

TERMS OF REFERENCE

POST TITLE:	Consultant to provide legal and policy advisory support to the African Union Commission and members state countries on the domestication of the AU Model Law on Medical Products Regulation
AGENCY/PROJECT NAME:	United Nations Development Programme (UNDP)
COUNTRY OF ASSIGNMENT:	Home based, with no travel required.

1) GENERAL BACKGROUND

The United Nations Development Programme (UNDP) is the UN's global development network, advocating for change and connecting countries to knowledge, experience and resources to help people build a better life, as envisaged by 2030 Agenda for Sustainable Development. We are on the ground in more than 170 countries and territories, working with governments and people on their own solutions to global and national development challenges. As they develop local capacity, they draw on the people of UNDP and our wide range of partners that can bring about results.

The Bureau for Policy and Programme Support (BPPS) has the responsibility for developing all relevant policy and guidance to support the results of UNDP's Strategic Plan and help countries to achieve the Sustainable Development Goals. BPPS's staff provides technical advice to Country Offices; advocates for UNDP corporate messages, represents UNDP at multi-stakeholder fora including public-private dialogues, government and civil society dialogues, South-South and Triangular cooperation initiatives, and engages in UN inter-agency coordination in specific thematic areas.

UNDP HIV, Health and Development Approach

First, UNDP helps countries to mainstream attention to HIV and health into action on gender, poverty and the broader effort to achieve and sustain the Sustainable Development Goals. For example, UNDP works with countries to understand the social and economic factors that play a crucial role in driving health and disease, and to respond to such dynamics with appropriate policies and programmes outside the health sector. UNDP also promotes specific action on the needs and rights of women and girls as they relate to HIV.

Second, UNDP works with partners to address the interactions between governance, human rights and health responses. Sometimes this is done through focused or specialized programmes, such as promoting attention to the role of the law and legal environments in facilitating stronger HIV responses, including the use of flexibilities in trade related legislation to lower the cost of drugs and diagnostics. UNDP also works to empower and include marginalized populations who are disproportionately affected by HIV, such as sex workers, men who have sex with men and people living with HIV. Beyond these focused efforts, UNDP plays a key role in ensuring attention to HIV and health within broader governance and rights initiatives, including support to municipal action on SDGs, sustainable responses for Health and HIV such as improving sustainability of AIDS financing, sustainable health procurement, strengthening of national human rights institutions and increasing access to justice for key populations.

Third, as a trusted, long-term partner with extensive operational experience, UNDP supports countries in effective implementation of complex, multilateral and multisectoral health projects, while simultaneously investing in capacity development so that national and local partners can assume these responsibilities over time. The UNDP/Global Fund partnership is an important part of this work, facilitating access to resources for action on SDG 3 by countries that face constraints in directly receiving and managing such funding. UNDP partners with countries in crisis/post-crisis situations, those with weak institutional capacity or governance challenges, and countries under sanctions. When requested, UNDP acts as temporary Principal Recipient in these settings, working with national partners and the Global Fund to improve management, implementation and oversight of Global Fund grants, while simultaneously developing national capacity to be able to assume the Principal Recipient role over time.

Access and Delivery of New Health Technologies for Neglected Tropical Diseases.

The majority of deaths caused by infectious disease are of poor people living in LMICs with many occurring in children under five. HIV, malaria, tuberculosis (TB) and other epidemics continue to devastate communities throughout the developing world. The prevalence of neglected tropical diseases (NTDs), endemic in 149 countries, also remains high. As part of its work on accelerating progress on the SDGs, UNDP is committed to working with partners to achieve the health-related SDGs specifically aimed to address the sector gap in research and development (R&D) funding for new global health technologies through our partnership with the Global Health Innovative Technology (GHIT) Fund.

New health technologies are broadly defined as drugs, diagnostic tools and vaccines that are relevant for the prevention, treatment or cure of TB, malaria and NTDs, but have not yet been introduced in LMICs. The introduction of new health technologies can place a weighty burden on existing health systems. These burdens may include new requirements for drug regulation, supply and distribution, and health personnel training. The Access and Delivery Partnership (ADP) supports LMICs to enhance their capacity to access, introduce and deliver new health technologies for TB, malaria and NTDs. The ADP focuses on strengthening the capacity of LMIC stakeholders to facilitate the development of the systems and processes required to effectively access new health technologies, and introduce them to the patients in need. Led and coordinated by UNDP, the ADP is a unique collaboration among UNDP, WHO, the Special Programme for Research and Training in Tropical Diseases at the World Health Organization (TDR) and PATH. Working together, the partners leverage the expertise within each organization to provide the full range of technical skills necessary to strengthen capacity in LMICs.

The ADP supports LMICs to enhance their capacity to access, introduce and deliver new health technologies for TB, malaria and NTDs, with a particular focus on policy coherence and South-South cooperation on health technology innovation and access. This work will contribute to the achievement of Target 3.8 of the 2030 Agenda for Sustainable Development which focuses on the achievement of universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all. This work is also in alignment with UNDP's Strategic Plan: 2018-2021 and its HIV, Health and Development Strategy 2016-2021 which similarly recognizes resilient and sustainable health systems as the foundation for achieving health and development broadly.

2) OBJECTIVES OF THE ASSIGNMENT

In line with the ADP's focus promoting South-South cooperation on strengthening national capacities for developing coherent policy and legal environments, this assignment will provide expert technical support to the African Union Commission (AUC) and the New Partnership for Africa's Development (NEPAD Agency), as part of its African Medicines Regulatory Harmonization initiative, to strengthen the enabling environment for drug

regulation, promotion of the domestic pharmaceutical industry and accelerating introduction of medicines across the African continent.

3) SCOPE OF WORK

In consultation with the ADP Programme Advisor, the consultant will support the AUC and its NEPAD Agency, which is the development agency of the African Union, coordinating and executing priority regional and continental development projects to promote regional integration towards the accelerated realisation of Agenda 2063 – Africa’s vision and action plan. The NEPAD Agency is mandated to strengthen capacity of Member States and regional bodies. The consultant will work with the Technical Working Group on Medicines Policy and Regulatory Reforms (TWG-MPRR) on scaling up the domestication process of the AU Model Law on Medical Products Regulation, which includes the development of a roadmap. The consultant will provide technical support to the AUC on the development and implementation of institutional and legal frameworks, business planning, and participation in technical committees, forums and consultations relating to the AMA (African Medicines Agency). This includes the additional technical support from UNDP requested by the African Union, which is part of on- going collaboration in Domesticating the AU Model Law on medical product regulation and the establishment of the AMA as a follow-up to the TWG-MPRR meeting held in Midrand on 22-24 October 2018.

4) DURATION OF ASSIGNMENT, AND DUTY STATION

Duration

The duration of the assignment is from **26 March 2019 to 31 March 2020**. The assignment is home-based. The substantive components of the assignment are expected to take approximately **50 working days** to complete. The table below provides a breakdown of the expected number of consultancy days for the tasks assigned, based on estimates, which may be subject to change according to identified needs.

Tasks	Estimated number of days
1. Support the survey/assessment on the domestication of the AU Model Law on Medical Products Regulation, including through the following tasks: <ul style="list-style-type: none"> - Review and provide inputs on the draft checklist of the survey questionnaire - Support the delivery of the survey in francophone AU member states during the specified timeframe - Develop a draft survey analysis report and a draft domestication roadmap based on country responses 	10 days
2. Support the development of guidance documents (manuals, case studies, etc.) to guide member states in the domestication process, including undertaking the following: <ul style="list-style-type: none"> - Develop needs assessment analysis per country or region based on survey responses and draft related guidance documents in the form of manuals, case studies or policy briefs - Provide policy and technical support on the development of enabling policy and legal environment for access and delivery of health technologies 	20 days
3. Support the technical preparations for relevant workshops, expert consultations and national stakeholders’ meetings and trainings, including the following:	20 days

<ul style="list-style-type: none"> - Develop a draft training agenda on facilitating the domesticating process in member state countries, which should include specificities of the francophone member state countries and regional economic commissions - Contribute to preparations for the training workshop for legal experts from SADC & ECOWAS scheduled for 1-3 May 2019 as requested, on enhancing the implementing capacity of RECs and national legal experts towards the adoption of the Model Law - Provide policy and technical support to countries upon request, on issues related to the domestication of the AU Model Law, or on the development of enabling policy and legal environment for access and delivery of health technologies and participation in OAPI secretariat meeting in relation to strengthening the legal and policy framework in AU RECs or AU countries 	
Total	50 days

Duty Station

The assignment is home based.

Travel

No travel is anticipated under this consultancy. In the case of unforeseeable travel, payment of travel costs including tickets, lodging and terminal expenses should be agreed upon, between the respective business unit and Individual Consultant, prior to travel and will be reimbursed.

5) FINAL PRODUCTS and MILESTONES

Deliverables	Due Date
1. Support the survey/assessment on the domestication of the AU Model Law on Medical Products Regulation	
1.1 Review and provide inputs on the draft checklist of the survey questionnaire	19 April 2019
1.2 Support the delivery of the survey in AU member states countries during the specified timeframe, specially to francophone AU member states	19 April 2019
1.3 Develop a draft survey analysis report and a draft domestication roadmap based on country responses	19 April 2019
1. Support the development of guidance documents (manuals, case studies, etc.) to guide member states in the domestication process	
1.1- Develop needs assessment analysis for each country or region based on survey responses and draft related guidance documents in the form of manuals, case studies or policy briefs	30 April 2019
1.2- Provide policy and technical support on the development of enabling policy and legal environment for access and delivery of health technologies	30 April 2019
2. Support the technical preparations for relevant workshops, expert consultations and national stakeholders' meetings and trainings, including the following:	
2.1- Develop a draft training agenda on facilitating the domesticating process in member state countries, which should include specificities of the francophone member state countries and regional economic commissions	30 April 2019

2.2-	Contribute to the preparations for the SADC and ECOWAS legal experts training scheduled for 1-3 May 2019 and prepare draft training report	31 June 2019
2.3-	Provide policy and technical support to countries upon requests, on issues related to the domestication of the AU Model Law, as well as on issues related to the development of an enabling policy and legal environment for access and delivery of health technologies and participation in OAPI secretariat meeting in relation to strengthening the legal and policy framework in AU RECs or AU countries	31 December 2019

6) PROVISION OF MONITORING AND PROGRESS CONTROLS

The consultant will regularly evaluate progress in meeting the specific deliverable with the ADP Programme Advisor.

7) DEGREE OF EXPERTISE AND QUALIFICATIONS

Education: An advanced degree in law, public policy, development or public health, and a knowledge of at least one of the other substantive areas.

Professional Experience:

- A minimum of 5-7 years of relevant work experience in public health, development or a related field;
- Work experience in Sub-Saharan African region in the field of law, development, public health or related field highly desirable, previous work experience with AU institutions will be an advantage;
- Excellent French writing, research and analytical skills, especially where they relate to the policy, legal and strategic aspects of intellectual property, innovation and R&D, pharmaceutical production and medicines regulatory framework;
- Comprehensive understanding and knowledge of key determinants of sustainable access and delivery of health technologies in LMICs, as evidenced by a strong publications record;

Functional / Technical Knowledge:

- Strong analytical, negotiation and communication skills, including ability to produce high quality practical advisory reports and knowledge products;
- Professional and/or academic experience in one or more of the following areas: intellectual property, innovation and R&D, pharmaceutical production, access to health technologies and medicines regulatory framework;
- Ability to produce high quality outputs in a timely manner while understanding and anticipating the evolving client needs;
- Strong legal and policy analysis, research and writing skills with demonstrated ability to think strategically;
- Strong capacity to communicate clearly and quickly.

8) REVIEW TIME REQUIRED

A review time of a maximum of three weeks is needed, after the receipt of the deliverable.

9) CONSULTANTS PRESENCE REQUIRED ON DUTY STATION/UNDP PREMISES

☒ NONE

☐ PARTIAL

☐ INTERMITTENT

☐ FULL-TIME

10) PAYMENT TERMS

Lump sum payment covering lump sum professional fee shall be made as per below schedule:

Payment Schedule	Percentage
- 1 st payment shall be made upon satisfactory receipt of a draft survey analysis report and a brief report detailing the support provided on the development of the domestication roadmap	20%
- 2 nd payment shall be made upon satisfactory receipt of a needs assessment analysis report, and related guidance documents in the form of manuals, case studies or policy briefs	30%
- 3 rd payment shall be made upon satisfactory receipt of a brief training report related to the AU model law domestication process, and related the training workshop for legal experts, TWG-MPRR meetings	30%
- 4 th payment shall be made upon satisfactory receipt of a report detailing support provided to countries and participation in OAPI secretariat meeting in relation to strengthening the legal and policy framework in AU RECs or AU countries	20%

In the event of unforeseeable travel not anticipated in this TOR, payment of travel costs including tickets, lodging and terminal expenses should be agreed upon, between the respective business unit and the Individual Consultant, prior to travel and will be reimbursed.

Travel costs shall be reimbursed at actual but not exceeding the quotation from UNDP approved travel agent. The provided living allowance will not be exceeding UNDP DSA rates. Repatriation travel cost from home to duty station in Bangkok and return shall not be covered by UNDP.

11) REQUIRED DOCUMENTS

Interested individual consultants must submit the following documents/information to demonstrate their qualifications. Please group them into **one (1) single PDF document** as the application only allows to upload maximum one document:

- **Letter of Confirmation of Interest and Availability** using the template provided in Annex III.

- **Personal CV**, indicating all past experience from similar projects, as well as the contact details (email and telephone number) of the Candidate and at least three (3) professional references.
- **Financial proposal with all-inclusive daily fee**, as per template provided in Annex III. If an Offeror is employed by an organization/company/institution, and he/she expects his/her employer to charge a management fee in the process of releasing him/her to UNDP under Reimbursable Loan Agreement (RLA), the Offeror must indicate at this point, and ensure that all such costs are duly incorporated in the financial proposal submitted to UNDP.

Incomplete proposals may not be considered. The shortlisted candidates may be contacted and the successful candidate will be notified

12) CRITERIA FOR SELECTION OF THE BEST OFFER

Individual consultants will be evaluated based on the following methodology: Cumulative analysis

The award of the contract shall be made to the individual consultant whose offer has been evaluated and determined as a) responsive/compliant/acceptable; and b) having received the highest score out of set of weighted technical criteria (70%). and financial criteria (30%). Financial score shall be computed as a ratio of the proposal being evaluated and the lowest priced proposal received by UNDP for the assignment.

Technical Criteria for Evaluation (70 points)

- Criteria 1 An advanced degree in law, public policy, development or public health, or any related field – *5 points*
- Criteria 2 Relevance of experience in French writing, research and analytical skill, where they relate to the policy, legal and strategic aspects of intellectual property, innovation and R&D, pharmaceutical production and medicines regulatory framework - *15 Points*
- Criteria 3 Relevance of experience in public health, development or a related field – *10 points*
- Criteria 4 Relevance of experience working in African region in the field of law, development, public health or related field – *20 points*
- Criteria 5 A demonstrated knowledge of key determinants of sustainable access and delivery of health technologies in LMICs, as evidenced by a publications record.(if applicable) – *20 Points*

Only candidates obtaining a minimum of 70% of the total technical points would be considered for the Financial Evaluation.

This TOR is approved by:

Signature
Ms. Cecilia Oh



Programme Advisor, Access and Delivery Partnership

Date of Signing 3 March 2019