STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company N.V. Organon submitted in 2009 an application for Exlutena 0.5mg tablets* (RH021) with the aim of including Exlutena 0.5mg tablets in the list of prequalified medicinal products for contraception for women.

Exlutena 0.5mg tablets 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. Based on the data submitted the team of assessors advised that Exlutena 0.5mg tablets is included in the list of prequalified medicinal products Exlutena 0.5mg tablets was listed on 02 June 2010.

Exlutena 0.5mg tablets's conformance to the requirements of the current SRA guideline† was re-evaluated by the team of WHO assessors.

Licensing status:
Exlutena 0.5mg tablets has been licensed / registered in Sweden.

The reference SRA changed from The Netherlands (MEB) to Sweden (MPA) in Sept 2019.

The name of the supplier changed to Merck Sharp & Dohme BV, Haarlem, the Netherlands in Nov 2017.

2. Steps taken in the re-evaluation of the product

Dec 2015	WHO letter of request for requalification was sent to the applicant.
March 2016	The application letter was received.
Feb 2017	The assessment team reviewed the submitted data and further information was requested
Nov 2017	The applicant's response letter was received.
Jan 2018	The assessment team reviewed the submitted data and further information was requested
July 2018	The applicant's response letter was received.
Oct 2018	The assessment team reviewed the submitted data and further information was requested
Jan 2019	The applicant's response letter was received.
Feb 2019	The assessment team reviewed the submitted data and further information was requested
May 2019	The applicant's response letter was received.

* Trade names are not prequalified by WHO. This is under local Drug Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

† "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"

May 2019	The assessment team reviewed the submitted data and further information was requested
July 2019	The applicant's response letter was received.
Sept 2019	The submitted data were reviewed and found to comply with the relevant WHO requirements.
12 Sept 2019	Requirements of requalification were met. Exlutena 0.5mg tablets remained on the list of prequalified medicinal products.