT, whose employment ceased within the last nine months and who was substantially involved in the design, preparation, appraisal, review and or daily management of this program.

3.1.9 Individuals with conflicting commitments and/or current or **Former DFAT Employees** must not be included in the proposal or engaged in proposal activities. DFAT may reject any proposal which does not comply.

3.1.10 Proposals compiled with the assistance of current DFAT employees or **Former DFAT Employees** will be excluded from consideration.

3.2 Proposal eligibility

3.2.1. Applicants must submit proposals using the form in SmartyGrants, accessed using the following URL: https://health.smartygrants.com.au. Details outlined below are reflected in the SmartyGrants form and questions.

3.2.2. Eligibility criteria specific to this Call for Proposals are included in the table below, and should be addressed in the SmartyGrants form:

Table 1: Eligibility criteria

Criteria	Description
Applicant	A single PDP or a consortium that includes a PDP.
Diseases of relevance for the region	The **Applicant** must provide proof of research and development activity in one or more of the following disease areas: vector-borne diseases, sexually transmitted diseases, tuberculosis and neglected tropical diseases (Neglected tropical diseases -- GLOBAL (who.int)).
Product scope type	The **Applicant** must provide proof of product pipeline in one or more of the following product types: vector control technologies, drugs/therapeutics, diagnostics, vaccines.
Financial range	The proposal budget is within the indicative range of AUD5 million to AUD20 million over five years.

3.2.3. In developing a proposal, please familiarise yourself with all documentation for this application process, including these Guidelines, the Invitation to Submit an Activity Proposal, Guidance notes on GEDSI and First Nations Engagement, the Budget Template and any addenda to ensure your proposal is complete and compliant. All addenda, including frequently asked questions and any changes to timeframes, will be posted at Product Development and Access Partnerships Call Webpage. Please visit this webpage regularly to check for any updates.

3.2.4. **Applicants must upload the following items in the SmartyGrants form to be eligible for assessment:**

a. **Consortium partners –** Where applicable, applicants must include a **letter of association** for each consortium partner providing information about the organisation and its relationship with **Lead Organisation** and partner organisation(s) and expressing the intent to collaborate.

b. **Safeguards, Due Diligence and Risks –** Applicants must include details of how they will comply with DFAT's Risks and Safeguarding policies and due diligence requirements as outlined in Section 6 below, including provision of organisational risk profile, framework, risk ratings and mitigation strategies.

c. **Budget** – each proposal must include an indicative budget which outlines how the proposed funding will be utilised. The indicative budget must be submitted using the budget spreadsheet template provided with the Invitation and Application Guidelines. Figures included in the indicative budget template must match high-level figures provided in the SmartyGrants form. Indirect costs must be kept to a maximum of 15% of direct costs.

d. **References** – Applicants must include letters of support from two referees for the Lead Organisation and where applicable for each

consortium partner. These should address the organisation's experience and capacity to achieve the objectives of the program.

e. **Organisation Certification** – An Organisation Certification form must be completed by each organisation involved in a proposal.

A note on ongoing reporting – DFAT will accept reporting in the format as agreed amongst members of the PDP Funders Group to utilise standardised annual progress reporting along with budget and expenditure updates.

Section 4: Application process and indicative timeline

4.1 Indicative timeline

4.1.1 The indicative timeline for this competitive process is summarised in the table below:

Table 2: PDAP Indicative timeline

Event	Time / Date
Call for proposals issued	23 February 2023
Registration to attend virtual briefing for applicants	By 6pm AEDT, 28 February 2023
Applicant virtual briefing	9am AEDT, 1 March 2023
Closing date for prospective applicants to submit questions	6pm AEDT, 13 March 2023
DFAT publishes responses to open questions	6pm AEDT, 22 March 2023
Proposal submission deadline	6pm AEST, 20 April 2023
DFAT conformity check	Completed by 3 May 2023
DFAT Assessment process and funding decisions	April – May 2023
Offers made to successful applicants *(indicative)*	Late May 2023
Agreements finalised *(indicative)*	June 2023
Timing of initial payment subject to negotiation with each awardee *(indicative)*	June 2023

DFAT reserves the right to adjust these timeframes if required.

4.2 Applicant briefings and questions

Online virtual briefing:

4.2.1 DFAT will hold one applicant briefing for potential respondents. It will take place from 9am-10am AEDT on 1 March 2023.

4.2.2 The applicant briefings will be an opportunity for interested organisations to ask questions on the **Product Development and Access Partnerships** design, application process and implementation.

4.2.3 All presentations and material from the briefings will be published on the DFAT website, to ensure that any organisation unable to attend has equal access to information.

4.2.4 Organisations planning to attend briefing must register via the Product Development and Access Partnerships Call Webpage by 6pm AEDT on 28 February 2023.

4.2.5 DFAT reserves the right to cancel an applicant briefing if fewer than three organisations register to attend.

4.2.6 Separately, applicants can submit questions in writing by 6pm AEDT on 13 March 2023 using the chs@dfat.gov.au email address. DFAT will respond to all questions by publishing the set of questions and answers on the Product Development and Access Partnerships Call Webpage by 6pm AEDT on 22 March 2023.

4.3 Deadline for proposal submission

4.3.1 The deadline for proposal submission is 6pm AEST on 20 April 2023.

4.3.2 A full proposal must be submitted in order to be considered for assessment.

4.4 Eligibility conformance check

4.4.1 Proposals received by the deadline will be checked to ensure the organisation and proposal meet the eligibility criteria outlined above and detailed in Section 3. At DFAT's sole discretion, proposals deemed ineligible will be excluded, and affected applicants will be advised by DFAT at this stage.

4.5 Assessment process and shortlisting proposals

4.5.1 Eligible proposals will undergo a **Stage One** assessment by a **Technical Assessment Committee** (**TAC**) comprising at least two DFAT representatives with global health expertise, and at least two external representatives with experience in global health product development but no conflicts of interest.

4.5.2 The **TAC** will evaluate each proposal against the evaluation criteria (see Section 5) and assign a score against each criterion in the assessment scoresheet along with justification notes and points of substantiation. Each score is weighted as detailed in the Section 5.2 Evaluation Criteria table. Each proposal will receive a total weighted score. The **TAC** will then jointly consider disease profiles, product types, geographic aspects and value for money alongside the weighted scores and provide an assessment summary to the **Evaluation Committee**.

4.5.3 **Stage Two** assessment will be undertaken by an **Evaluation Committee (EC)**. The **EC** will comprise at least two senior DFAT representatives with

global health expertise, and one external representative with experience in global health product development.

4.5.4 The **EC** will receive all proposals and the assessment summary from the **TAC** for consideration of the portfolio of activities for **Product Development and Access Partnerships** funding. The **EC** will make recommendations to the DFAT Delegate for funding, taking into account the following factors:

a. the evaluation criteria and weighted scores;
b. assessment summary and advice from the **TAC**; and
c. portfolio balance including of target diseases, product type and geographic spread.

4.5.5 While top ranking proposals will generally be recommended for funding, high-quality lower-ranked proposals may be given preference if necessary to address critical portfolio gaps.

4.5.6 At any stage of the assessment process, DFAT may seek clarification of any delivery, commercial, risk or other matter associated with the proposal.

4.5.7 The assessment is conducted on a confidential basis, and **TAC** and **EC** members must not discuss matters relating to the assessment of any proposal with any external party. Applicants must not seek contact with any members of the **TAC** or **EC**, and any such contact will be considered a breach of confidentiality and may result in DFAT rejecting the proposal of the applicant concerned.

4.5.8 In making its assessment of a proposal, the **TAC** and **EC** may have regard to other factors relevant to the suitability, capacity and qualifications of an applicant organisation including but not limited to:

a. checking with nominated referees and with other persons or organisations the accuracy of information and quality of previous work performed including the resourcing of previous work; and
b. information obtained from any legitimate, verifiable source, which is relevant to the capacity of the applicants.

Such information may be the result of inquiries made by DFAT and may be raised with the applicant consistent with principles of natural justice.

4.5.9 Previous performance information will only be provided to **TAC** and **EC** members where it is considered relevant. **TAC** and **EC** members may not introduce irrelevant issues or hearsay into the assessment or base their assessment on information that is hearsay and cannot be substantiated.

4.5.10 **TAC** and **EC** members may adjust technical scores agreed during the shortlisting process as a consequence of consideration of past performance. This will be done at the **TAC** and **EC**'s sole discretion.

4.6 Debriefing of applicants

4.6.1 DFAT will provide consolidated, generic feedback on the results of the assessment of proposals once a funding agreement has been signed with successful applicants.

4.6.2 DFAT will not enter into discussion or communications on the content of the debrief once it has been issued.

4.7 Complaints

4.7.1 DFAT's Complaints Handling Procedures Relating to Procurement will apply, see: DFAT Guideline: Complaints Handling in Procurement.

Section 5: Assessment

5.1 Assessment outcome

5.1.1 Through this process, DFAT shall select proposals to receive funding to implement the Product Development and Access Partnerships.

5.2 Evaluation Criteria

5.2.1 Proposals will be assessed based on the following Evaluation Criteria:

Table 2: PDAP Evaluation criteria

Evaluation Criteria	Description	Evaluation weighting
1. Organisational effectiveness and risk management	Applicants to describe: • Their respective roles and responsibilities as relevant to each criterion and scope of activity. • Key personnel and their demonstrated expertise relevant to the proposed activities (including CVs of proposed key personnel). Applicants are to: • Demonstrate effective governance and administrative structures including established and robust financial and human resource management systems and audit reporting. • Demonstrate effectiveness, including detail on: - the organisation's impact and programming to date; - how the proposal's End Of Program Outcomes align with and contribute to the **Product Development and Access Partnerships'** End of Program Outcomes and Intermediate Outcomes (as described in Section 2, Operational Objectives), within the context of the PHR's provisional program logic as in Annex 1; - proposed strategies to advance global policy and guidelines on product development, and other actions to maximise scalability and sustainability of product development and use; and - how the aims of the organisation improve public health, with a focus on those living in low-and - middle-income countries including evidence of public health impact to date. • Demonstrate efficiency and sound management, including mechanisms to: - leverage, secure and/or diversify funding bases; - manage administrative overheads; and - ensure equitable management of human resources, including transparent, fair and effective management of claims relating to inappropriate workplace behaviour. • Demonstrate effective risk management, including consideration of: - risk profile and proposed mitigation strategies; - the ongoing impact of COVID-19 on product development;	20%

Evaluation Criteria	Description	Evaluation weighting
	- fiduciary risk; and - ensuring compliance with social and environment safeguards in line with DFAT requirements, and attention to the principle of 'do no harm'.	
2. Maturity and breadth of lead organisation's portfolio	Applicant to: • Detail two or more candidate products in their portfolio which are in Phase One Trials or later; • Demonstrate relevant prior and ongoing research and development from the last five years; and • Demonstrate prior activity in Southeast Asia and/or the Pacific.	20%
3. Global Access Strategy	Applicant to articulate what mechanisms they have in place to facilitate access of their products including, but not limited to: • achieving pricing attainable for LMICs; • moving products through regulatory pathways in a timely fashion; • moving products into manufacturing and distribution in a timely fashion; • supporting products to be available where and when they are needed at a volume as determined by the disease burden and country demand; • supporting country-based knowledge and demand generation; and • participating in global guideline and policy setting to better facilitate access to new or modified products, including updated treatment guidelines.	20%
4. Regional Product Access Activities	Applicant to articulate proposed scope of activity within Southeast Asia and/or the Pacific which contributes to improved accessibility of the product(s) including but not limited to: product development, operational research, manufacturing, policy and guideline development and other access initiatives.	20%
5. Regional Trial Activity	Applicant to articulate current or future plans for clinical trials in Southeast Asia and/or the Pacific.	10%
6. GEDSI	Applicant to articulate a strategy to gender equality, disability and social inclusion (GEDSI) including detail on: • How analysis and expertise has informed strategy on GEDSI, including key strategies to address barriers and underlying norms that will align with and contribute to DFAT's frameworks and objectives on GEDSI. This should consider and address the following: - organisational capability, policies and commitment to GEDSI;	10%

Evaluation Criteria	Description	Evaluation weighting
	- how GEDSI relates to product design, target audience, trial design, purpose and characteristics as relevant to disease burden; - prioritisation and implementation of GEDSI; - who will benefit from the proposal, with attention to groups at increased risk and vulnerability; and - engagement with representative organisations (for example, women's groups, organisations of people with disabilities) • Resourcing of the proposed GEDSI approach; • Risks and safeguards, with attention to the 'do no harm' principle; and • How the applicant will monitor, evaluate and report on GEDSI related work. Applicants will be provided with access to DFAT's GEDSI and First Nations Engagement Guidance Note.	
7. Budget	Applicant to consider value for money principles (see DFAT's Value for Money principles webpage) in budget provided.	Unweighted

Section 6: Safeguards, due diligence and risks

6.1 Applicants must outline how they will ensure compliance with Australian requirements, including due diligence, transparency, accountability and fraud control.

6.2 Applicants must also explain how they will comply with DFAT's risk and safeguarding policies including:

a. preventing sexual exploitation, abuse and harassment (PSEAH);
b. child protection; and
c. environmental and social safeguards.

6.3 Where organisations have policies in place that meet DFAT's requirements, applicants are encouraged to include a link to these policies in their proposal.

6.4 All organisations (including all partners in a consortium) must comply with DFAT's risk and safeguarding policies.

6.5 Detailed information about DFAT's safeguards and risk management policies can be found on the DFAT's Development risk management webpage.

Section 7: Activity proposal format

7.1 Proposals must be submitted using the Product Development and Access SmartyGrants form available here: https://health.smartygrants.com.au

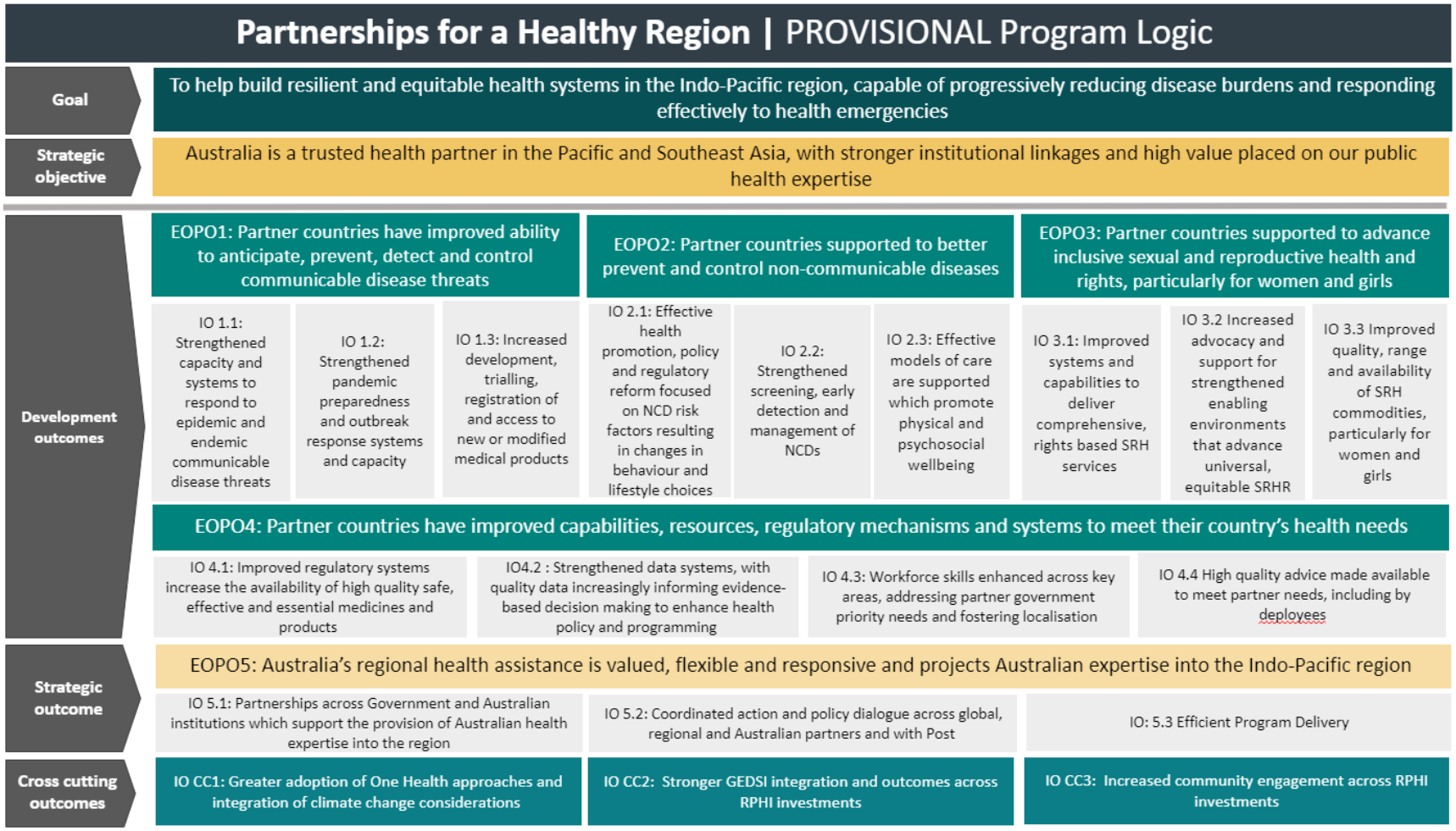
Section 8: Contractual, reporting and acquittal requirements

8.1 The successful applicant will be engaged via an Agreement with the Organisation and DFAT. Terms and conditions of the Agreement are included in Annex 2 to these Guidelines.

Section 9: Contact

9.1 Email contact: chs@dfat.gov.au

Annex 1: Partnerships for a Healthy Region Initiative Program Logic (Provisional)



Annex 2: Agreement template

Access the template on the Product Development and Access Partnerships webpage.