Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Edenbridge Pharmaceuticals LLC submitted in 2020 an application for Ivermectin Tablets USP[1] (NT009) to be assessed with the aim of including Ivermectin Tablets USP in the list of prequalified medicinal products the treatment of neglected tropical diseases.

Ivermectin Tablets USP 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

July 2020	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2020	The company's response letter was received.
September 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
16 September 2020	Ivermectin Tablets USP 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.