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: HP026-0/MS/FV

Your reference:

Mr Imtiyaz Basade
Sr Vice-President, Regulatory Affairs
Mylan Laboratories Ltd
Plot No. 564/A/22 Road No. 92
Jubilee Hills
Hyderabad 500096
Telangana
Inde

27 October 2020

Dear Mr Basade,

WHO Prequalification Unit – Medicines Assessment Team
FPP Prequalification – Letter of Prequalification

Application number: HP026-0

I refer to your letter expressing Mylan Laboratories 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.

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- **HP026 - Sofosbuvir/Velpatasvir Tablet, Film-coated 400mg/100mg**

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

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

ENCLS: (2)

Digitally signed by Chirtoacă Iurie
Date: 2022.09.29 14:55:16 EEST
Reason: MoldSign Signature
Location: Moldova

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and
- submit the respective information about the intended variations and the required additional data in electronic format (CD or DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Unit – Medicines
  Product Ref Number: HP026

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

  Please send the link to **FPPassessment@who.int**, if you prefer to submit the response via a file transfer link.

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, 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 an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list. The applicant or manufacturers is obliged to pay the annual maintenance fee, first payment due when the product has been prequalified (included in the prequalified) list for 12 months, and then annually (see https://extranet.who.int/prequal/content/prequalification-procedures-and-fees-0). Failure to pay the annual maintenance fee will lead to the removal of the product from the prequalified list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Mylan Laboratories Ltd and the WHO Prequalification Unit – Medicines, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Mylan Laboratories Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Unit – Medicines
MHP/RPQ/PQT Room 615
20 Avenue Appia
1211 Geneva 27
Switzerland

I look forward to receiving this information from within two weeks of the date of this letter at the latest. For further information please use the email address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Team Lead, Medicines Assessment Team
Prequalification Unit
Regulation and Prequalification Department