**Annex G. GDF access to Information for WHO Prequalified, and ERP assessed TB medicines**

By [*Manufacturer*]

To WHO Prequalification program

To The Global Fund ERP secretariat/QA Team

cc GDF

**To whom it may concern**

By this letter, we authorize the designated staff members of the Global Drug Facility (GDF) of the Stop TB Partnership, as listed below, to access information related to anti-tuberculosis (TB) medicines that have been prequalified by the WHO Prequalification Programme (PQP) and/or assessed by the Expert Review Panel (ERP). This authorization aims to enable GDF to remain informed of developments, progress, and outcomes related to the assessment and prequalification processes.

We permit GDF to access the following information:

* correspondence related to the submission of a new dossier or any variation to

the WHO Prequalification program/ERP;

* assessment report for the submitted dossier,
* correspondence relative to the assessment of the dossiers (request for additional data),
* correspondence informing about the request for an inspection and visit plan,
* outcomes of the inspection and inspection report,
* correspondence relative to the inspection (request for corrective actions plan).

The GDF staff who will have access to this information are:

* GDF Chief
* GDF Strategic Procurement and Business Intelligence Manager
* GDF Lead Quality Officer

The specified GDF staff will take all reasonable measures to ensure:

* that confidential information is not used for any other purpose than specified in this letter and,
* that confidential information is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

The above obligations of confidentiality shall not apply to any information that can be clearly demonstrated to:

* have been known to them prior to any disclosure by or on behalf of WHO (including by manufacturer); or
* have been in the public domain at the time of disclosure by or on behalf of WHO (including by manufacturer); or
* have entered the public domain through no fault of theirs; or
* have been obtained from a third party not in breach of any confidentiality obligations.

Thank you in advance for your cooperation.

Yours sincerely,

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Name and Title of the authorized representative of the Manufacturer

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Signature

Date/Stamp