I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company BrightGene Bio-Medical Technology Co., Ltd, China submitted in 2022 an application for Entecavir Tablets USP, 0.5 mg [1] (HP031) to be assessed with the aim of including Entecavir Tablets USP, 0.5 mg in the list of prequalified medicinal products for for the treatment of chronic hepatitis B virus infection.
Entecavir Tablets USP, 0.5 mg 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

January 2022	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2022	The company's response letter was received.
March 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
22 March 2022	Entecavir Tablets USP, 0.5 mg was included in the list of prequalified medicinal products.

Further information is available at:

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