I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Merck Sharp & Dohme Limited, Hoddesdon, United Kingdom, submitted in 2008 an application for STOCRIN® 200 mg film-coated tablets[1] (HA428) to be assessed with the aim of including STOCRIN® 200 mg film-coated tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

STOCRIN® 200 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. Based on the data submitted the team of assessors advised that STOCRIN® 200 mg film-coated tablets is included in the list of prequalified medicinal products. STOCRIN® 200 mg film-coated tablets was listed on 14 May 2008.

STOCRIN® 200 mg film-coated tablets' conformance to the requirements of the current SRA guideline[2] was re-evaluated by the team of WHO assessors.

Licensing status:
STOCRIN® 200 mg film-coated tablets has been licensed / registered in the European Union.

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.
Dec 2016	The assessment team reviewed the submitted data and further information was requested.
March 2017	The applicant's response letter was received.
Aug 2017	The submitted data were reviewed and found to comply with the relevant WHO requirements.
28 Sept 2017	Requirements of requalification were met. STOCRIN® 200 mg film-coated tablets remained on the list of prequalified medicinal products.

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

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