Scoping review and report on national policies, legislative and regulatory approaches for the supply, prescribing and use of antimicrobials

Request for Proposals (RFP)

Bid Reference
HQ/MVP/EMP/IAU/2018/006

Unit Name
Innovation, Access and Use

Closing Date:
Friday 25 May, 2018
17h00 CEST
The World Health Organization (WHO) is seeking from bidders to undertake a scoping review and report on national policies, legislative and regulatory approaches for the supply, prescribing and use of antimicrobials. Companies or institutions are invited to submit a proposal for the work in response to this Request for Proposals (RFP).

WHO is a public international organization, consisting of 194 Member States, and a Specialized Agency of the United Nations with the mandate to act as the directing and coordinating authority on international health work. As such, WHO is dependent on the budgetary and extra-budgetary contributions it receives for the implementation of its activities. Bidders are, therefore, requested to propose the best and most cost-effective solution to meet WHO requirements, while ensuring a high level of service.

1. Requirements

WHO requires the successful bidder, to carry out a scoping review and report of national policies, legislation and/or regulatory approaches for the prescribing, supply and use of antibiotics. The findings of the review are to be considered in a meeting of technical experts at WHO HQ, Geneva.

See attached detailed Terms of Reference for complete information.

The successful bidder shall be a company or institution operating in the field of pharmaceutical policy and legislation with proven expertise in this area.

Bidders should follow the instructions set forth below in the submission of their proposal to WHO.

2. Proposal

The proposal and all correspondence and documents relating thereto shall be prepared and submitted in the English language.

The proposal should be concisely presented and structured to include the following information:

- Presentation of your Company / Institution (please complete Annex 2)
- Technical proposal of the proposed approach/methodology for the scoping review
- Proposed time-line
- Financial proposal

Information which the bidder considers confidential, if any, should be clearly marked as such.

3. Instructions to Bidders

Bidders must follow the instructions set forth in this RFP in the submission of their proposal to WHO.

A prospective bidder requiring any clarification on technical, contractual or commercial matters may notify WHO via email at the following address no later than 10 working days prior to the closing date for the submission of offers:

Email for submissions of all queries: emlsecretariat@who.int

(use Bid reference in subject line)

A consolidated document of WHO's responses to all questions (including an explanation of the query but without identifying the source of enquiry) will be sent to all prospective bidders who have received the RFP.
From the date of issue of this RFP to the final selection, contact with WHO officials concerning the RFP process shall not be permitted, other than through the submission of queries and/or through a possible presentation or meeting called for by WHO, in accordance with the terms of this RFP.

The bidder shall submit, in writing, the complete proposal to WHO, no later than Friday 25 May 2018, 17:00 Central European Summer Time ("the closing date"), by email at the following email address:

emlsecretariat@who.int

(use Bid reference in subject line)

To be complete, a proposal shall include:
- A technical proposal, as described under part 2, above;
- A financial proposal, as described under part 2, above;
- Annex 2, duly completed and signed by a person or persons duly authorized to represent the bidder, to submit a proposal and to bind the bidder to the terms of this RFP.

Each proposal shall be marked Ref: HQ/MVP/EMP/IAU/2018/006.

WHO may, at its own discretion, extend the closing date for the submission of proposals by notifying all bidders thereof in writing before the above closing date and time.

Any proposal received by WHO after the closing date for submission of proposals may be rejected. Bidders are therefore advised to ensure that they have taken all steps to submit their proposals in advance of the above closing date and time.

The offer outlined in the proposal must be valid for a minimum period of 90 calendar days after the closing date. A proposal valid for a shorter period may be rejected by WHO. In exceptional circumstances, WHO may solicit the bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. Any bidder granting such an extension will not, however, be permitted to otherwise modify its proposal.

The bidder may withdraw its proposal any time after the proposal's submission and before the above mentioned closing date, provided that written notice of the withdrawal is received by WHO at the email address indicated above, before the closing date for submission of proposals.

No proposal may be modified after its submission, unless WHO has issued an amendment to the RFP allowing such modifications.

No proposal may be withdrawn in the interval between the closing date and the expiration of the period of proposal validity specified by the bidder in the proposal (subject always to the minimum period of validity referred to above).

WHO may, at any time before the closing date, for any reason, whether on its own initiative or in response to a clarification requested by a (prospective) bidder, modify the RFP by written amendment. Amendments could, inter alia, include modification of the project scope or requirements, the project timeline expectations and/or extension of the closing date for submission.

All prospective bidders that have received the RFP will be notified in writing of all amendments to the RFP and will, where applicable, be invited to amend their proposal accordingly.
All bidders must adhere to the UN Supplier Code of Conduct, which is available on the WHO procurement website at [http://www.who.int/about/finances-accountability/procurement/en/](http://www.who.int/about/finances-accountability/procurement/en/).

4. Evaluation
Before conducting the technical and financial evaluation of the proposals received, WHO will perform a preliminary examination of these proposals to determine whether they are complete, whether any computational errors have been made, whether the documents have been properly signed, and whether the proposals are generally in order. Proposals which are not in order as aforesaid may be rejected.

The evaluation panel will evaluate the technical merits of all the proposals which have passed the preliminary examination of proposals based on the following weighting:

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<th>Technical Weighting:</th>
<th>60% of total evaluation</th>
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<tr>
<td>Financial Weighting:</td>
<td>40% of total evaluation</td>
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Please note that WHO is not bound to select any bidder and may reject all proposals. Furthermore, since a contract would be awarded in respect of the proposal which is considered most responsive to the needs of the project concerned, due consideration being given to WHO's general principles, including the principle of best value for money, WHO does not bind itself in any way to select the bidder offering the lowest price.

WHO may, at its discretion, ask any bidder for clarification of any part of its proposal. The request for clarification and the response shall be in writing. No change in price or substance of the proposal shall be sought, offered or permitted during this exchange.

NOTE: Individual contact between WHO and bidders is expressly prohibited both before and after the closing date for submission of proposals.

5. Award
WHO reserves the right to:

a) Award the contract to a bidder of its choice, even if its bid is not the lowest;
b) Award separate contracts for parts of the work, components or items, to one or more bidders of its choice, even if their bids are not the lowest;
c) Accept or reject any proposal, and to annul the solicitation process and reject all proposals at any time prior to award of contract, without thereby incurring any liability to the affected bidder or bidders and without any obligation to inform the affected bidder or bidders of the grounds for WHO's action;
d) Award the contract on the basis of the Organization's particular objectives to a bidder whose proposal is considered to be the most responsive to the needs of the Organization and the activity concerned;
e) Not award any contract at all.

WHO has the right to eliminate bids for technical or other reasons throughout the evaluation/selection process. WHO shall not in any way be obliged to reveal, or discuss with any bidder, how a proposal was assessed, or to provide any other information relating to the evaluation/selection process or to state the reasons for elimination to any bidder.
NOTE: WHO is acting in good faith by issuing this RFP. However, this document does not oblige WHO to contract for the performance of any work, nor for the supply of any products or services.

At any time during the evaluation/selection process, WHO reserves the right to modify the scope of the work, services and/or goods called for under this RFP. WHO shall notify the change to only those bidders who have not been officially eliminated due to technical reasons at that point in time.

WHO reserves the right at the time of award of contract to extend, reduce or otherwise revise the scope of the work, services and/or goods called for under this RFP without any change in the base price or other terms and conditions offered by the selected bidder.

WHO also reserves the right to enter into negotiations with one or more bidders of its choice, including but not limited to negotiation of the terms of the proposal(s), the price quoted in such proposal(s) and/or the deletion of certain parts of the work, components or items called for under this RFP.

Within 30 days of receipt of the contract between WHO and the successful bidder (the "Contract"), the successful bidder shall sign and date the Contract and return it to WHO according to the instructions provided at that time. If the bidder does not accept the Contract terms without changes, then WHO has the right not to proceed with the selected bidder and instead contract with another bidder of its choice. The Contract will include, without limitation, the provisions set forth in Annex 3.

Any and all of the contractor's (general and/or special) conditions of contract are hereby explicitly excluded from the Contract, i.e., regardless of whether such conditions are included in the Contractor's offer, or printed or referred to on the Contractor's letterhead, invoices and/or other material, documentation or communications.

We look forward to receiving your response to this RFP.

Yours sincerely,

Dr Suzanne Hill
Director
Department of Essential Medicines and Health Products

Annexes

1. Detailed Terms of Reference
2. Vendor Information Form
3. Contractual provisions
Annex 1: Detailed Terms of Reference

1. Purpose
To support the Department of Essential Medicines and Health Products and the Department of Regulations and Health Technologies provide guidance for countries on how to ensure safety, efficacy and quality of antimicrobials, optimize their appropriate use, and in particular, on how to adopt and implement the AWaRe categorization of antibiotics as part of their national pharmaceutical policy and regulatory systems. This will be delivered through development of a report describing national policy, legislative and regulatory system approaches for the supply, prescribing and use of antimicrobials.

2. Background
WHO recommends that all countries formulate and implement a comprehensive national medicines policy as a means to improve access to safe, effective medicines of good quality. However, the safety, efficacy and quality of the medicines is not always up to the required standards due to weak market authorization, licensing, inspection, post marketing surveillance and other regulatory processes. This may encourage the proliferation of unauthorized medical products including Substandard and Falsified (SF) medical products in the health care delivery system and antimicrobials are amongst the medicines preferred for illegal circulation and/or falsification. Many countries do not have functional medicine regulatory systems and their capacity to enforce national legislation and regulations is limited.

Optimizing the use of antimicrobial medicines is a key priority of the global strategies to combat antimicrobial resistance (AMR). Objective 4 of WHO’s Global Action Plan on AMR focuses on optimizing the use of medicines by promoting rational use and improving evidence-based prescribing. It also states that the regulation of the use of antibiotics is inadequate or poorly enforced in many areas. High antibiotic use is a known driver of AMR and may be the result of over-prescribing, easy access to antibiotics without a prescription, and more recently, internet sales. Moreover, Objective 4 articulates the need for effective and enforceable regulation and governance for licensing, distribution, use and quality assurance of antimicrobial medicines. It also stresses on the need for provision of marketing authorization only to antimicrobial agents that are quality assured, safe and efficacious. Therefore, it would be important to review the policy, legal and regulatory situation and enforcement capacity of member states and recommend strategic actions needed to ensure effective implementation of policy and regulations to meet the objective.


To optimize the use of antibiotics, more emphasis needs to be given to strengthening the national regulatory systems, especially in low- and middle-income countries. Studying the medicines policies, regulations, enforcement capacities, and their impact on the prevention and control of AMR is imperative in understanding the situation and preparing appropriate strategies to tackle the challenges. The data which will be generated through this RFP can provide evidence for the implementation of core activities in the Department of Essential Medicines and Health Products and the Department of Regulations and Health Technologies, including antibiotic selection, use, stewardship, regulation and governance. WHO benchmarking (Self, Rapid or full benchmarking) reports of some national regulatory authorities would also provide information/data on the institutional and legal frameworks, maturity levels, capacity gaps and implementation of the institutional development Plans (IDP).

The WHO Model List of Essential Medicines serves as a guide for the development of national and institutional essential medicine lists. In 2017, the WHO Expert Committee on Selection and Use of Essential Medicines considered a comprehensive review of antibiotics on the WHO Model List of Essential Medicines and Model List of Essential Medicines for Children. Taking account of the global recognition of the need for effective
antimicrobial stewardship, as well as the need to ensure access to necessary antibiotics and appropriate prescribing, the Expert Committee also proposed that antibiotics could be categorized in three groups – Access, Watch and Reserve – the ‘AWaRe’ categorization:

- Access – first- and second-choice antibiotics for the empirical treatment of most common infectious syndromes;
- Watch – antibiotics with higher resistance potential whose use as first- and second-choice treatment should be limited to a small number of syndromes or patient groups; and
- Reserve – antibiotics to be used mainly as “last-resort” treatment options.


This RFP is expected to support the development of strategies and tools and thereby provide practical guidance for national implementation of the AWaRe categorization into medicines regulations and policies. The outcome of the scoping review will provide evidence leading to strategic recommendations/advice to countries to effectively implement national pharmaceutical policies, strengthen national regulatory systems and contribute to the implementation of the Global Action Plan on AMR.

3. Work to be performed

- Undertake a scoping review of existing national policies, legislation and regulatory approaches for the supply (market authorization, licensing, inspection and post marketing surveillance), prescribing and use of antimicrobials, incorporating high-, middle- and low-income countries;
- Analyse the effect(s) of identified policies, legislation and regulatory system approaches on antimicrobial supply, prescribing and access, with a focus on the EML AWaRe groups;
- Analyse the effect(s) of identified policies, legislation and regulatory system approaches on patterns or levels of antimicrobial resistance;
- Identify any barriers to access or other unintended consequences identified due to policies, legislation and/or regulatory approaches;
- Present the findings of the review and analyses at a meeting of technical experts at WHO HQ in Geneva, to develop strategic actions for countries on how to implement appropriate legislation and regulation to ensure the safety, efficacy and quality and proper use of antimicrobials based on the findings of the review.

4. Deliverables

Written report of the key findings of the scoping review and analyses, including implementation advice for countries.
Annex 2: Vendor Information Form

**Company Information** to be provided by the Vendor submitting the proposal

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<th>UNGM Vendor ID Number:</th>
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<td>If available – Refer to WHO website for registration process*</td>
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<th>Company Website:</th>
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**Corporate Information:**

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<th>Organization structure (include description of those parts of your organization that would be involved in the performance of the work)</th>
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<th>Relevant experience (how could your expertise contribute to WHO's needs for the purpose of this RFP) – Please attach reference and contact details</th>
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Within 30 days of receipt of the contract between WHO and the successful bidder (the “Contract”), the successful bidder shall sign and date the Contract and return it to WHO according to the instructions provided at that time. If the bidder does not accept the Contract terms without changes, then WHO has the right not to proceed with the selected bidder and instead contract with another bidder of its choice. The Contract will include, without limitation, the provisions set forth below (with the successful bidder referred to below as the “Contractor”):

1. **Compliance with WHO Codes and Policies.** By entering into the Contract, the Contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below).

In connection with the foregoing, the Contractor shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by its employees and any other persons engaged by the Contractor to perform any services under the Contract.

Without limiting the foregoing, the Contractor shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the Contractor becomes aware.

For purposes of the Contract, the term “WHO Policies” means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research; (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: http://www.who.int/about/finance-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

2. **Zero tolerance for sexual exploitation and abuse.** WHO has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein:

   (i) each legal entity Contractor warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform any services under the Contract; and (ii) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the contractor becomes aware; and

   (ii) each individual Contractor warrants that he/she will (i) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and (ii) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Contractor becomes aware.

3. **Tobacco/Arms Related Disclosure Statement.** The Contractor may be required to disclose relationships it may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Contractor undertakes not to permit work on the Contract to commence, until WHO has assessed the disclosed information and confirmed to the Contractor in writing that the work can commence.
4. **Anti-Terrorism and UN Sanctions; Fraud and Corruption.** The Contractor warrants for the entire duration of the Contract that:

i. it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;

ii. it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the Contract; and

iii. the Contractor shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the Contract.

Any payments used by the Contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

5. **Breach of essential terms.** The Contractor acknowledges and agrees that each of the provisions of paragraphs 1, 2, 3 and 4 above constitutes an essential term of the Contract, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

i. terminate the Contract, and/or any other contract concluded by WHO with the Contractor, immediately upon written notice to the Contractor, without any liability for termination charges or any other liability of any kind; and/or

ii. exclude the Contractor from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any violation of such provisions to WHO’s governing bodies, other UN agencies, and/or donors.

6. **Use of WHO Name and Emblem.** Without WHO’s prior written approval, the Contractor shall not, in any statement or material of an advertising or promotional nature, refer to the Contract or the Contractor’s relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

7. **Assurances regarding procurement.** If the option for payment of a maximum amount applies, to the extent the Contractor is required to purchase any goods and/or services in connection with its performance of the Contract, the Contractor shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

8. **Audit.** WHO may request a financial and operational review or audit of the work performed under the Contract, to be conducted by WHO and/or parties authorized by WHO, and the Contractor undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under the Contract, or within five years of completion of the work. In order to facilitate such financial and operational review or audit, the Contractor shall keep accurate and systematic accounts and records in respect of the work performed under the Contract.
The Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:

i. the Contractor’s books, records and systems (including all relevant financial and operational information) relating to the Contract; and

ii. reasonable access to the Contractor’s premises and personnel.

The Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Contractor to provide complementary information about the work performed under the Contract that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Contractor and related to the work performed under the Contract.

9. **Publication of Contract.** Subject to considerations of confidentiality, WHO may acknowledge the existence of the Contract to the public and publish and/or otherwise publicly disclose the Contractor’s name and country of incorporation, general information with respect to the work described herein and the Contract value. Such disclosure will be made in accordance with WHO’s Information Disclosure Policy and shall be consistent with the terms of the Contract.