Consent of applicants/manufacturers of a vaccine or a pharmaceutical product, diagnostics and vaccines for WHO to share information with the national regulatory authority(ies) confidentially in Emergency Situations

**Product Details:**

Name of the product:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Description/Platform:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

WHO reference number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Applicant/Manufacturer details:**

Name of entity:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“the Applicant”)

Street:

City and country:

Name of contact person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email:

Telephone:

The Applicant hereby confirms its consent to the World Health Organization (WHO) providing access to the following information and documentation to the national regulatory authority(ies) (NRA) of the countries participating in COVAX[[1]](#footnote-1) (“the NRA”) for the purpose of their assessment as to whether special authorizations, national registration, or emergency use authorization (EUA) of in-vitro diagnostics, pharmaceutical products and vaccines can be granted in the country (the “Purpose”) and authorizes WHO to freely discuss the same with the aforesaid NRA for the Purpose:

* the full WHO prequalification assessment and inspection outcomes (reports), results of laboratory testing, and, if relevant, also assessment and inspections reports of other regulatory authorities, provided that these regulatory authorities have provided their written consent to the use of such reports for the above-mentioned Purpose;
* information and documentation on subsequent variations (as defined in WHO guidelines[[2]](#footnote-2)), as well as information and documentation on any actions taken by WHO, post- prequalification or post-emergency use listing (EUL) of the Product; and
* all available quality data, nonclinical data, clinical data, all other Information regarding Good Practices inspections, and any other documentation provided to WHO by the Applicant for the purpose of WHO prequalification or EUL procedure, as may be reasonably requested by the NRAs.

The above-mentioned data, reports, information, and documentation are hereinafter referred to as “the Information”.

Only Information owned by the Applicant and/or WHO will be shared. Sharing of any other Information is subject to the additional agreement of the data owners concerned.[[3]](#footnote-3)

The Applicant’s consent hereunder is subject to the NRA having signed a Confidentiality Undertaking with WHO.

The Applicant understands that the Information may contain confidential commercial or financial information or trade secrets that are exempt from public disclosure. The Applicant agrees to hold WHO harmless for any injury or damage caused by WHO sharing the Information with the NRAs under the terms set out herein.

By signing this consent form, the signatory below warrants and represents to WHO that he/she has the full authority to sign on behalf of the Applicant and to provide the consents and authorizations mentioned herein.

## For the Applicant / Manufacturer

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manufacturer/Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date (dd/mm/yyyy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. <https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_15-12.pdf> [↑](#footnote-ref-1)
2. For pharmaceutical products: WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty‑seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981), (and any updates thereto).

   For vaccines: <http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/> (and any updates thereto). [↑](#footnote-ref-2)
3. In the case that certain data submitted to WHO by the WHO PQ holder in relation to PQ/EUL of the Product are not in its ownership, the WHO PQ holder should specify such data in an annex to this declaration of consent. [↑](#footnote-ref-3)