## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company P.T. Tunggal Idaman Abdi submitted in 2019 an application for [RH090 trade name]* (RH090) to be assessed with the aim of including [RH090 trade name] in the list of prequalified medicinal products for contraception in women..

[RH090 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

### 2. Steps taken in the evaluation of the product

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| May 2018 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| January 2019 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| February 2019 | The applicant's response letter was received. |
| March 2019 | During the meeting of the assessment team the quality data and the additional safety and efficacy data were reviewed and further information was requested. |
| July 2019 | The applicant's response letter was received. |
| September 2019 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| February 2020 | The applicant's response letter was received. |
| April 2020 | The additional quality data were reviewed and further information was requested. |
| May 2020 | The applicant's response letter was received. |
| May 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| July 2020 | The applicant's response letter was received. |
| July 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 2020 | The applicant's response letter was received. |
| September 2020 | The applicant's response letters were received. |
| September 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| October 2020 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| November 2020 | The applicant's response letters were received. |
| November 2020 | A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements. |

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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| December 2020 + March 2021 | The additional quality data were reviewed and further information was requested. |
| March 2021 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| May 2021 | The applicant's response letter was received. |
| May 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| May 2021 | The applicant's response letter was received. |
| June 2021 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| June 2021 | Product dossier accepted (quality assurance) |
| 01 July 2021 | [RH090 trade name] was included in the list of prequalified medicinal products. |

## II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacturer and Inspection status

**Manufacturer of the finished product and responsible for batch release**

PT Tunggal Idaman Abdi
Jl. Jend. Ahmad Yani No.7
Jakarta 13230
Indonesia

**Inspection status**

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements

### 2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products