I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company GlaxoSmithKline Research & Development Limited submitted in 2001 an application for Ziagen 300 mg film-coated tabets[1]) (HA106) to be assessed with the aim of including Ziagen in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Ziagen 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.

Ziagen 300 mg film-coated tablets' conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

The name of the supplier was changed to "ViiV Healthcare BV" in 2021.

2. Steps taken in the re-evaluation of the product

December 2015	WHO letter of request for requalification was sent to the applicant.
April 2016	The application letter was received.
June 2016	The assessment team reviewed the submitted data and further information was requested.
February 2017	The applicant's response letter was received.
March 2017	The submitted data were reviewed and found to comply with the relevant WHO requirements.
28.Sept 2017	Requirements of requalification were met. Ziagen 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/ziagen
EMEA/H/C/000252

[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