I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company F. Hoffmann-La Roche Ltd submitted in 2019 an application for Bactrim Forte 800 mg/160mg tablets[1] (HA748) to be assessed with the aim of including Bactrim Forte 800 mg/160mg tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

Bactrim Forte 800 mg/160mg 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.

The applicant changed to Eumedica Pharmaceuticals AG in March 2021.

2. Steps taken in the evaluation of the product

Sept 2019	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2019	The company's response letter was received.
Nov 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
17 Dec 2019	Bactrim Forte 800 mg/160mg tablets was included in the list of prequalified medicinal products.

[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.

*Formerly Roche AB