WHO’s performance evaluation fees

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1. Introduction

This document provides information to manufacturers on the fees associated with WHO's performance evaluation of in vitro diagnostics (IVDs) pursuant to document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics*" (hereinafter, the "PE Procedure") and the payment process of those fees.

Manufacturers wishing to submit an Expression of Interest for WHO's performance evaluation of their product(s) should read this document before doing so.

2. WHO's performance evaluation fees and payment process

The fees, costs and expenses arising from or relating to any activities that are necessary for WHO's performance evaluation of a product including, but not limited to, the commissioning, implementation and, if necessary, WHO's coordination thereof (collectively, "WHO's performance evaluation fees") will be fully paid for and covered by the manufacturer, and no liability or obligation in connection with WHO's performance evaluation fees shall attach to WHO.

Note: WHO's performance evaluation fees are non-refundable. They are separate from and in addition to any fees, costs and/or expenses arising from or in connection with WHO's prequalification assessment of IVDs.

Payment of WHO's performance evaluation fees does not mean, imply or guarantee that the product will meet, to WHO's satisfaction, the technical requirements for WHO's performance evaluation in accordance with WHO's performance evaluation protocol, or that the product will be accepted for WHO's prequalification assessment, or that the product will be granted WHO prequalification listing.

2.1. Fees and payment process for performance evaluations directly commissioned by the manufacturer

If WHO's performance evaluation is directly commissioned by the manufacturer (i.e., under option A[1]), the amount WHO's performance evaluation fees will be communicated and charged to the manufacturer directly by the Confirmed PEL. As used in this document, the term "Confirmed PEL" means the Performance Evaluation Laboratory that has been selected by the commissioning party and accepted by WHO (in accordance with the terms of the PE Procedure including, without limitation, Section 12 thereof) to implement WHO's performance evaluation of the product.

The amount of WHO's performance evaluation fees under option A will be comprised of:

- All fees, costs and expenses arising from or relating to the implementation of WHO's performance evaluation of the product, as determined by the Confirmed PEL including, without limitation, in light of the expected steps, duration and complexity of such performance evaluation.

The Confirmed PEL will issue an invoice to the manufacturer to request payment of WHO's performance evaluation fees.

[1] Refer to section 8.1. PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics".*

Under option A, the manufacturer is responsible for directly paying to the Confirmed PEL (and any other relevant person or entity) all WHO's performance evaluation fees in a timely and appropriate manner including, without limitation, to the bank account(s) and by the deadline(s) communicated by the Confirmed PEL to the manufacturer.

Without prejudice to any conditions set forth in Section 7.2 of the PE Procedure, WHO's performance evaluation of a product will not commence or proceed unless and until, among other things, the manufacturer has paid and the Confirmed PEL has received the relevant amount of WHO's performance evaluation fees pursuant to and in accordance with the signed contract between the manufacturer and the Confirmed PEL.

Failure to pay WHO's performance evaluation fees within the applicable timelines will result in the termination of the EOI and WHO's performance evaluation of the product pursuant to the PE Procedure.

2.2. Fees and payment process for performance evaluations directly commissioned and coordinated by WHO

If WHO's performance evaluation is directly commissioned and coordinated by WHO (i.e., option B[2]), the amount of WHO's performance evaluation fees will be communicated and charged to the manufacturer directly by WHO.

WHO will issue an invoice to the manufacturer to request payment of WHO's performance evaluation fees. The amount of WHO's performance evaluation fees under option B will be comprised of the following:

a. All fees, costs and expenses arising from or relating to WHO's performance evaluation of the product, as determined by WHO following consultation with the Confirmed PEL. Such amount may vary in light of, e.g., the expected steps, duration and complexity of the performance evaluation; and

b. WHO's coordination cost, in an amount equal to 13% of the full cost of the performance evaluation referred to in clause (a) above (WHO 13% PSC).

Under option B, the manufacturer is responsible for directly paying to WHO all WHO's performance evaluation fees in a timely and appropriate manner including, without limitation, to the bank account(s) and by the deadline(s) communicated by the WHO to the manufacturer in writing (e.g., as part of the provisions of the PE Letter of Agreement).

Without prejudice to any conditions set forth in Section 7.2 of the PE Procedure, WHO's performance evaluation of a product will not commence or proceed unless and until, among other things, the manufacturer has paid and WHO has received the full amount of WHO's performance evaluation fees as well as written evidence of payment thereof.

Failure to pay WHO's performance evaluation fees within the applicable timelines will result in the termination of the EOI and WHO's performance evaluation of the product pursuant to the PE Procedure.

[2] Refer to section 8.1. of document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics".*

3. Date of effect

The terms and conditions of this document will apply to any products for which an Expression of Interest for WHO's performance evaluation is received by WHO on or after 1 January 2026.

4. Contact information

Any inquiries regarding WHO's performance evaluation should be addressed to: diagnostics@who.int