I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company ViiV Healthcare UK Limited submitted in 2018 an application for Kivexa[1] (Abacavir (as sulfate)/Lamivudine 600mg/300mg tablets), (HA706) to be assessed with the aim of including Kivexa in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Kivexa 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 Kivexa is included in the list of prequalified medicinal products. Kivexa was listed on 18 June 2018.

ViiV Healthcare UK Limited changed to ViiV Healthcare BV in 2018.

2. Steps taken in the evaluation of the product

May 2018	During the meeting of the assessment team, the quality data were reviewed and found to be in compliance with the relevant WHO requirements
19 June 2018	Kivexa 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/finished-pharmaceutical-products

https://www.ema.europa.eu/en/medicines/human/EPAR/kivexa
EMEA/H/C/000581

[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.