

TERMS OF REFERENCE: Summaries of Recommended Products Consultancy

1. BACKGROUND INFORMATION	2
1.1 Partner country	2
1.2 Contracting authority	2
1.3 Country background	2
1.4 Current situation in the sector.....	2
1.5 Related programmes and other donor activities	3
2. OBJECTIVE, PURPOSE & EXPECTED RESULTS	3
2.1 Overall objective	3
2.2 Purpose	3
2.3 Results to be achieved by the contractor	3
3. ASSUMPTIONS & RISKS	4
3.1 Assumptions underlying the project	4
3.2 Risks	4
4. SCOPE OF THE WORK.....	4
4.1 General	4
4.2 Specific work.....	4
4.3 Project management	6
5. LOGISTICS AND TIMING	6
5.1 Location.....	6
5.2 Start date and period of implementation of tasks	6
6. REQUIREMENTS	6
6.1 Staff	6
6.2 Office accommodation	7
6.3 Facilities to be provided by the contractor	7
6.4 Equipment	7
7. REPORTS	8
7.1 Reporting requirements	8
7.2 Submission and approval of reports	8
8. MONITORING AND EVALUATION	8
8.1 Definition of indicators.....	8
8.2 Special requirements	9

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 promote the establishment of post-authorization surveillance resources, tools, trainings, and procedures for new vaccines and new therapeutics introduced in response to COVID-19.

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 list of products recommended by the CRS, including COVID-19 medical products, is available on the website at: <https://carpha.org/What-We-Do/CRS/Product-Review>.

Publicly available profiles of the recommended COVID-19 vaccines and other medical products will improve the transparency of the CRS, and allow regulators, health workers and the public to understand basic details of the product and the administrative information of the recommendation.

1.5 Related programmes and other donor activities

The World Health Organization's Prequalification programme conducts assessments of medicines and vaccines to assist countries with regulatory decision-making. This programme extends to COVID-19 vaccines for emergency use listing, and to medicines that may be prequalified for COVID-19 treatment, such as dexamethasone. The CRS participates in the Collaborative Registration Procedure for the accelerated registration of WHO prequalified medicines and vaccines. 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 proposed contract will enable the CARPHA-CRS to provide public profiles of medicines and vaccines that have been reviewed and recommended by the CRS, including products for COVID-19.

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:** Templates for CRS Summaries of Product Characteristics of recommended products developed and submitted for the approval of the Project Manager
- **Result 3:** Summaries of Product Characteristics for COVID-19 products recommended by the CRS

- **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 sufficiently qualified experts who may tender for the consultancy.

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 templates for the web-based publication of Summaries of Product Characteristics of medical products recommended by the CRS, and to develop Summaries of Product Characteristics for recommended COVID-19 medicines and vaccines.

4.1.2 Geographical area to be covered

The geographical area is the Caribbean Community (CARICOM)

4.1.3 Target groups

The target groups for the Summaries of Product Characteristics will be:

- Regulatory units of Ministries of Health in CARICOM
- Procurement agencies for public sector procurement in CARICOM
- Health workers in CARICOM
- Members of the public in CARICOM.

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: Templates for CRS Summaries of Product Characteristics of recommended products developed and submitted for the approval of the Project Manager.

- 2.1 Prepare and submit draft templates for web-based Summaries of Product Characteristics (SPCs) for various types of products that are reviewed by the CRS, based on listed pathways as follows:
 - Market authorisation / importation: medicines, vaccines, test kits
 - Emergency use authorisation: medicines, vaccines, test kits.
- 2.2 Prepare revised versions of the SPC templates based on feedback received from the Project Manager for inclusion in the final report.
- 2.3 Prepare an Interim report for approval of the Project Manager, which includes the draft templates, and a description of any anticipated challenges and solutions.

Result 3: Summaries of Product Characteristics for COVID-19 products recommended by the CRS

- 3.1. Develop draft Summaries of Product Characteristics (SPC) for up to 30 COVID-19 medical products (vaccines, medicines and test kits) recommended by the CRS, as individual files for web posting.
- 3.2. Prepare revised versions of the SPCs for COVID-19 products based on feedback received from the Project Manager for inclusion in the final report.

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 that includes:
 - (i) a description of:

- the implementation of the scope of work (as per the specific work in Section 4.2)
- the challenges encountered and action taken to address challenges
- key lessons learned, and
- recommendations for the periodic revision of templates in the future

- (ii) the SPC Report that describes at minimum, the following:

- Details of method of template development
- Descriptions of templates developed, including the purpose of each
- Final template designs
- Examples of templates used as resources or references
- SPCs of CRS Recommended COVID-19 vaccines, medicines, and test kits.

Result 5: Final Report: 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. Provide the Contractor with the list of COVID-19 vaccines, medicines and test kits recommended by the CRS for which SPCs are to be developed
- iv. Assume responsibility for the logistical and administrative arrangements for document sharing and meetings.

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 and period of implementation of tasks

The intended start date is July, 2022 and the period of implementation of the contract will be three and half months (3 ½) 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 expert

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 are as follows:

Qualifications and skills

- At least a Postgraduate qualification in pharmacology or pharmacy or pharmaceuticals or medicine or a life science or related field.
- Prior training in technical writing or writing research reports in a health science or life science is desirable.

General professional experience

- No less than five years' experience in public health, or 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 basic research skills.

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 to select these other experts shall be transparent, and shall be based on pre-defined criteria, including professional qualifications, language 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 it must ensure that there is sufficient administrative, secretarial and interpreting provision to enable experts to concentrate on their primary responsibilities. It 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. The contractor is responsible for obtaining all supplies needed to complete the project.

In addition, the Contractor shall be required to provide his or her personal computer (e.g. laptop or tablet) and Internet connectivity for use during this project.

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 after **one week** from the start of implementation. In the report the contractor shall describe initial findings, work plan, progress in SPC 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 **three weeks after the start of the contract**. This report will consist of a 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 include as an Annex, the SPC templates as described under section 4.2.
- **Draft final report** of maximum 20 pages (excluding annexes). The submission must be a comprehensive report comprising the work conducted in respect of section 4.2. This submission will include as Annexes the templates for SPCs of recommended products, SPCs of COVID-19 products recommended by the CRS. This report shall be submitted no later than **two weeks before the end** of the period of implementation of tasks.
- **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 reports 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 SPC templates, and SPCs for COVID-19 medical products
- 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.