

Accelerated procedure for accepting second-line TB product dossiers for assessment by the WHO Prequalification of Medicines Programme

With immediate effect and for second-line TB products only, the requirement for stability **at the time of submission only**, may be reduced to no less than **3 months accelerated, plus 3 months long-term data**, for not less than **two primary batches of at least pilot scale**, or in the case of an uncomplicated¹ FPP (e.g. immediate-release solid FPPs (with noted exceptions), non-sterile solutions), not less than one batch of at least pilot scale and a second batch which may be smaller (e.g. for solid oral dosage forms, 25 000 or 50 000 tablets or capsules) of each proposed strength of the FPP. One of the primary batches (also called exhibit, pre-approval, registration, submission, or test batches) should be the batch that was used for bioequivalence studies.

In some cases, several years of long-term stability data on batches under uncontrolled storage conditions may also be accepted from Zone IV countries.

Please note that all prequalification requirements for final acceptability of the dossier remain in effect, without exception, including but not limited to the submission of updated stability data during the assessment period as it becomes available, and a commitment to provide:

- 1) stability data on three production batches, and
- 2) process validation of three consecutive production batches, to be completed prior to marketing.

Manufacturers of second-line TB products may choose to follow the above accelerated procedure or continue to follow the usual requirements for acceptance of dossiers into assessment by the WHO Prequalification of Medicines Programme.

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¹ The term "complicated FPP" includes sterile products, metered dose inhaler products, dry powder inhaler products and transdermal delivery systems. Other specific products under "complicated FPP" include ritonavir/lopinavir FDC tablets and FDCs containing rifampicin or an artemisinin. As the invitations for EOI change over time, the listing of individual "complicated" FPPs is not meaningful and applicants should contact the Head of Assessments, Prequalification of Medicines Programme in case of doubt.