I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Krka, d.d., Novo mesto, 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 in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Darunavir Krka 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 Darunavir Krka is included in the list of prequalified medicinal products. Darunavir Krka was listed on 11 June 2019.

Darunavir Krka's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

August 2024	WHO letter of request for requalification was sent to the applicant.
November 2024	The application letter was received.
December 2024	The submitted data were reviewed and found to comply with the relevant WHO requirements.
12 December 2024	Requirements of requalification were met. Darunavir Krka 600 mg film-coated tablets remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

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

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.