

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 do authorize limited number of designated GDF staff (indicated below) of the Global Drug Facility (GDF) of the Stop TB Partnership to access information relevant to TB medicines as prequalified by the WHO Prequalification Programme and as assessed by the ERP, in order for GDF to inform on new developments, progress and outcomes of the assessment process.

We permit GDF access in relation to the following items:

- ▶ correspondence informing about 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 Quality Assurance Officer

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

- ▶ that the 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 specified GDF staff will not, however, be bound by any obligations of confidentiality and non-use to the extent they are clearly able to demonstrate that any part of the confidential information:

- ▶ was known to them prior to any disclosure by or on behalf of WHO (including by manufacturer); or
- ▶ was in the public domain at the time of disclosure by or on behalf of WHO (including by manufacturer); or
- ▶ has become part of the public domain through no fault of theirs; or
- ▶ has become available to them from a third party not in breach of any legal obligations of confidentiality.

Thank you in advance for your cooperation.

Yours sincerely,

Name and Title of the authorized representative of the Manufacturer

Date/Stamp