

**TERMS OF REFERENCE: CONSULTANCY FOR THE
DEVELOPMENT OF JOINT REVIEW PROCESS BETWEEN CARPHA-
CRS AND REGULATORY FOCAL POINTS OF CARICOM MEMBER
STATES FOR THE REVIEW OF COVID-19 MEDICINES AND
VACCINES**

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1. BACKGROUND INFORMATION

1.1. Partner country

The principal beneficiaries are CARICOM Member States particularly the fourteen countries that are not overseas territories: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago.

1.2. Contracting authority

Caribbean Public Health Agency

1.3. Country background

CARPHA's mission is to provide strategic direction, in analysing, defining and responding to public health priorities of Member States, in order to prevent disease, promote health and to respond to public health emergencies. To support solidarity in health, as one of the principal pillars of functional cooperation, in the Caribbean Community.

The Caribbean Regulatory System is a subregional mechanism housed at CARPHA that supports Member States in conducting regulation of pharmaceuticals, including market registration and pharmacovigilance. The global pandemic of the novel coronavirus 2019 (COVID-19) has required governments of CARICOM to implement systems of approval of vaccines and medicines to mitigate against COVID-19. With the deployment of vaccines in 2021, CARPHA has supported the response of CARICOM in various areas of work including registration and procurement of vaccines, and pharmacovigilance of deployed vaccines, through the work of the Caribbean Regulatory System (CRS). In collaboration with the Pan American Health Organization and the Government of Canada, CARPHA-CRS will undertake activities to strengthen mechanisms for the market authorisation and safety surveillance of novel COVID-19 vaccines and therapeutics along their entire life cycle.

The project, within the framework of the COVID-19 crisis and its impact on member countries, will have a regional approach to improve regulatory mechanisms for the efficient incorporation of quality-assured vaccines and therapeutics for COVID-19 in CARICOM.

1.4. Current situation in the sector

The regulation of medicines in Member States of CARICOM has been identified as one area of public health that requires strengthening in the region, particularly among low- and middle-income countries that lack legislative frameworks for regulation. Only six Member States have legislated systems for market registration of medicines, whereas others apply procurement-based systems that do not assess medical products. With the global pandemic, Member States are further challenged in their ability to assess medicines and vaccines for COVID-19 prior to market approval. In the absence of processes for the assessment of the medical products to be procured for use to prevent COVID-19 or to treat patients, Member States remain vulnerable to procurement of products that have not been assessed or quality-assured.

The CARPHA Caribbean Regulatory System applies regulatory reliance approaches to conduct verification reviews of medical products that have been approved for market authorisation by trusted regulatory authorities. This procedure aims to ensure sameness and to make recommendations for market authorisation or procurement by Member States. This enables countries that lack national

systems to identify quality products for procurement, and enables those with national systems to use the recommendations to support market authorisation decisions. In response to the pandemic, the CRS extended its work to the review of COVID-19 vaccines and medicines to assist Member States with market decisions for these products.

The identification of quality-assured medicines and vaccines enables Member States with established systems of medicines assessment to make faster decisions for market access than would be possible through traditional pathways. For CMS that lack a legislated system for the assessment and registration of medical products, whereby a process of approval of suppliers or approval of importation of products exist, the CRS' work provides a key regulatory function. A process of joint review with the CRS and regulatory focal points of CARICOM Member States will help develop a standardized approach to product reviews, build capacity among regulators, and increase transparency of the CRS review process.

1.5. Related programmes and other donor activities

The CRS is supported by a grant from the Bill and Melinda Gates Foundation, and technical / advisory support by the Pan American Health Organization (PAHO) to conduct regulatory support activities. The CRS relies on the assessments of the WHO prequalification team or selected reference authorities and verifies sameness prior to recommending the products to CARICOM. The CRS participates in the Collaborative Procedure for accelerated market registration of WHO prequalified medicines and vaccines, which also assists to build internal capacity. This also applies to WHO prequalified medicines for COVID-19, and COVID-19 vaccines for emergency use listing, provided the required confidentiality agreements are signed.

2. OBJECTIVE, PURPOSE & EXPECTED RESULTS

2.1. Overall objective

The overall objective of the project of which this contract will be a part of, is:

- **To contribute to the improved health and protection from COVID-19 for populations in situations of vulnerability in the Caribbean.**

2.2. Purpose

The purpose of this contract is:

To support countries to strengthen regulatory processes, quality assurance and plans for introduction of COVID-19 vaccines and other related medical products.

More specifically, the services of a consultant will be contracted to develop:

- (i) A procedural framework and tools for a joint review process between CARPHA-CRS and regulatory focal points of CARICOM Member States for the review of COVID-19 medicines and vaccines, and
- (ii) A manuscript describing the development of the joint review process, anticipated challenges to implementation of the joint review process and recommendations for implementation of the joint review process.

2.3. Results to be achieved by the contractor

The contractor is expected to achieve the following results:

- **Result 1:** Inception Report developed and submitted for the approval of the Project Manager

- **Result 2:** Procedural framework and tools for a joint review process between CARPHA-CRS and regulatory focal points of CARICOM Member States for the review of COVID-19 medicines and vaccines developed and submitted for the approval of the Project Manager
- **Result 3:** Manuscript describing the development of the joint review process, anticipated challenges to implementation of the joint review process and recommendations for implementation of the joint review process developed and submitted for the approval of the Project Manager
- **Result 4:** Draft Final Report developed, submitted, and reviewed by the Project Manager in accordance with the reporting requirements in section 7.1 of these Terms of Reference
- **Result 5:** Final Report developed based on feedback from submission of the draft final report, submitted and approved in accordance with the reporting requirements in section 7.1 of these Terms of Reference.

3. ASSUMPTIONS & RISKS

3.1. Assumptions underlying the project

The assumptions underlying this project are:

- There are suitably qualified personnel who may be eligible for the project.

3.2. Risks

There are no anticipated risks.

4. SCOPE OF THE WORK

4.1. General

4.1.1. Description of the assignment

The consultant will be required to develop a procedural framework and tools for a joint review process for the review of COVID-19 medicines and vaccines, and to develop a manuscript describing the development of the joint review process, anticipated challenges to implementation of the joint review process and recommendations for implementation of the joint review process.

4.1.2. Geographical area to be covered

The geographical area is the Caribbean Region.

4.1.3. Target groups

The target groups for the joint review process and manuscript will be:

- Regulatory focal points for medicines and/or vaccines registration
- Procurement personnel and/or personnel responsible for approval of importation of medicines and/or vaccines.

4.2. Specific work

Result 1: Inception Report developed and submitted for the approval of the Project Manager.

- 1.1 Engage in an initial briefing with the Project Manager and other relevant CARPHA personnel to discuss the scope of the work to be undertaken, the approach, and any other issues pertaining to the Project, upon the commencement of the Consultancy
- 1.2 Prepare and submit for the approval of the Project Manager, an Inception Report which includes as a minimum, the following:
 - The process for project completion
 - Project timeline / workplan
 - Potential risks and strategies to mitigate risks.

Result 2: Procedural framework and tools for a joint review process between CARPHA-CRS and regulatory focal points of CARICOM Member States for the review of COVID-19 medicines and vaccines developed and submitted for the approval of the Project Manager.

2.1 Prepare and submit a procedural framework describing the requirements, and steps for a collaborative process of joint review of COVID-19 medicines and vaccines between the CARPHA-CRS and CARICOM Member States.

The procedural framework should include the following:

- Rationale and expected outcomes
- Key stakeholders, and roles of reviewers
- Technical requirements
- Description of the procedural steps
- Templates and instructions for documentation of reviews
- Examples of completed templates
- Indicators for evaluation of the collaborative process.

2.2 Prepare a revised procedural framework and tools for the joint review process based on feedback received from the Project Manager for inclusion in the final report.

2.3 Prepare Interim Report 1, in accordance with the reporting requirements in section 7.1 of these Terms of Reference, for approval of the Project Manager.

Result 3: Manuscript describing the development of the joint review process, anticipated challenges to implementation of the joint review process and recommendations for mplementation of the joint review process developed and submitted for the approval of the Project Manager

3.1 Develop a draft manuscript describing the development of the joint review process, anticipated challenges and recommendations for the implementation of the joint review process for COVID-19 vaccines and medicines.

The manuscript should:

- Include an appropriate layout suitable for peer-reviewed publication
- Describe existing collaborative or joint review systems for medicines or vaccines
- Describe the role and successes of the CARPHA-CRS in supporting access to essential medicines and vaccines to CARICOM
- Describe the requirements for successful implementation of a joint review procedure in the context of Good Reliance Practices in low- and middle-income countries
- Describe the general procedure for the joint review process and its development
- Identify the various stakeholders and their roles in the procedure
- Describe anticipated challenges to implementation of the procedure
- Make recommendations for implementation of the procedure for subregional mechanisms with low- and middle-income countries
- Include appropriate figures, tables and references.

3.2 Create a repository (folder) of the key references and resources to be submitted to the Project Manager.

3.4 Prepare a revised manuscript based on feedback received from the Project Manager

Result 4: Draft Final Report developed, submitted, and reviewed by the Project Manager in accordance with the reporting requirements in section 7.1 of these Terms of Reference.

4.1 Prepare and submit for the approval of the Project Manager, a Draft Final Report in accordance with the reporting requirements in section 7.1 of these Terms of Reference.

Result 5: Final Report developed based on feedback from submission of the draft final report, submitted and approved in accordance with the reporting requirements in section 7.1 of these Terms of Reference.

5.1 Prepare a final report based on feedback from submission of the draft final report, submitted and approved in accordance with the reporting requirements in section 7.1 of these Terms of Reference.

4.3. Project management

4.3.1. Responsible body

The Caribbean Regulatory System (CRS) of CARPHA will be responsible for the management and coordination of the Project.

4.3.2. Management structure

The Programme Manager of the Caribbean Regulatory System, CARPHA, will be the Project Manager and will have overall responsibility for the Project. The Project Manager will retain oversight for the consultancy and will also be responsible for the day-to-day supervision of project activity. The Director Surveillance, Disease Prevention and Control, CARPHA may be consulted from time to time and may

review reports of the Contractor and provide recommendations to the Project Manager. External stakeholders such as PAHO Advisors may also be consulted from time to time.

The Project Manager shall be responsible for approving all reports.

4.3.3. Facilities to be provided by the contracting authority and/or other parties

CARPHA shall:

- i. Notify participating Member States about the Project
- ii. Provide the Contractor with any documentation required for the execution of the Project
- iii. Assume responsibility for the logistical and administrative arrangements for document sharing and meetings
- iv. Provide funds for publication fees for manuscript.

5. LOGISTICS AND TIMING

5.1. Location

The operational base for this consultancy is Port of Spain, Trinidad (CARPHA-POS Campus). The contractor will work remotely.

5.2. Start date & period of implementation of tasks

The intended start date is June 2022 and the period of implementation of the contract will be five (5) months from this date.

6. REQUIREMENTS

6.1. Staff

Note that civil servants and other staff of the public administration of the partner country, or of international/regional organisations based in the country, shall only be approved to work as experts if well justified. The justification should be submitted with the tender and shall include information on the added value the expert will bring as well as proof that the expert is seconded or on personal leave.

6.1.1. Key experts

All experts who have a crucial role in implementing the contract are referred to as key experts. The profile of the key expert needed for this contract is as follows:

Qualifications and skills

- At least a Postgraduate qualification in pharmacology, or pharmaceuticals, or health systems administration, or pharmacy administration, or regulatory affairs, or a related field.
- Prior training in technical writing or writing research reports in a health science or life science
- Certification or training in regulatory affairs or pharmaceutical regulation.

General professional experience

- No less than five years' experience in pharmaceutical public health, medicines regulation, academia, or in a health profession
- No less than three years' experience writing technical reports or research papers
- The contractor should possess good management skills, good technical or research writing skills, and research skills.

Specific professional experience

- Listed author of at least one article published in a peer-reviewed journal
- Preferred: First author of at least one published article on pharmaceutical regulation, or related topic published in a peer-reviewed journal

All experts must be independent and free from conflicts of interest in the responsibilities they take on.

6.1.2. Other experts, support staff & backstopping

CVs for experts other than the key experts should not be submitted in the tender but the tenderer will have to demonstrate in their offer that they have access to experts with the required profiles. The contractor shall select and hire other experts as required, according to the needs. The selection procedures used by the contractor shall be transparent, and be based on pre-defined criteria, including professional qualifications, skills, and work experience.

The costs for backstopping and support staff, as needed, are considered to be included in the tenderer's financial offer.

6.2. Office accommodation

Office accommodation for each expert working on the contract is to be provided by the contractor.

6.3. Facilities to be provided by the contractor

The contractor shall ensure that experts are adequately supported and equipped. In particular, he or she must ensure that there is sufficient administrative, secretarial and interpreting provision to enable experts to concentrate on their primary responsibilities. He or she must also transfer funds as necessary to support their work under the contract and to ensure that its employees are paid regularly and in a timely fashion.

6.4. Equipment

No equipment is to be purchased on behalf of the contracting authority as part of this service contract or transferred to the contracting authority at the end of this contract.

7. REPORTS

7.1. Reporting requirements

The contractor will submit the following reports in English in one electronic copy each:

- **Inception Report** of maximum 10 pages (excluding annexes) to be produced **two weeks after the start of the contract**. In the report the contractor shall describe initial findings, work plan, progress

in procedure development, any difficulties encountered or expected in addition to the work programme. The contractor should proceed with his/her work unless the contracting authority sends comments on the inception report.

- **Interim Report 1:** Interim Report of maximum 12 pages (excluding annexes) to be produced no later than **two months after the start of the contract**. This report will consist of a detailed summary of progress with implementation of the specific work set out in Section 4.2, (up to Result 2) including challenges encountered and action taken/proposed to address challenges. This report will also include, as an Annex, the procedural framework and tools as described under section 4.2.
- **Draft final report** of maximum 20 pages (excluding annexes) in the format given below. This report will include a detailed description of the work done, details of challenges encountered, and recommendations (as described in Section 4.1, 4.2). This report shall be submitted no later than **one month before the end** of the period of implementation of tasks.

The Draft Final Report will include as Annexes:

- Procedural framework describing the requirements, and steps for a collaborative process of joint review of COVID-19 medicines and vaccines between the CARPHA-CRS and CARICOM Member States
- Manuscript describing the development of the joint review process, anticipated challenges and recommendations for the implementation of the joint review process for COVID-19 vaccines and medicines
- **Final report** with the same specifications as the draft final report, incorporating any comments received from the parties on the draft report. The deadline for sending the final report is **seven (7) calendar days** after receipt of comments on the draft final report. The report shall contain a sufficiently detailed descriptions of the different options to support an informed decision on the product. The detailed analyses underpinning the recommendations will be presented in annexes to the main report. The final report must be provided along with the corresponding invoice.

7.2. Submission and approval of reports

The report referred to above must be submitted to the project manager identified in the contract. The project manager is responsible for approving the reports.

8. MONITORING AND EVALUATION

8.1. Definition of indicators

Implementation performance will be measured by:

- Submission of joint review procedure, related tools and resources for COVID-19 medical products
- Submission of manuscript for publication
- Compliance with the schedule for the submission of reports on the outputs of the Project as outlined in Section 7.1.

8.2. Special requirements

There are no special requirements to be added.