DECLARATIONS

GlaxoSmithKline Export Limited, having its registered office at 79 New Oxford Street, London, United Kingdom, WC1A 1DG, hereby affirms its commitment to ensure the delivery of the vaccine to be awarded under procurement procedure no. ocds-b3wdp1-MD-1755099700999 dated 13/08/2025, in full accordance with the technical specifications, regulatory provisions, and logistical requirements stipulated by the contracting authority. The delivery will adhere to the following conditions:

1. Delivery Terms and Logistics

- Delivery Conditions: In accordance with Incoterms CIP 2020, to Chișinău International Airport, Republic of Moldova (RMO)
- Delivery Timeline: Between January and March 2026, in a single shipment
- Delivery Point: Chișinău International Airport, under CIP 2020 terms

2. Cold Chain Integrity

GSK guarantees that the vaccines will be transported under strict, uninterrupted cold chain conditions maintained between 2˚C and 8˚C from the manufacturing site to the final consignee. Each shipment will include validated electronic temperature monitoring devices, ensuring full traceability, with data made available for verification upon receipt.

3. Shelf Life at Delivery

At the moment of delivery, each vaccine batch will have a **remaining shelf life of at least 60%** of its original validity period, as established by the manufacturer.

4. Product Eligibility and Regulatory Compliance

- The offered product will be accompanied by the Summary of Product Characteristics (SmPC), indicating that it is suitable for administration from 2 months of age.
- The vaccine complies fully with applicable regulatory, safety, and quality standards for pediatric use.

5. Accompanying Documentation

Each delivered batch will be supported by the following documentation:

- A Batch Release Certificate issued by the National Competent Authority of the country of manufacture
- The Manufacturer’s Certificate of Analysis / Test Protocol, attesting to the quality and conformity of the product

6. Packaging and Labelling Requirements

The vaccine targeting Neisseria meningitidis serogroup B will be provided in pre-filled syringes, packed in cardboard boxes or plastic containers. Each unit will include Instructions for Use in English.

Outer packaging will be clearly marked with:

- Manufacturer’s name and address
- Product name and relevant characteristics
- Batch number
- Expiry date (month and year)
- Number of units per pack
- Storage specifications (temperature, humidity, pressure)
- Handling instructions

7. Temperature Monitoring

Each transport unit will be equipped with an appropriate **temperature monitoring device**, to ensure continuous compliance with cold chain requirements throughout the entire delivery process.

This declaration is made in good faith and in recognition of GlaxoSmithKline Export Limited’s contractual obligations. We reaffirm our commitment to providing vaccines that are safe, effective, and compliant with the highest standards of quality and reliability.

Sincerely,
James Bringloe
Partner Markets Head
GlaxoSmithKline Export Limited
03/09/2025