I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company GlaxoSmithKline Inc., Greenford, Middlesex, United Kingdom submitted in 2001 an application for Ziagen 20 mg/ ml oral solution[1] (HA107) 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 20 mg/ ml oral solution 's 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.
June 2016	The application letter was received.
December 2016	The assessment team reviewed the submitted data and further information was requested.
March 2019	The applicant's response letter was received.
June 2019	The submitted data were reviewed and found to comply with the relevant WHO requirements.
27 June 2019	Requirements of requalification were met. Ziagen 20 mg/ ml oral solution 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