I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Merck Sharp Dohme Ltd submitted in 2008 an application for STOCRIN 50 mg film-coated tablets [1] (HA427) to be assessed with the aim of including STOCRIN 50 mg film-coated tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

STOCRIN 50 mg film-coated 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.

STOCRIN 50 mg film-coated tablets' conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

The marketing authorization holder changed from Merck Sharp & Dohme Limited to Merck Sharp & Dohme B.V. on 04 June 2018.

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

March 2016	WHO letter of request for requalification was sent to the applicant.
June 2016	The application letter was received.
December 2016	The assessment team reviewed the submitted data and further information was requested
March 207	The applicant's response letter was received.
August 2017	The submitted data were reviewed and found to comply with the relevant WHO requirements.
28 September 2017	Requirements of requalification were met. STOCRIN 50 mg film-coated tablets remained on the list of prequalified medicinal products.

Further information is available at:

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

https://www.ema.europa.eu/en/medicines/human/EPAR/stocrin
Agency product number EMEA/H/C/000250

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.