Standard letter B - Prequalification information pack

Dear Sir/Madam,

Application for prequalification of a product under the IMD-PQS system: Prequalification information pack.

We refer to your letter dated <dd.mm.yy> in which you expressed an interest in offering <product/device description> for evaluation under the terms of the IMD-PQS system.

We now enclose a prequalification information pack. If, after reading this, you still wish your product/device to be evaluated against the enclosed product verification protocol, please supply us with a complete Product Dossier which contains all the information requested below, together with the Dossier Examination Fee of <currency><amount>.

We enclose the following:

- Performance specification <description and reference, including revision ref.>
- Product verification protocol <description and reference, including revision ref.>
- Details of the product verification process, including details of the Product Verification Fee.

Your product will be assessed against these documents. If the documents are subsequently amended to an extent which affects your prequalification status, then you will be invited to comment on the proposed changes to the performance specification and/or product verification protocol.

The Product Dossier must include the following:

- General information on the manufacturer or approved installer (including name, address and <licence, where relevant>

EITHER:

- Confirmation that you are either the legal manufacturer or a reseller licensed to act on behalf of the legal manufacturer, carrying product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

OR:

- Confirmation that you are an approved installer, licensed for this purpose by the legal manufacturer(s) of each of the products that you are offering to install.
- All information listed in clause(s) <clause number(s)> of the attached performance specification.
- Indicative cost of the product per unit, <Incoterm> for <specify range numbers, e.g. 1-39 units>.

In addition, in order to evaluate the product/device we will require <detail the number of production-run product samples and all conditions relating to identification, packaging etc.> to be delivered free of charge to <address for delivery>. We also refer you to the general terms and conditions attached to this letter.

Yours faithfully,

World Health Organization

WHO/PQT/VAX/IMD/T&C 1.0
January 2024

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

WHO IMD PQS Standard Terms & Conditions

APPLICABILITY: The Terms & Conditions set out below will apply to all IMD-PQS Prequalification Holders or *prospective* Prequalification Holders.

PREQUALIFICATON HOLDER **OBLIGATIONS:** Prequalification Holders and *prospective* Prequalification Holders should familiarize themselves with this document and ensure that they comply fully with the on-going reporting requirements set out therein. Failure to do so may result in the suspension or withdrawal of prequalified status.

PREQUALIFICATON HOLDER **MANDATORY SIGNATURE:** At the application stage, *prospective* Prequalification Holders must **countersign** these Terms & Conditions as acknowledgement that they understand and agree to be bound by them. The signature zone is found at the end of the document.

STANDARD TERMS & CONDITIONS
1. **Manufacturer intellectual property declaration:** You confirm that you are the legal manufacturer of, and that you have intellectual property ownership of, the IVD to be prequalified. If you have concluded agreements or otherwise established arrangements with any third-party regarding production and/or distribution of the product, you must clearly state the same in the product dossier. In addition, you are responsible for obtaining all cooperation, assistance and information from such third party as are necessary or reasonably requested by WHO in connection with the prequalification process.
2. **Dossier review:** Each product application dossier is screened for completeness before being evaluated, to make sure that all the required information and documentation have been submitted. If the application is incomplete, the applicant will be contacted and will be provided with a single opportunity to submit the missing information or material. If, after a reasonable period has elapsed, the applicant fails to supply the missing information or sample, the application will be rejected. Complete applications will be retained for evaluation.
3. **Acceptable products:** An immunization device (IMD) which has been accepted to proceed in the prequalification assessment must be identical to the IMD described in the pre-submission form and any issues identified at the pre-submission stage must be addressed as part of the eventual product dossier submission. The IMD to be prequalified must be a commercially available product.
4. **Dossier Examination Fee:** The Dossier Examination Fee is non-refundable and must be paid in full in US Dollars, upon receipt of the invoice, before WHO can begin formal evaluation of the dossier.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

5. **Evaluation procedure:** The WHO unit responsible for the evaluation will be independent from all UN agency procurement units. Every product, device or service will be evaluated against the relevant IMD PQS performance specification and product verification protocol(s), current at the time of the evaluation. The applicant will receive a formal decision from WHO, via the e-prequalification (ePQS) portal, advising on the outcome of the evaluation process with regard to each product(s) submitted for prequalification.

   You understand and agree that WHO will have absolute, exclusive, unfettered control over the manner in which the prequalification assessment is carried out, including the publication of the results of the prequalification assessment, regardless of the outcome.

6. **Communication related to ongoing dossier evaluation:** WHO staff will provide all relevant information to your authorized contact as the product proceeds through the prequalification process.

7. **Laboratory testing:** You understand and agree that, where laboratory testing is specified in the relevant product verification protocol, these test will be carried out on production-run products (not prototypes or models of products), supplied by the applicant, in a WHO-accredited laboratory. All the tests specified will be carried out each and every time a product is submitted for testing.

   An applicant whose product has failed one or more of the tests is entitled to resubmit a revised product for the complete sequence of tests; the applicant is not entitled to resubmit solely for the tests that his product has previously failed.

8. **Provision of production-run products:** You understand and agree that sufficient quantities from different lots of the IVD, as defined in the relevant performance evaluation protocol, shall be provided at no charge to the WHO evaluating sites, for the performance evaluation of your product. The product shall be sent ***Free Domicile***, and detailed shipping instructions shall be given to you in due time.

9. **Field testing:** You understand and agree that, in some specific cases, the results of additional testing of a product or device in its intended operating environment must be included in the application dossier. WHO is responsible for identifying product types for which field-testing is mandatory, and will specify the appropriate generic testing method for each product type.

10. **Inspections:** You understand and agree that, subject to a successful review of the product dossier, an inspection of the manufacturing site(s) may be conducted to assess the adequacy and effectiveness of the quality management system under which your product is manufactured. You agree to grant the inspection team unfettered access to the manufacturing site(s) in question and to all relevant documents and records. You also agree to make available relevant staff to provide additional information to, and answer questions of, the inspection team.

11. **Meaning of prequalification:** The granting of prequalified status following a successful evaluation process indicates that the product or device is technically satisfactory for use in national immunization programmes, subject to any limitations set out on the IMD-PQS website or catalogue. There is no possibility to obtain prequalified status via a waiver based on other certification: only the WHO IMD PQS product evaluation may lead to prequalification.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

- The granting of prequalified status does not guarantee that an acceptable commercial arrangement can be reached between the supplier of the product or device and the purchaser; nor does it guarantee that the quality of the delivered product or device will be acceptable to the purchaser. In this context the word, 'purchaser' includes, but is not limited to, national immunization programmes or more than one of the UN agency procurement units, including UNICEF, PAHO, UNDP/IAPSO, UNFPA and WHO.
- Once granted, the ongoing maintenance of prequalified status is wholly dependent on the satisfactory fulfilment of a variety of post-prequalification obligations and requirements on the part of the prequalification-holder. Refer to Clause 8 of these Terms & Conditions.

12. **Publication:** Following satisfactory evaluation, the product, as manufactured at the specified manufacturing site, will be included in the list of 'prequalified' IMD-PQS products and WHO will inform the interested UN agency procurement unit(s) accordingly. Details of the product will then be posted on the IMD-PQS website and will be published in the IMD-PQS catalogue.

13. **Maintaining prequalified status:** Once granted, a product's prequalified status will be maintained until 31st May (the next IMD-PQS Annual Review) without need for further testing as long as there and no major product changes, serious complaints or other faults and issues identified via post-market monitoring (PMM), IMD-PQS WHO quality management (QMS) investigations or via any other source validated by WHO.

→ **IMD-PQS Prequalification Holders are obliged to report ALL product issues, including but not limited to reported product defects, product failures and performance complaints, in real time and without hesitation to the IMD-PQS Secretariat throughout the period of prequalification-holding, not only during the annual review.**

It is essential that Prequalification Holder also keep WHO IMD-PQS fully informed about any administrative or technical changes relative to the product(s) or to the manufacturing process. In this way, the IMD-PQS endorsement of the performance, quality and safety of all prequalified products available for procurement remains valid. Prequalification Holders should also be aware that a change specifically to the manufacturing location/site automatically removes prequalified status and requires a new prequalification application and a new IMD-PQS PQ number/product code.

Re-evaluation of prequalified products may be required in any of the following cases:

- omission(s) by the Prequalification Holder in the initial evaluation procedure or during the follow-up activities, in relation to the requirements, including compliance with quality system standards and failure to notify complaints;
- A batch(es) of supplied product(s) are documented by WHO, Ministries of Health, or one or more of the UN agencies or organizations, not to be in compliance with the agreed specifications of the product or to reveal failure(s) regarding safety, performance or quality of the device;
- the investigation or report of any product-related defects or performance complaints validated by WHO that concludes that the quality and/or safety of the product does not meet performance requirements;

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

- planned or ad-hoc QMS inspections of manufacturing facilities reveal non-conformities with the ISO 9001 or ISO 13485 and/or the specific requirements of WHO performance specifications and verification protocols. Non-conformities will necessitate the satisfactory implementation of corrective or preventive action plans (CAPAs) to avoid the removal of prequalified status.

14. **Monitoring of complaints:** You understand and agree that WHO will investigate reported complaints (from any source) concerning a product, in collaboration with the Prequalification Holder. WHO will maintain a database of complaints.

15. **Confidentiality undertaking:** WHO will treat, and will require evaluators of product dossiers to treat all information to which they will gain access during the evaluation, or otherwise in connection with the discharge of their responsibilities in regard to the prequalification of products in the strictest confidence. In addition, the evaluators of product dossiers will be required to sign a Declaration of Interest with WHO VAX-IMD, including signature of Annex C: Confidentiality Undertaking. If, based on this Declaration of Interest, it is felt that there is no risk of real or perceived conflict of interest and it is thus deemed appropriate for evaluators to undertake this work, they will discharge their functions exclusively as advisers to WHO.

16. **Scope of WHO responsibilities:** For the sake of good order, we should like to emphasize that it is not in WHO's mandate to issue any approvals, certificates or licenses for IMDs. This responsibility lies with the regulatory authority of each country. Furthermore, WHO does not, as a matter of policy, endorse any specific commercial product over others. As mentioned above, the purpose of the WHO Prequalification of Immunization Devices is to provide guidance to WHO Member States and interested UN agencies in their procurement decisions. In this regard, please note that the results of the prequalification assessment, the participation in the WHO prequalification process, the inclusion of any product in the list of prequalified IMDs and/or the WHO name and emblem, may not be used for commercial and/or promotional purposes. WHO will not accept any liability or responsibility whatsoever for an injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with the procurement, distribution and use of any product, as to which WHO has published the assessment results and/or which is included in the WHO list of prequalified IMDs.

17. **WHO Privileges & Immunities**: You understand and agree that, by virtue of WHO's status as a specialized agency of the United Nations, WHO, its officials and experts performing missions for WHO (including, e.g., the prequalification inspectors) enjoy privileges and immunities under national and international laws and conventions, including the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the "1947 Convention"). Nothing contained in or relating to this Letter of Agreement or the prequalification assessment will constitute or be deemed as a waiver of any of the privileges or immunities which WHO, its officials and/or experts performing missions for WHO enjoy pursuant to the 1947 Convention or otherwise under any national or international law, convention or agreement, and/or as submitting WHO, its officials and/or experts aforesaid to any national court jurisdiction.

World Health Organization

WHO/PQT/VAX/IMD/T&C 1.0
January 2024

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

18. The following disclaimer applies to all products that are accepted for inclusion on the IMD-PQS database.

Disclaimer: Inclusion in the list of IMD PQS-prequalified products does not constitute an endorsement, or warranty of fitness, of any product for a particular purpose, including in regard to its safe and appropriate use in immunization programmes. Furthermore WHO does not warrant or represent that: 1) the database is complete or error free and/or that 2) the products that have been found to meet the standards recommended by WHO, will continue to do so and/or that 3) the products listed have obtained regulatory approval for use in every country of the world or that its use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. In addition, WHO wishes to alert procurers (including but not limited to UN procurement agencies) that the improper storage, handling and transportation of products may affect their quality, efficacy and safety. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of products included in the list.

APPLICANT MANDATORY SIGNATURE

If you agree to these Terms & Conditions, please arrange for a duly authorized representative to countersign below on behalf of your company and return it to us, in the manner described below, as part of the product dossier submission.

You must complete, sign and upload a copy of these Terms & Conditions to the WHO e-Prequalification (ePQS) platform, as a part of a complete online prequalification application. You must also include a copy of the first fee's payment attestation (proof of payment) as part of that dossier submission.

Only upon WHO's receipt of the product dossier, this signed Terms & Conditions and the proof of payment of the first fee referred to under paragraph 4 above, will the product dossier be screened for completeness.

→ *Mandatory signature on next page*

World Health Organization

WHO/PQT/VAX/IMD/T&C 1.0
January 2024

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Prequalification Holder COMPANY full legal name:
(In English, printed)

Prequalification Holder company REPRESENTATIVE full name:
(In English, printed)

Commercial PRODUCT name:
(In English, printed)

SIGNATURE of company representative:

Date (DD – MM – YYYY)

Place (Town, Country)