STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Krka, d.d., Novo mesto, Slovenia, submitted in 2019 an application for Darunavir Krka 600 mg film-coated tablets[1] (HA733) to be assessed with the aim of including Darunavir Krka 600 mg film-coated tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Darunavir Krka 600 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.

2. Steps taken in the evaluation of the product

March 2019	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 2019	The company's response letter was received.
May 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
11 June 2019	Darunavir Krka 600 mg film-coated tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified-lists

https://www.ema.europa.eu/en/medicines/human/EPAR/darunavir-krka

[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