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In reply please
refer to: P5-447-3/MS/TC/NoS/TB024

Your reference:

Dr Tayyab Mohyuddin
Technical Director
Wyeth Pakistan Limited
S-33, Hawks Bay Road, S.I.T.E.
P.O. Box 167
75730 Karachi
Pakistan

27 April 2009

Dear Dr Mohyuddin,

**Prequalification of Medicines Programme
Notice of Suspension**

TB024: Ethambutol/isoniazid/pyrazinamide/rifampicin 275 mg/75 mg/400 mg/150 mg tablets

The above-mentioned product has reference. According to the information provided by Wyeth Pakistan Limited on 25 April 2008, in response to the World Health Organization (WHO) letter dated 10 April 2008 regarding "Maintenance of prequalified status", several changes (variations) to the aforementioned prequalified product have been introduced and implemented without submitting corresponding variation applications to the WHO Prequalification of Medicines Programme. These variations include introduction of new rifampicin and pyrazinamide Active Pharmaceutical Ingredient (API) sources and change in storage condition of the product, all of which are major variations requiring prior approval by the WHO Prequalification of Medicines Programme before implementation (see http://healthtech.who.int/pq/info_applicants/Guidelines/Variation_Guide.pdf).

We further wish to remind you that the conclusion from the last inspection performed on site in 2005 was that the company was considered not to be in compliance with current Good Manufacturing Practices (GMP).

For the above reasons WHO is no longer assured of the quality of the product TB024.

Please note the provision in section 11 of the Procedure for Prequalification of Medicinal Products adopted by the Expert committee on specifications for pharmaceutical products in October 2008. (<http://www.who.int/medicines/services/expertcommittees/pharmprep/43rdpharmprep/en/index.html>) which states that WHO may suspend a product until results of further investigations become available and are evaluated by WHO.

.../...

Kindly note that the World Health Assembly Resolution WHA57.14 *"Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS"* of 22 May 2004, which among other actions, requests WHO:

"3.(4) to ensure that the prequalification review process and the results of inspection and assessment reports of the listed products, aside from proprietary and confidential information, are made publicly available;"

As a result of the above we herewith notify you that:

1. WHO will suspend this product with immediate effect until the necessary variation applications have been submitted and approved by the Programme and the site has been inspected and has been found compliant with WHO Good Manufacturing Practices.
2. WHO will withhold prequalification of all new products manufactured at this site until the major observations have been satisfactorily addressed and WHO has verified and confirmed the acceptability of the corrective actions.
3. WHO will now publish this Notice of Suspension on its website. (Please note that a Notice of Suspension will remain active on the WHO Prequalification of Medicines Programme web site until satisfactory corrective actions have been submitted and accepted by WHO).

Please do not hesitate to contact me should you require any information or clarification.

Yours sincerely,



Dr Lembit Rago
Coordinator
Quality Assurance and Safety: Medicines