

31 October 2025

Q&A ITB-Iplus/GDF-MED/2025/2

Q1: Clarification Request – ITB-Iplus/GDF-MED/2025/2 – Pretomanid Market Share Allocation.
We would appreciate your clarification with regard to Pretomanid 200mg tablets under ITB-Iplus/GDF-MED/2025/2.

Based on the market share allocation table on page 20 of the ITB document (pasted alongside), could you please confirm whether Pretomanid is expected to be awarded to one, two, or three suppliers?

A1: Please refer Article 3.9.3 of the ITB document - All eligible Bidders will be considered for awards under this ITB to facilitate a sustainable and secure supply of quality-assured products by maintaining a sufficient number of suppliers in the market.

Q2: Page 5, As per clause 1.4: Cut-off date for final submission of clarifications is 29th Oct 2025, 17h00 IST.

Can we request an extension for this deadline? Currently, our team members are travelling and occupied with CPhI activities.

A2: The deadline for submitting the Request for Clarification on the ITB shall remain as currently stated in the timeline within Article 1.4 of the ITB document, with no further extension granted.

Q3. Page 5, As per clause 1.4: Cut-off date for final submission for this tender is 3rd Nov 2025, 17h00 IST.

Can we request an extension for this deadline? Currently, our team members are travelling and occupied with CPhI activities.

A3: As stipulated in Article 1.4 of the ITB document, Monday 03 November 2025, 17h00 IST (India Standard Time) or 12h30 CET (Central European Time) is the cut-off date for any data change in CDP. The deadline for electronic submission of Technical and Financial Bids is Tuesday 04 November 2025, 17h00 IST (India Standard Time) or 12h30 CET (Central European Time) and shall remain in effect without further extension.

Q4. Page 18, As per clause 3.8.9: If the price offered to GDF/i+solutions is higher than the price offered to specific countries (regardless of any difference in the product's quality status), GDF will formally request the Bidder to provide justification for this price difference. GDF reserves the right to submit this justification for independent validation. Suppliers are required to fully cooperate with this independent evaluation. Request you to kindly remove this clause as the bid to other countries are totally based on different QA requirements.

A4: Article 3.8.9 of the ITB document will not be removed. The process stipulated in Article 3.8.9 must be followed. GDF/i+solutions will take the necessary action, as applicable, based on the outcome of the independent evaluation, following the provisions set out in Articles 3.8.9.1 and 3.8.9.2.

Q5. Annex A – Financial Bid Form mentions *DAP MEG warehouse (SEA and AIR)*.

Could you please confirm which quantity we should consider for this? For DAP Sea, should we quote our pricing based on a full-container quantity?

Please confirm if we are also required to quote DAP MEG warehouse (by road). Our understanding is that this pricing condition applies to European suppliers; however, we would appreciate your

confirmation.

A5: Regarding Annex A – Financial Bid Response Form: Please submit the price based on DAP MEG Netherlands (Sea freight) for a full 40-foot container. The DAP MEG Netherlands price by road is not required from Indian suppliers.

Q6. Page 14, As per clause 3.2.6.1. – Products whose registration is confirmed by supporting documents in the CDP Portal FPP registration. Since all the products required in the tender are new, we request you to kindly consider under-registration products as well for evaluation.

A6: As per Article 3.2.6.1 of the ITB, only Products whose registration is confirmed by supporting documents in the CDP Portal FPP registration will be considered for the ITB evaluation.

Q7. Annex L – T.B medicines target prices-As the products are new with very limited players, request you not to restrict bidders by giving target prices, as the cost of developing the product along with the API prices etc are high.

A7: Please refer to Article 3.2.4.4 of the ITB document.

Q8. Page 16, Evaluation weightage of Technical and Financial Bids

Technical bid: 20 points

Financial Bid: 80 points

In previous tenders, we have observed that the evaluation criteria were typically bifurcated as 60% Financial and 40% Technical.

We request that you to kindly adhere to the same bifurcation for this tender as well.

A8: The current evaluation criteria, featuring 20 points for the Technical Bid and 80 points for the Financial Bid, are final and will not be revised. This specific weighting has been established by GDF/i+solutions based on the products currently available in the market and the strategic objectives of this tender. These criteria will be strictly adhered to throughout the bid evaluation process.

Q9. Page 19, as per clause 3.9.4.3 The number of bidders selected for each item will depend on the initial price being within 15% of the competitive price range.

Could you please clarify what exactly is meant by the term “competitive price range” in this context. Additionally, could you provide an indication or reference for the price range that GDF/IPlus is referring for products like Rifapentine 150mg dispersible tablets and Pyridoxine 10mg tablets.

A9: Please refer to the definition of the Competitive Price Range as stipulated in Article 3.8.7 of the ITB document. This definition applies uniformly to all Products included in this ITB, including rifapentine 150mg dispersible tablets and pyridoxine 10mg tablets.

Q10. Page 19, Market Share Allocation- The annex illustrates bidder ranking and price compliance for three bidders. We would appreciate clarification on the methodology or parameters that will be used to assign Ranks 1, 2, and 3 to the bidders and their market share allocation, especially for “Bids within 15% price range”.

We also request you to consider providing secondary or tertiary allocations to bidders whose prices fall outside the 15% price range, in order to maintain a healthy market environment and prevent potential

supply shortages.

A10: The evaluation criteria and scoring methodology used to determine the total points for the Technical and Financial Bids are stipulated in Article 3.8.4. The bidder receiving the highest number of points will be assigned Rank 1, followed by Rank 2, and Rank 3, and so forth.

Market Share Allocation will be awarded based on the specific factors and methodology described in Article 3.9.4.3 of the ITB document.

Bidders whose initial price falls outside the 15% Competitive Price Range may be considered for secondary or tertiary supplier status only if they agree to revise their offer to meet the 15% price range.

Please also refer to Article 3.9.3 and Article 3.9.5. for more details.

Q11. Can we have second round of clarifications as well.

A11: Please refer to the response provided in Answer A2

Q12. Clause 3.2.2.4 – Target Price (Annex L)

We understand and support GDF's intent to use target prices as a mechanism to promote transparency and competitiveness. However, the indicated target price (USD 115 per treatment course / USD 63 per 10x10s) appears substantially lower than the prevailing cost structure for compliant manufacturing, API sourcing, and finished product supply, especially for US FDA Compliant/ WHO-prequalified facilities operating under stringent quality and regulatory frameworks.

We request clarification on the following:

1. Whether the target price is indicative only
2. Whether offers above the target price will still be considered for evaluation, as they are justified by cost drivers such as higher API cost, stability data, or improved supply reliability and many other factors

A12: The answer to both questions is Yes. The target price is indicative only. Offers submitted above the target price will still be considered for evaluation.

Q13. Clause 3.8.7 – Competitive Range (Within 15% of Lowest Bid)

While we appreciate GDF's effort to ensure competitive pricing, we seek clarification for introducing the 15% competitive range clause, as this criterion has not been part of previous tenders.

We would like to highlight that each manufacturer operates under different cost structures influenced by:

1. Scale and geographic
2. API sourcing and supply chain volatility
3. Investments in product development, stability studies, dossier maintenance, and global regulatory filings other factors
4. Efforts in market shaping
5. Ongoing support for clinical studies and post-market surveillance

Restricting the competitive range to within 15% of the lowest bid may unintentionally impacts sustainability We would request removal of this clause as it will be healthier long-term competition without compromising affordability.

A13: Article 3.8.7 of the ITB document will not be removed.

Q14. Clause 3.8.9 – Higher Price to GDF Compared to Other Markets

We fully endorse the principle of equitable and fair pricing. However, it is important to note that differences in price across regions can legitimately arise due to:

1. Regional factors where regulatory standards are different
2. Variations in product requirements, packaging, or labeling requirements,
3. Country specific factors,
4. Volume commitments,
5. Forecast predictability and supply chain risk allocation

We request confirmation that such legitimate commercial and operational factors will be duly considered before interpreting any pricing differential as non-compliance. Ensuring this flexibility is essential to preserving supplier sustainability while maintaining fairness across markets dynamics

A14: Please refer to the response provided in Answer A4

Q15. Exclusion of 26s jar pack:

We also noticed that 26s jar is not included in the tender. We would request you to retain 26s jar as well as some countries may prefer this option

A15: To facilitate a smooth transition and optimize stock management efficiency for pretomanid 200mg (Item n°1 of Schedule 1), GDF/i+solutions has made a strategic decision to harmonize the pack size. Therefore, only the primary and secondary pack configurations detailed in Annex B will be accepted for this ITB.