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.
Based on the data submitted the team of assessors advised that Ziagen is included in the list of prequalified medicinal products. Ziagen 20 mg/ ml oral solution was listed on 20 March 2002.

Marketing Authorisation changed to ViiV Healthcare UK Limited in 2010.
The name of the supplier changed to "ViiV Healthcare BV" in 2018.

Ziagen's conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. 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.
May 2025	The submitted data were reviewed and found to comply with the relevant WHO requirements.
15 May 2025	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