I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bristol Myers Squibb Pharma EEIG submitted in 2016 an application for Daklinza 60mg film coated tablet,[1] (HP008) to be assessed with the aim of including Daklinza in the list of prequalified medicinal products for the treatment of chronic hepatitis C infections.

Daklinza 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 countries of origin of the assessors involved with Daklinza were Germany and South Africa.

Licensing status:
Daklinza has been licensed / registered in at least one of the ICH regions.

2. Steps taken in the evaluation of the product

Sept 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
14 Oct 2016	Daklinza 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 (NMRA) responsibility Throughout this WHOPAR the proprietary name is given as an example only