

February 2015

Dear Sir,

Access to Information: WHO Prequalification Programme for TB medicines

By this letter, the Global Drug Facility (GDF) of the Stop TB Partnership requests your pharmaceutical company, “_____” to provide its authorization for a limited number of designated GDF staff (indicated below) to access relevant information submitted to the WHO Prequalification Programme for TB medicines in order for GDF to appreciate new development, progress and outcomes of the assessment process. The GDF is a strong financial and political supporter of the Prequalification Programme and relies upon its list of prequalified TB products to guide the development of its eligibility criteria for suppliers invited to participate in its tenders.

The GDF therefore requests _____ to permit access to the information related to all current and future TB product dossiers under the WHO Prequalification Programme (<http://mednet3.who.int/prequel/>) in relation to the following items:

- correspondence informing about the submission of a new dossier or any variation to the WHO Prequalification programme,
- 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 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 manufacturers); or
 - was in the public domain at the time of disclosure by or on behalf of WHO (including manufacturers); 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
- 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,

Dr Lucica Ditiu
Executive Secretary

In relation to the GDF requests herein, agreed and accepted on behalf of “_____”.

Name and Title:

Date: