

to the Standard Documentation from

Order of the Minister of Finance
no. 115 of September 15, 2021

Technical Specifications

[This table shall be completed by the bidder in columns 2, 3, 4, 6, and 7, and by the contracting authority in columns 1 and 5.]

Tender's Number: ocds-b3wdp1-MD-1755099700999 from 13.08.2025

Object of the procurement: **Procurement of the vaccine against meningococcal infection caused by Neisseria meningitidis serogroup B, for the year 2026**

	Name of goods /services	Name of goods and / or services	Country of origin	Manufacturer	The full technical specification requested by the contracting authority	Full technical specification proposed by the bidder	Reference Standards
	1	2	3	4	5	6	7
Lot No.	Goods						
1	Meningococcal group B vaccine	Bexsero suspension for injection in pre-filled syringe Meningococcal group B Vaccine (rDNA, component, adsorbed)	Italy	GSK Vaccines S.r.l. Bellaria-Rosia 53018 Sovicelle (Siena) Italy	Meningococcal group B vaccine for the prophylaxis of meningococcal infection caused by Neisseria meningitidis serotype B. ATC code: J07AH09. Pharmaceutical form: Injectable suspension. Unit of measurement: Dose.The vaccine shall be packaged in 0.5 ml single-dose in pre-filled syringes. Accepted will be: 1.Medicines authorized in the Republic of Moldova (at the time of bid opening), or 2.Medicines authorized (at the time of bid opening) by the Drug Committee of the Medicines and Medical Devices Agency (MMDA), included in the Register of Medicines positively evaluated as a result of expert review and testing by the Medicines Quality Control Laboratory (according to the information published on the MMDA official website), or 3.Medicines not authorized in the Republic of Moldova (at the time of bid opening). In the case of offering medicines not authorized in the Republic of Moldova (at the time of bid opening), the following must be submitted: 1. Proof of holding a Good Manufacturing Practice (GMP) certificate issued to the manufacturer of the vaccine, issued in accordance with the recommendations of the European Medicines Agency (EMA), the World Health Organization (WHO), or the U.S. Food and Drug Administration (FDA), authenticated copies (with additional application of the bidder's electronic signature); and 2. Proof of authorization of the offered medicine by the European Medicines Agency (EMA). Additionally, the bidder must submit (both in the case of an authorized and unauthorized medicine in Moldova): 1. Summary of Product Characteristics (SmPC), specifying the minimum age from which the offered medicine can be administered. The vaccine must be eligible for administration to children starting from 2 months of age. 2. A declaration guaranteeing delivery of the vaccine under uninterrupted cold chain conditions (temperature 2°C-8°C) throughout the entire route from the manufacturer to the recipient, confirmed by special temperature recording devices. 3. A declaration guaranteeing that the shelf life of the vaccine at the time of delivery will be: no less than 80% for products with a total shelf life of up to 2 years, and no less than 60% for products with a total shelf life of more than 2 years.. At the time of delivery: Each vaccine batch shall be accompanied by a batch release certificate issued by the national competent authority from the country of origin and the test and investigation protocol performed by the manufacturer certifying the product's quality. General packaging requirements for the vaccine against meningococcal infection caused by Neisseria meningitidis serotype B: 1.Pre-filled syringes must be packed in cardboard boxes or plastic packs, each including instructions for use in Romanian or English, and the outer packaging must contain the following inscriptions: name and address of the manufacturer; type of product and its characteristics; the word "Sterile" (or corresponding symbol); batch number; expiration date (month and year); number of units per pack; storage conditions (temperature, pressure, humidity, etc.); transport and handling conditions. Each transport package must be equipped with a temperature monitoring device.	Bexsero Meningococcal group B vaccine for the prophylaxis of meningococcal infection caused by Neisseria meningitidis serotype B. ATC code: J07AH09. Pharmaceutical form: Suspension for injection for intramuscular use. Unit of measurement: Dose.The vaccine shall be packaged in 0.5 ml single-dose in pre-filled syringe (glass) with needles. We are providing the next documents: 1. Proof of holding a Good Manufacturing Practice (GMP) certificate issued to the manufacturer of the vaccine, issued in accordance with the recommendations of the European Medicines Agency (EMA), the World Health Organization (WHO), or the U.S. Food and Drug Administration (FDA), electronic copy which is also available on EUDRA database; and 2. Proof of authorization of the offered medicine by the European Medicines Agency (EMA). 3. Summary of Product Characteristics (SmPC), specifying the minimum age from which the offered medicine can be administered. The vaccine is eligible for administration to children starting from 2 months of age. 4. A declaration guaranteeing delivery of the vaccine under uninterrupted cold chain conditions (temperature 2°C-8°C) throughout the entire route from the manufacturer to the recipient, confirmed by special temperature recording devices. 5. A declaration guaranteeing that the shelf life of the vaccine at the time of delivery will be: no less than 60% for products with a total shelf life of more than 2 years. We confirm that at the time of delivery: Each vaccine batch shall be accompanied by a batch release certificate issued by the national competent authority from the country of origin and the test and investigation protocol performed by the manufacturer certifying the product's quality. Packaging for the vaccine against meningococcal infection caused by Neisseria meningitidis serotype B: 1.Pre-filled syringes is packed in cardboard boxes or plastic packs, each including instructions for use in English, and the outer packaging contains the following inscriptions: name and address of the manufacturer; type of product and its characteristics; batch number; expiration date (month and year); number of units per pack; storage conditions (temperature, pressure, humidity, etc.); handling conditions. Each transport package is equipped with a temperature monitoring device.	
TOTAL							

Signed:  Name, Surname: James Bringlee In the capacity of Partner Markets Head

Bidder: GLAXOSMITHKLINE EXPORT LIMITED Address: 79 New Oxford Street, London, United Kingdom, WC1A 1DG

Electronically
signed by:
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Bringlee
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signing for the
company as
authorized by
the
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