Abacavir (sulfate)/Lamivudine   WHOPAR part 7   May 2025
600mg/300mg film-coated tablets
(ViiV Healthcare BV) HA706

I   BACKGROUND INFORMATION ON THE PROCEDURE

1.   Submission of the dossier

The company ViiV Healthcare UK Limited submitted in 2018 an application for Kivexa 600 mg/300 mg film-coated tablets [1] (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.
Kivexa's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

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

Steps taken in the re-evaluation of the product

August 2024	WHO letter of request for requalification was sent to the applicant.
September 2024	The application letter was received.
December 2024	The assessment team reviewed the submitted data and further information was requested
February 2025	The applicant's response letter was received.
March 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
25 March 2024	Requirements of requalification were met. Kivexa 600 mg/300 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/kivexa
EMEA/H/C/000581

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[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.