EXPRESSION OF INTEREST (EOI) BRIEFING SESSION: QUESTIONS AND ANSWER SESSION

Date: 17 March 2026
Time: 15:00 – 16:00
Venue: Ms Teams

1. Licensing structure and number of manufacturers

Question
Will there be multiple awards for specific offerings, so multiple manufacturers of the injection, API and/or oral solid formulation, or will it be limited to a certain number per format?

Response
It was highlighted during discussions with Gilead that there has been agreement not to look for a single supplier with end-to-end capabilities. Instead, there could be manufacturers focusing on specific components, including tablets, API (including imported API), and injectable capacity. It was further indicated that this approach may result in identifying two to three companies, allowing time to build local capacity towards full technology transfer by Gilead.

Question
Does the possibility exist for two manufacturers of the API, or two manufacturers of the injectable, or two of the tablets, or will it only be one?

Response
It was further clarified that the decision will be guided by the technical capacity identified during the assessment. It was indicated that all applications will be considered, and comparisons will be made across South African based manufacturers, once all assessments are completed, the recommendations will be made to Gilead who will undertake their own assessment and the final decision.

2. Product information and costing

Question
With regards to costing, will you make available packaging formats and information such as the API being used, the chemistry makeup of the product, and testing methods, so that we can understand and develop a costing?

Response
Detailed innovator process parameters, final specifications, and full technical dossiers are not available for distribution at this initial stage of the EOI process. While some information regarding lenacapavir is in the public domain, the specific manufacturing processes used by Gilead have not yet been shared for this forum.
The current objective of the EOI is to evaluate the technical manufacturing capability and readiness of South Africa-based manufacturers to undertake the development and production

of lenacapavir (API, tablet, and/or injection). Manufacturers are requested to provide information based on their own:

- Cost structures and standard operating procedures (SOPs) for determining development and commercial production costs.
- Technical approach to activities such as API characterization, formulation development, and manufacturing process scale-up.
- Infrastructure and expertise currently in place to support quality assurance and regulatory compliance.

The EOI includes certain indicative requirements to assist with initial costing, for example, the specific need for specialized injectable packaging components such as sterile vials, vial access devices, syringes, and needles. However, deeper technical data exchange and access to tailored technical assistance from SANAC partners will only occur following the evaluation, shortlisting, and execution of Non-Disclosure Agreements (NDAs). This staged approach ensures that sensitive information is protected while identifying the most competitive and capable regional partners.

Cover page and annual volume band

Question

Is there a specific form for the cover page or can we use a generic one? Also, can you elaborate on what is meant by the annual volume band?

Response

It was indicated that an email would be sent following the meeting with details regarding the cover page and the required form.

The SBD 1 form should be sufficient however should manufacturers choose to add a cover letter they are welcome to do so

Response

It was explained that the annual volume band is used to determine how pricing varies with target volumes. Annual volume bands are manufacturer-defined tiers that show ex-works pricing at different annual volumes, reflecting scale effects (batch size, utilization, fixed-cost absorption, QC release burden).

Annexures, marketing authorisation and timelines

Question

The annexures refer to marketing authorisation and manufacturing licence for Lenacapavir, which nobody will be able to provide at this stage. Are you referring to general manufacturing licences for injectables or tablets? Also, the deadline seems tight given the level of detail required. Can the timeline be extended?

Response

It was highlighted that when the EOI was developed and shared with Gilead, a key discussion

point was how to revise timelines to fast-track the process. It was noted that other countries are also exploring securing a Lenacapavir license. Furthermore, based on experience in responding to such EOIs, the one-month period provided was discussed and viewed to be sufficient. It was further stated that the intention is to ensure that the process is not overtaken by developments in other countries.

Response (on WHO PQ / capability):
It was explained that the ideal situation is to have a company with a site that is WHO prequalified. It was further noted that there are situations where the product may not be prequalified, but the site has been inspected or validated by a recognised authority. It was indicated that this information would assist in assessing the robustness and maturity of the manufacturer's quality systems and the annexure was asking for existing manufacturing licenses, GMP evidence, and registration certificates for comparable products/platforms to demonstrate regulatory and quality maturity.

3. Third-party manufacturers and product development

Question
As a third-party manufacturer, we manufacture based on information provided by the holder of the certificate of registration. Some of the requirements, such as product development, are not functions we perform. How should we respond?

Response
It was acknowledged that manufacturers may not currently be producing the product. It was highlighted that, for example, in the case of injectables, manufacturers would have SOPs in place for how products are developed or formulated. It was indicated that the assessment is not based on whether Lenacapavir is currently being produced, but on how manufacturers would approach the process. It was further noted that this would assist in identifying any gaps from an evaluation perspective.

It was emphasised, building on the above response that the focus is on South African-based manufacturers with demonstrated capability and capacity, as captured in the EOI.

It was acknowledged that manufacturers may not currently be producing the product however, taking an example of injectables, manufacturers do have SOPs in place for how products are developed or formulated. As such, the assessment would not based on whether Lenacapavir is currently being produced, but on how manufacturers would approach the process. It was further noted that this would assist in identifying any gaps from an evaluation perspective.

In the case where the manufacturer operates as a CMO, manufacturers were encouraged to respond by describing for example their tech transfer model, development activities they perform in-house vs via partners, and provide SOPs/protocol templates and examples from analogous sterile/OSD products.

4. API manufacturing and process flexibility

Question
Will API manufacturers be required to follow the Gilead process, or will there be an option to look at alternative cheaper routes to produce Lenacapavir API?

Response

It was explained that this question has two components: the first relates to having the licence to operate, and the second to optimisation of the API. It was indicated that this level of discussion had not yet taken place with Gilead, however, in previous cases, provisions for optimisation have existed; but this was dependent on the licensing agreement. These aspects would be addressed during the negotiation stage between the manufacturer and Gilead. Any alternative route would still need to meet agreed impurity profiles/specs and be acceptable under the license and regulatory comparability expectations

5. Quality consistency across manufacturers

Question
If multiple companies are selected to produce a single dosage form, will there be a standardised QC protocol or central oversight mechanism to ensure consistency in product quality across manufacturers?

Response

Consistency is typically ensured through harmonized specifications and validated methods, method transfer packages, shared reference standards, and comparability protocols across sites, supported by licensor/partner technical assistance and inspection readiness. It was highlighted that Gilead has emphasised the need for consistency in the quality of the product across all licensees. It was further noted that there will be some level of support, although what this will look like has not yet been defined. It was indicated that these aspects will be discussed further with Gilead at a later stage.

6. Technology transfer capability

Question
Do you want to see company procedures or SOPs to do a tech transfer from another company, such as Gilead?

Response
It was confirmed that the intention is to understand which companies have procedures and SOPs in place to support readiness for engagement with Gilead. It was further noted that the presence of such SOPs may indicate an understanding of the process and readiness for technology transfer.

7. Additional Clarifications

It was stressed that there are three annexures accompanying the Expression of Interest and that companies must ensure that all required information and documentation are submitted and follow the order listed in the Annexures. It was noted that failure to respond to the annexures may result in disqualification.

Participants were also informed that they could submit questions after the session once they had further considered the EOI document. The closing date for submissions was confirmed as 7 April 2026 at 16:00.