World Health Organization

Country Office for Viet Nam
304 Kim Ma, Hanoi, Viet Nam

Call for Expressions of Interest and Proposal

This consultancy is to (1) provide support to the Ministry of Health of Viet for capacity building of National Regulatory Authority (NRA) for vaccines and medicines including support for development of a roadmap for FDA model; (2) provide technical support for developing a new Pharmaceutical Strategy (DAV); and (3) provide technical support to National Centralized Procurement Centre (NCPC) to improve access to affordable essential medicines

1. Background

National Regulatory Authority (NRA) Vietnam is one of the 37 countries in the world certified by WHO since April 2015 in vaccine regulation. In November 2018, NRA Viet Nam was re-assessed by WHO and the external assessment team against a new Global Benchmarking Tool comprising of 9 regulatory functions. According to the preliminary results of the re-benchmarking for NRA for vaccines, there were 21 sub-indicators that were not implemented and 26 recommendations for five remaining functions towards a functional NRA. In response to this report, NRA Viet Nam submitted a corrective and preventive action plan (CAPA) in early 2019, with a detailed Institutional Development Plan (IDP) to follow. The joint visit from WHO team in mid-2019 has taken place to follow up on the outcome of aforementioned benchmarking and implementation status of provided recommendations as well as corrective and preventive actions. The final result of Vietnam NRA maturity level for vaccines is expected to be announced in 2020.

Given this background, WHO's work in 2020 is to support MOH for implementing the actions laid out in the CAPA and the revised IDP as a short-term objective, as well as to help develop a roadmap for the NRA to transition to an autonomous, unified and intendent agency such as a FDA (Food and Drug Administration) as a long-term objective. In addition, WHO Viet Nam aims to support MOH to expand its scope of regulatory systems strengthening to include medicines and other medical devices for the future.

Since 2014, Vietnam Prime Minister has approved the Decision No. 68/QD-TTg on the National strategy on development of the Vietnam pharmaceutical industry up to 2020, with a vision toward 2030. The strategy with the aims of providing adequate, timely, quality, and reasonably priced medicines according to each disease model corresponding to each stage of socio-economic development; and ensuring safe and rational use of medicines. The strategy also paid attention to providing medicine to social policy beneficiaries, ethnic minorities, the poor, remote and isolated areas. To align with new Pharmacy Law promulgated in 2016 and to keep up with rapid development of local and international pharmaceutical industry, Vietnam DAV as the main agency in collaboration with other ministries and government agencies, to develop a new National strategy on

development of the Vietnam pharmaceutical industry strategy up to 2030, with a vision toward 2035.

2. Work to be performed

Method(s) to carry out the activity

The consultant will be required to report regularly to the office of WHO Viet Nam located in Ha Noi, Viet Nam as agreed with the supervisor(s). The work will involve but not limited to:

- Facilitating collaboration among institutions within the NRA Office to implement activities specified in CAPA, IDP, FDA model and Pharmaceutical Sector Strategy. Liaison with WHO Country Office, Regional Office and Headquarters to ensure clear lines of communication and effective monitoring of CAPA, IDP implementation and Pharmaceutical Sector Strategy.
- Organising technical support to help build workforce capacity and organisational efficiency at different NRA agency. These include but not limited to; compliance with head agreements, demand planning, overseas fellowships to learn about strategies, workshops, online training and international consultancies to strengthen on the job training etc.
- Facilitating collaboration between ministries and government agencies to champion the review and development of the new Pharmaceutical Strategy; to advocate for an inclusive Strategy that covers the entire medicine cycle. These include, NRA to ensure quality and safety, access to affordable medicines and rational use of medicines under a new "National Medicines Policy".
- Under direct supervision of the UHC Team Coordinator, work with a GO-fellow in charge of essential medicines and regulatory systems strengthening as a team and help the fellow's communication with the government counterparts and national stakeholders.
- Participation in meetings and workshops
- Reviewing reports and documents
- Supporting visiting missions or experts including interpretation/translation
- Providing technical advice where needed.

Output/s

Output 1: The implementation of Viet Nam NRA's CAPA and IDP including regular monitoring and evaluation as well as capacity building and technical support provided.

Deliverables

- 1.1.: Technical reports on CAPA and IDP implementation monitoring including document updates through Sharepoint.
- 1.2.: Summary report of capacity building activities provided by WHO, including those provided by external consultants or experts with attention on MSC functions
- 1.3: Technical reports on plan and timeline in the roadmap toward FDA Model for Vietnam with attention to integration of medicines, vaccines and medical devices

Output 2: WHO's technical inputs provided on the draft national strategy on development of the Vietnam pharmaceutical industry up to 2030, with a vision toward 2035

Deliverables

- 2.1.: Technical reports on plan including timelines to review and develop the national strategy for the Vietnam pharmaceutical industry up to 2030, with a vision toward 2035
- 2.2.: Summary report of WHO's inputs on the draft strategy

Output 3: Technical support to National Centralized Procurement Center (NCPC) for capacity building including strategic price reductions

Deliverables

3.1: Report on support provided to include key essential medicines such as hepatitis into the 2021 central negotiations and procurement cycle

3. Specific requirements

Qualifications required:

- Education:

- Essential: University Degree in relevant areas including medicine, pharmacy or public health from a recognized university
- Desirable: Post-graduate degree in relevant areas including medicine, pharmacy or public health from a recognized university

Experience required:

- Experience:
  - Essential: At least five (05) years of experience in public health or pharmaceutical related field
  - Desirables: Experience in a national regulatory authority (NRA) or supporting NRA systems strengthening at international setting and working knowledge of pharmaceutical system and/or management, including systems of central medicine procurement

Skills / Technical skills and knowledge:

Language requirements:

- Good knowledge on the WHO Global Benchmarking Tool for evaluation of national regulatory systems
- Expertise in project management
- High level of computer literacy including Microsoft excel and use of SharePoint

Competencies

- Teamwork: Works collaboratively with team members and counterparts to achieve results
- Respecting cultural difference: Relates well to people with different cultures, gender, orientations, background and/or positions
- Communication: Adopts communication style and written content to ensure they are appropriately and accurately understood by the audience

- Language requirements:

  - Essential: High level of proficiency in English and in Vietnamese, both verbal and written

5. Place of assignment

Viet Nam Country Office, Hanoi, Viet Nam

6. Medical clearance

The selected Consultant will be expected to provide a medical certificate of fitness for work.

7. Travel

The Consultant may be expected to undertake some domestic duty travel.

8. Budget

Please take note of the following when submitting application:

- The contractor will be responsible for paying taxes, if any.

Those who are interested can contact our focal person with contact detail at the end of the announcement before/by **10 March 2020**

Full proposal with estimation of costs, description of technical team, and supporting documents should be received **on/or 10 March 2020** and should be addressed to:

Administrative Officer
World Health Organization
UN Building, 304 Kim Ma Street,
Hanoi, Viet Nam

OR

wpvnmapplicants@who.int
For further information on this TOR, please contact:
wpvnmwr@who.int