Terms of Reference for Institutional/Individual Contract

1. Identification

Description of the service: Consultancy to conduct a scoping study for PrEP affordability in the Asia-Pacific region

Expected start date: 1 July 2021

Expected completion date: 30 November 2021

2. Background:

The use of antiretroviral (ARV) drugs as pre-exposure prophylaxis (PrEP) is WHO recommended HIV prevention strategy to be included in combination prevention approaches for people at substantial risk of HIV infection. In 2015, WHO recommended tenofovir-containing ARVs for use as PrEP in people at substantial risk of HIV infection.

Several manufacturers are prequalified by WHO and/or USFDA approval or tentative approval for antiretroviral drugs (ARVs) used for PrEP[1] and additional manufacturers supply directly in-country. However, PrEP rollout has been slow in the Asia-Pacific, with a handful of relatively small demonstration projects and only two Asian countries with national and/or large-scale rollout (Thailand and Vietnam).

Pricing is an important determinant of inclusion in a public health PrEP program, and perhaps even more critical when a self-pay or co-payment system for PrEP is proposed. Many countries within the region have or will soon transition to purchasing their own ARVs for treatment and PrEP. Smaller countries, representing smaller markets, often have reduced negotiating power for achieving more affordable pricing. For example, there is currently a large disparity between countries and donors regarding the price of co-formulated ARVs such as TDF/FTC, ranging from $4.75 USD per bottle (30 pills) through the Global Fund's pooled procurement mechanism to more than $300 USD per bottle in China. Registration of multiple manufacturers and/or products for an indication such as PrEP has been effective in creating competition and thereby reducing drug costs for consumers and governments in many settings. Pooled procurement mechanisms have increased negotiating power, also contributing to more affordable pricing.

In Latin America, PAHO established the Strategic Fund that allows participating countries to achieving a single competitive price from manufacturers. The Global Fund is a further example of the use of pooled procurement mechanisms.

ASEAN represents a collective of 10 countries[2] in South East Asia, several of which may benefit from a pooled price negotiation and/or procurement mechanism. Consideration will be given to focusing initially on ASEAN countries as there are already mechanisms for collaboration between participating

[1] Aurobindo Pharma Ltd, Emcure Pharmaceuticals Ltd, Hetero Labs Ltd, Mylan Laboratories Ltd, Cipla Ltd, Strides Pharma Science Ltd, Lazarus Labs Ltd, Lupin Ltd, Micro Labs Ltd, McLeods Pharmaceuticals Ltd and Sun Pharmaceuticals Ltd. GPO (Thailand) also manufactures TDF/FTC, primarily for use in the Thai PrEP market

[2] Brunei, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Viet Nam

countries that could be leveraged. Endorsement through ASEAN would be indispensable in the legitimacy of any mechanism.

This piece of work is a scoping study for a mechanism within Asia-Pacific to negotiate lower prices for PrEP drugs from manufacturers that shall be accessible by public and private sector in participating low- and middle-income countries, thereby lowering the price in Asia-Pacific overall and reducing disparity between countries.

3. Purpose of the consultancy:

This consultancy is intended to provide evidence-based recommendations for a 'regional' mechanism to achieve more affordable pricing and increase access for ARVs for PrEP in the Asia-Pacific that is accessible by public and private sector in participating low- and middle-income countries, thereby lowering the price in Asia-Pacific overall and reducing disparity between countries.

4. Activities

Activity 1: Develop a workplan outlining methodology including data collection plan, activities and timelines and milestones.

Activity 2: Desk review and key informant interviews of relevant stakeholders including governmental and regional institutions, manufacturers/distributors, to elucidate the status of PrEP access in a selection of 5-7 ASEAN countries (e.g. Cambodia, Indonesia, Lao PDR, Malaysia, The Philippines, Thailand and Viet Nam, or as agreed). The information collected should answer the following questions:

a) Which, if any, ARVs are registered as PrEP in these countries? Is PrEP included in the prevention guidelines and/or essential medicines list (if applicable)? Which ARVs are included as PrEP?
b) What is the patent landscape for PrEP products in the countries?
c) How is PrEP currently accessed in these countries (i.e. through public and/or private sector)? If PrEP is available through the public sector, was it through tendering (public procurement), negotiation of reimbursement price, price-volume agreement, donor programs etc.?
d) What is the price of PrEP in the public and private sector? Who are the suppliers of PrEP in these countries?
e) Feasibility assessment. What are the key policy and functional challenges and risks in participating in transnational pooled procurement/ for PrEP?

Activity 3: Conduct desk review of existing good practice models of transnational collaboration for collective pharmaceutical price-setting, information sharing and/or negotiation (e.g. BeNeLuxA), and pooled procurement of pharmaceuticals (e.g. Latin American countries through PAHO, UNDP, Global Fund, and others). The desk review should include for each relevant model identified:

a) Analyses of the impact on pharmaceutical prices in the private and public sector;
b) Relevant aspects of the historical 'journey' towards creating the collaborative platform, key challenges faced, and solutions implemented;
c) the strategic approach and governance framework of existing platforms;
d) the key actors involved in coordinating these initiatives.

Activity 4: Based on the findings of the desk reviews and key informant interviews, develop recommendations on creating a regional mechanism in Asia-Pacific for lowering PrEP drug pricing, e.g. price transparency, collective price negotiation, purchasing of PrEP. These recommendations should include:

a) Key principles and good practices for effective transnational collaboration for the mechanism for the Asia-Pacific context.

b) Matrix of recommended options with pros and cons clearly articulated, and a final view on feasibility.
c) Strategic approaches and next steps for the recommended option(s) for establishing the regional mechanism in Asia-Pacific, considering the political economy within interested countries.

Activity 5: revision of draft report with feedback from UNAIDS.

5. Outputs/deliverables:

A. Detailed workplan with outlining methodology including data collection plan, activities and time-bound milestones

B. Comprehensive report detailing findings from the desk reviews and key informant interviews: status of PrEP in 6 countries, good practice models for transnational collaboration on collective price setting/negotiation, recommendations for creating a regional mechanism for price negotiation and purchasing of PrEP, including but not limited to pool procurement, and next steps.

6. Indicative milestones

1) Consultancy commences
2) Workplan developed in consultation with key stakeholders
3) Desk review and key informant interviews on PrEP status
4) Desk review and key informant interviews of good practice models
5) Development of recommendations and submission of draft report
6) Finalisation and submission of final report

7. Technical Supervision

The Consultant will work under the joint supervision of UNAIDS. Reporting to the UNAIDS Regional Office on activity progress approximately every 2 weeks or as otherwise agreed will be required.

8. Qualifications and Requirements

The consultant must have:

- A degree in public health, economics, social sciences, health policy or similar, or extensive experience in a related field.
- Experience in conducting similar activities, including key informant interviews, policy and technical document reviews and policy analyses.
- Excellent understanding of the Asia-Pacific region and the HIV response.
- Knowledge of procurement processes and systems, pricing negotiations, management of intellectual property rights, pharmaceuticals and/or other health-related commodities, or related topics, at a national and/or international level. Understanding of the procurement of ARVs for HIV prevention and/or treatment would be an asset.
- Expert proficiency in written and spoken English. Proficiency in a regional language would be an asset.
- Demonstrated capacity to complete the activities based on previous related works.
- Demonstrated ability to work and collaborate with other technical partners of UNAIDS.

9. Other conditions

Any data, information or documents generated during the period of this consultancy will be treated as strictly confidential, and the rights of dissemination and/or publication will reside with the UNAIDS and WHO.

Closing Date:

Interested applicants are requested to send their application letter, proposal including CVs with references and financial proposal with costs itemized by technical (professional) fees for each respective activity to rstap@unaids.org ***the closing date is 14 June 2021***. Only short-listed candidates will be contacted**.**