World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: TB369/MS/FV

Your reference:

Ms Sandhya Jadhav
Manager - Drug Regulatory Affairs
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade Marol Church Road
Andher-Kurla Road Andheri (E)
Mumbai 400 059
Maharashtra
Inde

12 March 2019

Dear Ms Jadhav,

WHO Prequalification Team – Medicines
FPP Prequalification: Acceptance for assessment – Fee request

Application number: TB369-0

Thank you for your letter expressing Macleods Pharmaceuticals Ltd's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and published in the WHO Technical Report Series No. 908, and amended subsequently in the Forty-fifth report, as published in the WHO Technical Report Series No. 961 in 2011.

Your company's product dossier on:

- **Isoniazid/Rifapentine Tablet, Film-coated 300mg/300mg - TB369**

was received by WHO on 20 February 2019, has been screened and is accepted for assessment, with the assigned WHO Reference Number, on condition that payment as indicated below is made. Please quote this reference number in all future correspondence with WHO.

WHO will arrange for the evaluation of the product to be conducted in accordance with the terms of the recommended norms and standards, as specified in the relevant guidelines for the submission of product data and information (as found on the prequalification web page: www.who.int/prequal).

If and when, as a result of the above-mentioned evaluation process, any of the above-mentioned products and corresponding sites are found to meet the WHO recommended standards set out in the Guiding Principles, such products will be included in the list of suppliers whose medicinal products, as manufactured at the specified manufacturing sites, are considered to be acceptable, in principle, for procurement by UN organizations (the list of WHO prequalified medicinal products). This list is published by WHO at www.who.int/prequal. Please refer to the General Notes and Disclaimer, which apply to this list.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the products in question will actually be procured from the suppliers indicated. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the manufacturers or suppliers for commercial or promotional purposes.

In line with the recent announcement regarding application fees (http://www.who.int/medicines/news/prequal_finance_model_q-a/en/), the applicable fee for this application is **US$ 25 000**. The invoice for the fee is attached.

Digitally signed by Chirtoacă Iurie
Date: 2021.09.02 12:24:09 MSK
Reason: MoldSign Signature
Location: Moldova

…/…

In order not to delay assessment, this application has been accepted for assessment on condition that correct payment will be made within 30 days from the date of this letter. Should the required fee not be received within 30 days of the date of this letter, this application will not proceed for assessment and ultimately may be considered abandoned.

Instructions for payment:

1. Payment must be paid by bank transfer into WHO bank account in US$ (no other currency is accepted).

2. All bank charges are to be borne by the payer.

3. Please send a **scanned copy of the bank transfer** by email immediately to prequalassessment@who.int, which will enable us to timely validate receipt of your payment.

Finally, we would like to draw your attention to the fact that the list of WHO prequalified medicinal products will be reviewed and updated at regular intervals. In this regard, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. The failure of a manufacturer or supplier to participate in the reassessment procedure (as set out in the above-mentioned Guiding Principles) will also lead to removal of the list.

Submission of the missing data and information

1. Please provide a clear copy of Isozid (Isoniazid comparator product) labelling with the batch number and expiry date clearly visible.

2. Please provide a copy of valid marketing authorization for the FPP in section 1.2.2 of the product dossier.

3. Please add pdf bookmarks to the Rifapentine API document (Applicant part) to the level 3.2.S.x.x for ease of navigation through the information.

4. Please submit a written commitment to perform process validation for the largest intended commercial batch size (400,000 tablets) in accordance with the process validation protocol, and stating that information from the study will be available for verification after prequalification by the WHO inspection team.

5. Please update the QOS-PD with respect to the following:
   i). Include information on pH, pK, specific optical rotation, hygroscopicity and UV absorption maxima/molar absorptivity of isoniazid API; and specific optical rotation and UV absorption maxima/molar absorptivity of rifapentine API, in the respective tables under section 2.3.S.1.3 (d).
   ii). Include information on process validation of the largest intended commercial batch size (400,000 tablets) under section 2.3.P.3.5
   iii). Replace the batch numbers in the table under section 2.3.P.8.2(c) with annual allocation for ongoing stability studies.

…/…

Please note that product samples and CD/DVDs should be sent to the following address with all packages/containers clearly marked as indicated below.

CONFIDENTIAL
Attention: WHO Prequalification Team – Medicines
Product Number: TB369
UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn, Copenhagen
Denmark

The documentation may also be sent via a secure link to an online document repository. The link should be sent in an email to the following email address : FPPassessment@who.int. The Subject line of the email should clearly indicate "New dossier submission" and the WHO reference number. The date of receipt will be the date the file is successfully downloaded.

Confirmation of administrative data

WHO welcomes your company's interest in voluntarily participating in this programme. In order to facilitate the performance of evaluation in accordance with the terms of the current WHO norms and standards, as well as to foster communication between Macleods Pharmaceuticals Ltd and the WHO Prequalification Team – Medicines, please complete the enclosed form and return it, signed by the authorized person from Macleods Pharmaceuticals Ltd, to the below address in Geneva. We look forward to receiving this information from you within two weeks of the date of this letter at the latest.

WHO Prequalification Team – Medicines
Attention: Prequalification Secretariat
World Health Organization
MVP/EMP/RHT/PQT Room 615
20 Avenue Appia
1211 Geneva 27
Switzerland

For further information regarding the submitted dossier of product **TB369** please use the email address – **prequalassessment@who.int** – ensuring that any such email mentions the corresponding WHO product reference number. Due to confidentiality and security reasons dossier information should not be submitted by email.

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

In relation to the WHO letter
acknowledging receipt of the following dossier
for evaluation in the WHO Prequalification Team – Medicines:

- **Isoniazid/Rifapentine Tablet, Film-coated 300mg/300mg - TB369**

1. The company hereby confirms that the administrative data, as described in the table below, is correct:

		Please enter "confirmed", if correct, or enter precise data
Name of manufacturer	Macleods Pharmaceuticals Ltd	
Address for surface mail	304 Atlanta Arcade Marol Church Road Andher-Kurla Road Andheri (E) MumbaiMaharashtra 400 059 India	
Name and title of primary contact person	Ms Sandhya Jadhav Manager - Drug Regulatory Affairs	
Email address, tel number and fax number of contact person	sjadhav@macleodspharma.com Tel: Fax:	
Name and title of secondary contact person (if applicable)		
Email address, tel number and fax number of secondary contact person	Tel: Fax:	
Name and title of tertiary contact person (if applicable)		
Email address, tel number and fax number of tertiary contact person	Tel: Fax:	

2. In order to foster communication during the evaluation process, the WHO Prequalification Team – Medicines asks Macleods Pharmaceuticals Ltd to kindly:

1) nominate a person responsible for communication with WHO and inform WHO of any change of contact person;

2) correspond with WHO within stated timelines or request WHO for further time in case the timelines cannot be kept and to notify WHO of the date of expected communication;

3) send an invitation for WHO to perform the inspection to assess compliance with GMP at the specified manufacturing site(s) and, if applicable, the compliance with GCP at the specified clinical site(s);

4) allow WHO to reveal the status of product and site evaluation exclusively only to the duly authorized representatives of the UN Procurement agencies, upon their motivated request, without revealing any confidential and commercial information.

Signed on behalf of Macleods Pharmaceuticals Ltd

_____ (Date)

_____ (Name and title)