WHO/UNFPA Guidance on Notice of Concern and Suspension (Quality Alert)

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Background

A Notice of Concern (NOC) is a letter that is issued to a manufacturer by UNFPA to remind the manufacturer of its obligation to maintain quality assurance procedures and practices. A NOC may also be issued to procurement agencies and other purchasers to alert them to any potential risks associated with a given product or manufacturer.

A Notice of Suspension (NOS), or Quality Alert, is a letter issued by UNFPA to a manufacturer after serious concerns have arisen about the quality of products or services supplied by that manufacturer.

1. Why is an NOC issued?

An NOC is issued both to remind a manufacturer of its obligation to maintain quality assurance procedures and practices, and to inform other procurement agencies of any potential risks associated with a given product or manufacturer.

An NOC is not necessarily cause for public concern. It does not necessarily mean that products or services supplied by the manufacturer are defective or unsatisfactory. If, however, UNFPA does identify a public health risk linked to a given product and manufacturer, it will take appropriate additional steps, including provision of advice to the public. These may include:

- suspension of procurement/distribution of products listed on the UNFPA website for a manufacturer
- issuing an order to temporarily or permanently suspending procurement of products or services from a prequalified manufacturing site.
- temporarily or permanently suspending the prequalified status of a manufacturer.
- recall batches of UNFPA prequalified products that have been procured from a manufacturer or cleared for procurement/distribution by the testing laboratory.
- reject an application for prequalification assessment submitted by the manufacturer.

2. When is an NOC issued?

A notice of concern (NOC) may be issued to a manufacturer for the following reasons:

- when product or service quality issues are identified as a result of prequalification testing, pre-shipment testing, surveillance testing or in-country testing
- when purchasers or users identify serious deficiencies in product quality or services provided
- following observations made during an inspection indicating poor compliance with standard operating procedures or failure to comply with specified quality standards
- if an inspection report identifies an insufficiently robust response to identified nonconformities
- where the corrective actions taken or proposed to be taken are considered and unlikely to deal with the underlying root cause of a critical or major observation; this may include not providing suitable objective evidence of corrective actions
- a requested response to the observations noted in an inspection report detailing corrective actions to be taken or proposed to be taken, has not been received by UNPFA on or before the due date (i.e. 90 days from the inspection date)
- if a manufacturer refuses inspection of a manufacturing site.

If immediate public health concerns have been identified, or if the inspection observations relate to misrepresentation of data, falsification or manipulation of data with the intent to deceive, the NOC will be posted immediately on the UNFPA website (UNFPA has a zero tolerance policy in relation to such activities since they indicate a serious quality system failure that needs to be urgently addressed by senior management responsibility).

3. What does an NOC contain?

An NOC states observations made during an inspection that are considered to be:

- "major" or "minor" non-conformances with UNFPA norms, relevant standards or relevant standard operating procedures that are of concern in relation to quality management or quality assurance
- "major" or "minor" non-compliances with UNFPA norms, relevant standards or relevant standard operating procedures that were not satisfactorily addressed in the response from the company to an inspection.

For example, deficiencies relating to GMP are as follows:

major deficiency — a major nonconformity or observation of a deficiency that has resulted in or that presents a significant risk of producing a product that is harmful to the user

minor deficiency — a non-critical deficiency which either:

- resulted in production or may result in production of product that does not comply with the relevant prequalification requirements and/or
- indicates a major deviation from quality or GMP guidelines
- and/or indicates a failure to carry out satisfactory procedures for release of batches and/or

- indicates a failure of the person responsible for quality assurance/quality control to fulfil his/her duties and/or
- consists of several other deficiencies, none of which in itself is major, but which, combined, may represent a major deficiency and should be explained and reported as such.

4. Is there a right of appeal?

Yes, an NOC contains the factual information based on product testing and/or observations made during an inspection. Results from testing will have been shared with the manufacture and observations will have been discussed during the inspection and listed in the inspection report. Generally, the results or facts that form the basis of the observation(s) are not in dispute. However, the manufacturer, testing laboratory or agencies may disagree that a risk exists or with the level of risk identified by UNFPA and that has resulted in the issuing of the NOC.

If the manufacturer disagrees with any aspect of the inspection report and subsequent NOC, it should send information to UNFPA that gives the basis for its disagreement by email (psb.prequalification@unfpa.org). The matter will then be investigated and a response provided within 15 working days. Should the site not be satisfied with the response, a one to one discussion, via teleconference may be arranged.

5. How long is an NOC in effect?

An NOC will remain on the UNFPA website until UNFPA is satisfied that adequate and appropriate corrective actions have been implemented effectively by manufacturer.

i. When is an NOC lifted?

During the period that an NOC is in place, UNFPA may perform additional and more frequent inspections if the NOC relates to a manufacturing site that is continuing to supplying prequalified product(s). If the manufacturing site has been suspended the next inspection will be performed after the manufacturer has advised that it considers that it has adequately dealt with the observations that led to the issuing of the NOC. Following such follow-up inspection(s), and if satisfied that sufficient improvements have been made, UNFPA will lift the NOC and recommend that the site inspected be named/continue to be named in the relevant dossiers under prequalification or already prequalified. The NOC will be removed from the UNFPA website and archived, and a notice to this effect posted on this website.

ii. Advice to procurement agencies

In all cases where a number of critical and/or a significant number of major observations have been made, and particularly where an NOC was issued and subsequently lifted, UNFPA reminds the relevant manufacturer, testing laboratory, or agencies that the improvements made and the level of compliance with the relevant UNFPA guidelines and/or specifications must be sustained and continue to be improved. Therefore, in accordance with UNFPA's risk-based approach to planning inspections, the next full

inspection — in the case of a manufacturing site testing laboratory — will be performed at an earlier date than usual, and subsequent inspections performed more frequently until evidence has been provided that the improvements implemented are permanent.

Procurement agencies should monitor their suppliers, including monitoring their compliance with international standards. UNFPA therefore expects that they will take appropriate action when an NOC is issued, and after lifting of an NOC apply an enhanced level of due diligence, as part of their supply chain audit and assurance systems, when dealing with suppliers that have failed to comply adequately with international standards.

Organizations supplying products and/or services from a manufacturer for which an NOC has been lifted may expect greater scrutiny from their customers, and should plan to support this in the foreseeable future.

6. Why is an NOS issued?

An NOS is issued not only to remind the manufacturer concerned of its obligations to procurers and product users but also to inform procurement agencies of potential risks associated with a product, if these have been identified. An NOS is also intended to motivate manufacturers to take appropriate corrective and/or preventive actions in a timely manner, and to address observations and non-compliances. Issuing an NOS also helps maintain transparency about UNFPA prequalification activities and decisions.

An NOS will not disclose commercially-sensitive information.

In situations of immediate public health concern an NOS may lead to the:

- withdrawal of product(s) from the UNFPA List of Prequalified Medicinal Devices and Essential Medicines
- recall of batches of products on the UNFPA List of Prequalified Medicinal Device and Essential Medicines that have been supplied by the manufacturer concerned

i. How long will the suspension remain in force?

An NOS will remain on the UNFPA website until the necessary corrective actions have been implemented by the manufacturer and approved by UNFPA. An NOS will be removed from the UNFPA website and archived, and a notice to this effect posted on this website.

ii. Advice to procurers

Procurement agencies should monitor their suppliers, including monitoring their compliance with international standards. UNFPA therefore expects that they will take appropriate action when an NOS is issued, and after lifting of an NOS apply an enhanced level of due diligence, as part of their supply chain audit and assurance systems, when dealing with suppliers that have failed to comply adequately with international standards.

UNFPA advises agencies supplying products from a manufacturing site for which an NOC has been lifted that they should reasonably expect an enhanced level of supervision by their customers, and should plan to support this in the foreseeable future.