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Annex 6
Procedure for assessing the acceptability, in principle, of procurement agencies for use by United Nations agencies

1. Introduction

The World Health Organization (WHO) could provide United Nations agencies with advice on the acceptability, in principle, of procurement agencies which are found to meet WHO recommended quality standards, for use by United Nations agencies. This will be done through a standardized quality assessment procedure.

The purpose of the quality assessment procedure is to evaluate whether the procurement agencies meet the requirements recom-

mended by WHO and operate in compliance with relevant principles for good pharmaceutical procurement.

The quality assessment procedure established by WHO is based on the following principles:

— reliance on the information supplied by the procurement agency;
— general understanding of the activities performed by the procurement agency;
— evaluation of information submitted by the procurement agency in a procurement agency information file (PAIF);
— assessment of consistency in pre-qualification, purchasing, storage and distribution through compliance with interim guidelines for the assessment of a procurement agency or a Model Quality Assurance System (MQAS)[1] as recommended by WHO.

WHO should collaborate with national authorities in the quality assessment. WHO will advise United Nations agencies of the procurement agencies that have been found acceptable in principle for use through a procedure of quality assessment based on WHO recommended guidelines and standards.

2. Steps of the procedure

WHO requires information related to the activities of the procurement agency to enable it to perform the assessment. Interested procurement agencies provide this information by submitting a procurement agency information file (PAIF) with the information requested about the procurement agency to WHO. In addition to the evaluation of the information submitted, a site inspection(s) may be performed. WHO reserves the right to terminate the quality assessment procedure of a procurement agency when the procurement agency is not able or fails to provide the required information within a specified time period, or when inadequate information is supplied to complete the quality assessment effectively.

In the context of this document, procurement is defined as the entire process of planning, design, determination of standards, writing of specifications, assessment (of products, manufacturers and suppliers), purchasing mechanism and selection of offers, financing, contract administration, storage, distribution, disposals and other related functions.

[1] *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth report.* Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 917, Annex 8).

2.1 Publication of Invitation for Expression of Interest

WHO will publish an invitation widely in the international press and on its web pages at regular intervals, when necessary, to request procurement agencies to submit an Expression of Interest (EOI) to perform procurement activities on behalf of United Nations agencies. The invitation should be open and transparent, inviting any procurement agency to submit the EOI for the performance of the activities to be listed in the invitation.

Procurement agencies should submit their EOI with the relevant information requested before the date specified by WHO.

WHO will receive the EOI and record the receipt of the EOI from each procurement agency. Guidelines developed for the submission of the PAIF shall then be sent to the interested procurement agencies.

2.2 Submission of a procurement agency information file

Each interested procurement agency should provide the focal point indicated in the EOI with a PAIF containing the required information before a specified date set by WHO.

The information should be submitted as described in the document "Guidelines for preparing a Procurement Agency Information File (PAIF)"[2] and provide the information listed below:

— general information
— documentation
— personnel
— pre-qualification
— purchasing
— storage
— quality control
— contract operations and activities
— distribution
— complaints and recalls
— self inspection.

2.3 Screening of submitted procurement agency information file

Each PAIF submitted by the procurement agency will be screened for completeness prior to its evaluation.

[2] *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth report.* Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 917).

PAIFs that are incomplete will not be considered for evaluation. The procurement agency will be informed that an incomplete file has been received, and be requested to complete the file within a specified time period. In the event that this is not complied with, the file will, in principle, be rejected on grounds of incompleteness and returned to the procurement agency.

PAIFs that comply with the requirements of WHO will be (1) retained for evaluation purposes and (2) the site will be considered for a possible inspection (if this is warranted based on the outcome of the evaluation of the PAIF).

2.4 Assessment of the procurement agency information file

The PAIF will be evaluated by WHO in accordance with a standard operating procedure for assessing PAIFs based on the WHO guidelines to ensure uniformity in evaluation.

2.5 Site inspection

Dependent on the outcome of the evaluation of the PAIF, WHO will plan and coordinate the performance of inspections at the sites to assess compliance with the "Interim guidelines for the assessment of a procurement agency" or a "Model quality assurance system" (MQAS)[3] as recommended by WHO. The inspection will be performed by an inspector or a team of inspectors consisting of experts appointed by WHO. A WHO staff member will coordinate the team and the team members will act as temporary expert advisers to WHO. The inspector or inspection team(s) will perform the inspections and report on the findings in accordance with standard operating procedures for planning and performing site inspections to ensure a standard harmonized approach.

Inspectors must have the relevant qualifications and experience.

2.6 Report and outcome of evaluation

The inspector or inspection team(s) will finalize a report according to the WHO format describing the findings of the inspection. These will be communicated to the procurement agency concerned.

If any additional information is required, or corrective action has to be taken by the procurement agency, WHO will postpone its final recommendations until such information has been evaluated, or the

[3] *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth report.* Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 917).

corrective action has been taken and found satisfactory in light of the specified standards.

In the event of any disagreement between a procurement agency and WHO, a standard operating procedure for the handling of appeals and complaints will be followed to discuss and resolve the issue.

As WHO is responsible for the quality assessment, the ownership of the reports lies with WHO (without prejudice, however, to any confidential and proprietary information of the procurement agency contained in this report).

2.7 Results of assessment

Once WHO is satisfied that the quality assessment process for the procurement agency is complete, and that the agency is acceptable in principle for use to carry out procurement on behalf of a United Nations agency (i.e. it has been found to meet the WHO recommended standards), the agency will be included in the "List of procurement agencies meeting the WHO standards".

Procurement agencies on the list will be considered to be performing procurement activities in compliance with WHO's recommended Interim guidelines for the assessment of a procurement agency or a MQAS.

Each procurement agency will receive a letter from WHO informing it of the outcome of the quality assessment process in regard of the particular activity performed by that procurement agency.

The list will be compiled in accordance with a standard operating procedure for final decision-making for inclusion in the list. The list should be reviewed and updated at least once a year. The list will be published and will be included on the WHO web page.

2.8 Re-qualification

Routine re-qualification

- Re-inspections of procurement agencies will be made at regular intervals at least once every 3 years.
- Re-evaluation of PAIFs will be done every 3 years.

Non-routine re-qualification

Re-qualification may also be done in the following situations:

— in case of changes that may have an impact on the pre-qualification, purchasing, storage and distribution of products, including changes to key personnel or to the procurement agency site;

— in case of any omission of information in the initial assessment, or if false or misleading information is suspected during the follow-up assessment;
— if any batch or batches of supplied product(s) are considered by WHO or one or more of the UN agencies or organizations, not to be in compliance with the agreed specification of the product (as accepted in the dossier as part of the pre-qualification procedure for products and manufacturers); or
— receipt of a complaint considered to be serious in nature by WHO or one or more of the United Nations agencies or organizations.

Withdrawal and suspension

WHO may suspend or withdraw a pre-qualified procurement agency from the list when there is evidence of noncompliance with the pre-determined general notes and conditions or interim guidelines for the assessment of a procurement agency or a MQAS.

2.9 Testing of samples

Random samples of pharmaceutical product(s) supplied by procurement agencies may be taken for independent testing as appropriate.

In the event of failure to meet the established criteria for re-qualification and testing, WHO will investigate the problem and communicate this to the procurement agency.

2.10 Monitoring of complaint(s)

Complaint(s) concerning the service provided by the procurement agency, or a pharmaceutical product(s) or batch of product(s) supplied by the procurement agency, communicated to WHO, will be investigated in accordance with a standard operating procedure.

After investigation, WHO will provide a written report and include recommendations for action where relevant.

WHO will make a copy of the report available to the procurement agency.

2.11 Cost recovery

WHO reserves the right to charge for the quality assessment procedure on a cost recovery basis.

2.12 Confidentiality undertaking

The inspectors will treat all information to which they will gain access during the inspections, or otherwise in connection with the discharge

of their responsibilities in regard to the above-mentioned project, as confidential and proprietary to WHO or parties collaborating with WHO in accordance with the terms set forth below and those contained in the attached Provisions for inspectors (team members participating in site visits) within the scope of the quality assessment procedure of procurement agencies (see Appendix).

Inspectors will take all reasonable measures to ensure:

— that confidential information is not used for any purpose other than the inspection activities described in this document; and
— that it is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

Inspectors will not, however, be bound by any obligations of confidentiality and non-use to the extent they are clearly able to demonstrate that any part of the confidential information:

— was known to them prior to any disclosure by or on behalf of WHO (including by procurement agencies); or
— was in the public domain at the time of disclosure by or on behalf of WHO (including by procurement agencies); or
— has become part of the public domain through no fault of theirs; or
— has become available to them from a third party not in breach of any legal obligations of confidentiality.

2.13 Conflict of interest

Before undertaking the work, each inspector will (in addition to the above-mentioned confidentiality undertaking) be required to sign a Declaration of Interest in accordance with the terms set forth below and those contained in the attached "Provisions for inspectors" (see Appendix). If based on this Declaration of Interest, it is felt that there is no risk of a real or perceived conflict of interest and it is thus deemed appropriate for the inspector in question to undertake this work, he/she will discharge his/her functions exclusively as adviser to WHO. In this connection, each inspector is required to confirm that the information disclosed by him/her in the Declaration of Interest is correct and that no situation of real, potential or apparent conflict of interest is known to him/her, including that he/she has no financial or other interest in, and/or relationship with a party, which:

— may have vested commercial interest in obtaining access to any confidential information disclosed to him/her in the course of the inspection activities described in this document; and/or
— may have a vested interest in the outcome of the inspection.

Each inspector will undertake to promptly advise WHO of any change in the above circumstances, including if an issue arises during the course of his/her work for WHO.

All inspectors furthermore agree, that at the procurement agency's request, WHO will advise the procurement agency in advance of the identity of each inspector and composition of the team performing the site inspection, and provide curricula vitae of the inspectors. The procurement agency then has the opportunity to express possible concerns regarding any of the inspectors to WHO prior to the visit. If such concerns cannot be resolved in consultation with WHO, the procurement agency may object to a team member's participation in the site visit. Such an objection must be made known to WHO by the procurement agency within ten days of receipt of the proposed team composition. In the event of such an objection, WHO reserves the right to cancel its agreement with the inspector, and the activities to be undertaken by that inspector, in whole or in part.

Appendix

Provisions for inspectors (team members participating in site visits) within the scope of the quality assessment procedure of procurement agencies

In the course of discharging your functions as an expert adviser to WHO under the attached Agreement for the Performance of Work (APW), you will gain access to certain information, which is proprietary to WHO or entities collaborating with WHO, including the procurement agencies which need to be assessed as part of the quality assessment procedure by WHO. You undertake to treat such information (hereinafter referred to as "the Information") as confidential and proprietary to WHO or the aforesaid parties collaborating with WHO. In this connection, you agree:

— *not to use the Information for any other purpose than discharging your obligations under the above-mentioned APW; and*
— *not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.*

However, you will not be bound by any obligations of confidentiality and non-use to the extent that you are clearly able to demonstrate that any part of the Information:

(i) was known to you prior to any disclosure by or on behalf of WHO (including by the procurement agency(s)); or
(ii) was in the public domain at the time of disclosure by or on behalf of WHO (including the procurement agency(s)); or
(iii) becomes part of the public domain through no fault of your own; or
(iv) becomes available to you from a third party not in breach of any legal obligations of confidentiality.

You also undertake not to communicate your deliberations and findings and/or those of the team(s) of experts in which you will participate, as well as any resulting recommendations to, and/or decisions of, WHO to any third party, except as explicitly agreed by WHO.

You will discharge your responsibilities under the above-mentioned APW exclusively in your capacity as an expert adviser to WHO. In this connection, you confirm that the information disclosed by you in the Declaration of Interest is correct and that no situation of real, potential or apparent conflict of interest is known to you, including that you have

no financial or other interest in, and/or other relationship with, a party, which:

(i) may have a vested commercial interest in obtaining access to any part of the Information referred to above; and/or

(ii) may have a vested interest in the outcome of the evaluation of the procurement agencies.

You undertake to promptly advise WHO of any change in the above circumstances, including if an issue arises during the course of your work for WHO.

I hereby accept and agree with the conditions and provisions contained in this document.

Signed _____

Name (typewritten) _____

Institute _____

Place _____ Date _____