

Supplier: All suppliers producing WHO-prequalified rifampicin-based tuberculosis medicines (Lupin, Macleods, Svizera).

Subject: Global supply challenges of WHO-prequalified rifampicin-based tuberculosis medicines

Context: Manufacturers of WHO-Prequalified (PQ) first-line TB medicines are currently experiencing supply constraints of rifampicin active pharmaceutical ingredient (API) which is essential for producing these critical products. The shortage of WHO PQ API is predominantly due to the sudden, temporary closure of one of the main WHO PQ API producers. The amount of WHO PQ API available is sufficient to meet GDF's demand from regular clients; but there is insufficient supply to meet an unexpected, recent surge in demand from a few high-burden countries that do not typically procure rifampicin-based products from GDF. These high-burden countries are at imminent risk of stockouts following failed domestic tenders and/or failure of local suppliers to deliver medicines.

Extent of supply delays: Expected delays will be communicated separately for each order.

Recommendations:

1. In light of these challenges, we urge all countries to plan and confirm their orders for rifampicin-based products with GDF at least 8 to 10 months in advance to ensure timely delivery. This proactive approach will assist GDF and its suppliers in managing the increased demand and sustaining the supply of these critical anti-tuberculosis medicines.
2. GDF urges all countries to collaborate closely with GDF, including sharing national data on procurement plans, inventory, and enrollment to ensure equitable prioritization of orders and continuous supply of rifampicin-based TB medicines.

GDF Mitigation Actions:

GDF is working to mitigate the risk of stockouts and ensure sufficient stock to meet programme needs via:

- **Weekly Production Planning:** GDF is coordinating closely with suppliers through weekly production planning meetings.
- **Prioritization Exercises:** GDF is conducting prioritization exercises across all countries to ensure that deliveries are prioritized and stockouts are minimized.
- **Ongoing Country Situation Assessments:** GDF is carrying out continuous assessment of the in-country situation in various countries which, in turn, feeds into the prioritization exercise, allowing GDF to make informed decisions on product allocation.
- **Splitting Shipments:** GDF is splitting large orders into multiple smaller shipments to address immediate country needs and reduce the risk of stockouts.
- **Expediting Shipments:** GDF is escalating efforts to expedite client approvals for shipments, ensuring quicker delivery and access to medicines.
- **Warehouse Expansion:** Key suppliers are expanding their warehouse capacities to better manage stock levels and distribution.
- **Exploring New Warehousing Options:** GDF is exploring the possibility of outsourcing a warehouse in India via its procurement agent in order to enhance logistical efficiency.
- **Expanding API Sources:** GDF is engaging with its suppliers and WHO PQP to expand the pool of quality-assured rifampicin API sources to secure access to rifampicin-based tuberculosis medicines.

- **Exploring Alternative Suppliers for Countries Procuring Directly from Suppliers:** GDF is conducting a landscape analysis to identify potential alternative suppliers for countries who typically procure rifampicin-based medicines directly from suppliers.

Contact Information: For additional information, or if you need support with order planning, please contact either the GDF Country Supply Officer for your programme or gdf@stoptb.org.

We remain dedicated to providing uninterrupted access to quality-assured anti-tuberculosis medicines and look forward to working together with you to address these challenges.

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