IMPAACT4TB
PREVENTING TB TO END TB

Responses to questions regarding the Request for Proposal (RfP) for selection of new manufacturer(s) for development and commercialization of affordable Rifapentine-based formulations

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The following questions related to the Request for Proposal (RfP) for selection of new manufacturer(s) for development and commercialization of affordable Rifapentine-based formulations, have been submitted by generic manufacturers. Through this document, CHAI is making all the questions submitted, and the corresponding responses to the questions available to all manufacturers.

1. Q: What is the treatment for: TB or latent TB? In latent TB the daily dose is INH 300mg and Rifapentine 600mg for one month and the weekly one dose is INH 900mg + Rifapentine 900mg for 12 weeks. Why is the development recommendation for INH/RPT 300mg?
A: The products covered under the RfP - RPT 300 mg and/or RPT/INH 300/300 mg – are meant for latent TB treatment. The product will be used as part of the 3HP regimen which comprises of a weekly dose of RPT 900 mg + INH 900 mg for 12 weeks and hence one dose would constitute 3 tablets of RPT 300 mg + 3 tablets of INH 300 mg OR 3 tablets of RPT/INH 300/300 mg FDC.

2. Q: Is the Quality Audit Agreement a mandatory requirement? If so, please provide a justification for the same because in practice we do not encourage 3rd party audit, unless it is by the regulatory agency or the buyer. In case this condition is not fulfilled, will this mean that we cannot be a party to the proposal or is there a way to overcome this requirement.
A: The quality audit is a mandatory requirement and positive results from the audit are required for the manufacturer to receive the award. As required by CHAI quality policies and Unitaid procurement policies, any manufacturer that we engage with must operate under cGMP and a 3rd party audit is required to confirm that this is the case.

3. Q: Could you provide further details on the QA Audit?
A: CHAI will schedule an audit with the top 2-3 manufacturers identified during the RfP process. The audit will be performed by an independent GMP auditor. CHAI will work with the manufacturer(s) to schedule a convenient time for all parties for the audit. The manufacturer must pass the audit in order to be eligible for the final award. The QA Audit will be performed at both API and finished product manufacturing and testing sites. API manufacturing facility will be exempted if that site has a stringent regulatory authority approval for Rifapentine.

4. Q: If our manufacturing site does not have much experience with colored substances, can we consider the option of providing it to a CMO?
A: As described in the eligibility criteria (section 5e, page 6 of the RfP PDF document), a manufacturer must have the proven ability to manufacturer highly colored FDF (e.g. rifampicin, rifabutin, rifapentine, clofazimine, etc.) at development and commercial scale. Therefore, it is not possible to outsource the manufacturing/packaging of finished product to a third-party contractor. However, GMP-assured API may be sourced using standard business practices for API procurement, but the applicant will still have to provide all the required documentation from that quality-assured API source for the program.

5. Q: Does physicochemical properties of API mean Certificate of Analysis of API?
A: The expectation is for a full physicochemical characterization report of the API, which includes a certificate of analysis (CoA). In addition to the CoA, this report should include details about, but not limited to: polymorphic form, crystalline structure, NMR spectrum, particle size, impurity identification, melting point, DSC, TGA, solubility and forced degradation.

6. Q: What does 'Institutional capabilities' refer to?
A: 'Institutional capabilities' refer to an organization's overall financial health, track record of working on TB products and demonstrated commitment towards project accountability through the project team structure.

7. Q: Will the selected manufacturer get a firm forecast on the advance market commitment for Unitaid-funded procurement volumes?
A: The details of the Unitaid-funded procurement volumes for an advance market commitment will be shared/discussed during contract negotiation phase with the award winning manufacturer(s). For now, manufacturers should fill out their expected volume commitments in the RfP questionnaire excel.

8. Q: What will be the amount of the incentive?
A: The incentive will be based on several factors, including:

- The development proposals and budgets that are received from manufacturers and CHAI's internal analysis of the COGS for the product
- Indicated preference for a development grant and/or an advance market commitment

Final incentive amounts will be discussed during the contract negotiation phase after the award is given out.

9. Q: What will be covered in the 1:1 meeting?
A: The 1:1 meeting will be an opportunity for manufacturers to present their development plans to the CHAI team and should be considered as a bid defense meeting. During the meeting, the presenters should cover:

- their detailed development and regulatory plan to meet project milestones;
- their anticipated regulatory pathway for development of the RPT- based formulation;
- any potential obstacles or risks to the development plan and contingency plans to overcome these issues;
- their project team structure and how they plan to incorporate CHAI into the team.

The manufacturer team attending the 1:1 meeting must include technical and regulatory representatives. Those attending must be able to discuss the proposed development and regulatory plan in detail and answer any questions that may be asked. Prior to the meeting, CHAI may request that specific evidence or details be presented to validate the input from the RfP questionnaire.

10. Q: Will all applicants get a 1:1 meeting?
A: No, only eligible manufacturers, as described on page 6 of the RfP PDF document, will be called for a 1:1 meeting.

11. Q: What is the second RfP submission deadline?
A: Following the 1:1 meeting, manufacturers can resubmit a final RfP for consideration with any edits they would like to make within ~10 days of the 1:1 meeting. The exact deadline will be communicated to each manufacturer.