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In reply, please refer
to: RH028-1/LN/MS/BQ

Your reference:

Mr Jiang Xiang Wu
VP Quality Assurance
Shanghai Dahua Pharmaceutical Co Ltd
3503 Changzheng Road
Changzheng Farm Chongming County
Shanghai 202174
Chine (République populaire de)

24 November 2023

Dear Mr Wu,

WHO Prequalification Unit – Medicines Assessment

REQUALIFICATION

Application number: RH028-1

I refer to your letter expressing Shanghai Dahua Pharmaceutical Co Ltd interest to participate in the confirmation of prequalification status of your product according to the "Guidelines on the requalification of prequalified dossiers", published as Annex 6 in WHO Technical Report Series 957 (2010), which forms part of 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 assessment procedure. The review of your company's product dossier on:

• **RH028 - Levonorgestrel Implant 75mg per rod (150mg in total)**

has been completed and, including 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 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 is 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.

ENCLS: (2)

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.

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 by email to **prequalassessment@who.int**, clearly marked as indicated, to the following address:

CONFIDENTIAL
Attention: Dr Matthias Stahl
Medicines Assessment Team
WHO Prequalification Unit
Product Ref Number: RH028

UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn, Copenhagen
Denmark

OR

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 emails should clearly indicate the application and the specific medicine procedure referred to.

Finally, I would 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.

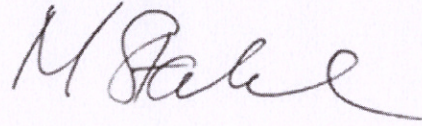
The quality information summary (QIS) reflecting the key characteristics of your product at the time of requalification, accompanies this letter. The QIS is a living document and provides an accurate record of technical data in the product dossier at the time of requalification and thereafter serves as an official reference document during the course of GMP inspections, variation assessments and requalification assessments as performed by WHO.

For variations and requalification dossiers, the QIS should be completed *in its entirety* (regardless of the proposed change). It should include information on *all strengths*, with any changes highlighted and the change history updated (see table at the end of the template), and it should be provided in Word format *at the time of filing*.

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

Undertaking of the applicant

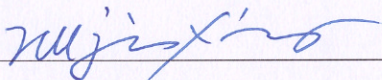
(to be signed by a duly authorized representative of the applicant and returned to WHO)

Shanghai Dahua Pharmaceutical Co Ltd **hereby confirms that it:**

- a) will inform the WHO Prequalification Unit – Medicines, in writing, of any variations to the product included, but not limited to, those specified in the quality information summary (QIS). according to *WHO guidelines on variations to a prequalified product* published in Annex 3 of the WHO Technical Report Series N° 981 in 2013;
- b) authorizes WHO to publish on the WHO Prequalification Unit – Medicines website administrative information and information related to the safe use of the product.
- c) confirms that, subject to the protection of any confidential and proprietary information of the applicant, manufacturer and/or CRO, WHO shall be entitled to use and publish the product and site evaluation information;
- d) furthermore, confirms that WHO shall also be entitled to share the full evaluation and inspection reports with the relevant authorities of any interested WHO Member State.

Signed on behalf of Shanghai Dahua Pharmaceutical Co Ltd.

2023/11/28 (Date)

 (Name and title)