

SECTION 2

SPECIFICATIONS

TENDER REFERENCE NO.: KK/17/2026/PHARM

**INVITATION TO TENDER
THE SUPPLY AND DELIVERY OF MEDICINES FOR THE DEPARTMENT OF PHARMACEUTICAL
SERVICES MINISTRY OF HEALTH**

NO.	ITEM	ESTIMATED REQUIREMENT	BUFFER STOCK REQUIRED	PACKING/ PRESENTATION	PACK SIZE	DELIVERY PERIOD
1	Dried Factor VIII injection with Von Willebrand Factor (VWF) 1000 iu per unit as Alphanate or its equivalent	600 vials	100 vials	Individual pack preferred	-	First order 2 months, subsequent order 1 month upon receipt of purchase order

Please note that only medicinal products registered with the Ministry of Health, Brunei Darussalam will be considered unless they meet the criteria for medicinal product registration exemptions.

The following documents and/or information are required with each offer. Failure to comply with the requirement may cause unnecessary delay in processing for approval from the relevant authority.

NO.	REQUIREMENTS
1	<p>Price Validity</p> <p>Validity of offer price shall be at least 12 months from the closing date of submission of quote. Where the price validity differs from that required by the Government i.e. 12 months, the LONGER VALIDITY PERIOD will be taken as the final validity period.</p>
2	<p>Sample</p> <p>Vendor is required to submit sample in untampered original pack including package insert and Summary of Product Characteristics (in English)</p> <p>For Controlled drugs and Psychotropics: In the event that sample cannot be submitted, photos and/or artwork are required. See 'Presentation'.</p>
3	<p>Presentation</p> <p>Vendor is to submit:</p> <ol style="list-style-type: none"> i. Clear colour-printed photo of the product offered with company's official stamp. Photo must show label details of the primary and secondary packaging from all sides/angles including name / brand of item, strength and form / preparation. ii. High resolution photo of the following <ul style="list-style-type: none"> ▪ For tablets / capsules: <ul style="list-style-type: none"> ○ Appearance of individual tablets / capsules; ○ If the item is in strip pack, the back and front of the strip ▪ For Injections: <ul style="list-style-type: none"> ○ Appearance of individual vial / ampoule / syringe
4	<p>Registration with Brunei Darussalam Medicines Control Authority (BDMCA)</p> <ul style="list-style-type: none"> ▪ A copy of any of the following: <ul style="list-style-type: none"> ▪ Product Licence Certificate ▪ Letter of authorization from product licence holder, if applicable <p>Priority will be given to medicinal products already registered with the BDMCA.</p>
5	<p>Manufacturer details</p> <p>Please provide manufacturer details with supporting documents.</p> <p>If manufacturer details are not available, please provide the following:</p> <ol style="list-style-type: none"> i. Hardcopy of declaration letter from the principal to inform any issues related to product safety, quality and efficacy as a result of a recall by the manufacturer, wholesaler or Department of Health ii. A copy of the principal's wholesaler license.
6	<p>Shelf life</p> <p>Please indicate the product shelf-life. Priority will be given to product with a minimum of 24 months.</p>

NO.	REQUIREMENTS
7	<p>Storage condition</p> <p>The storage labelling should be in accordance with the latest guideline on registration of medicinal products in Brunei Darussalam.</p> <p>Priority is given to products with specified storage conditions. Terms such as “ambient conditions”, “room temperature” or “does not require any special storage condition” should be avoided unless stability studies are provided.</p>
8	<p>Alcohol and animal content</p> <p>Declaration of source of animal origin and/or alcohol content (if any) is to be provided.</p>
9	<p>Certificate of Analysis</p> <p>A copy of the product’s Certificate of Analysis (CoA) is to be submitted.</p>
10	<p>New Product</p> <p>Where the product offered has never been supplied to the Ministry of Health, Brunei, detailed information on the product is to be submitted. The information required include, but not limited to, the following:</p> <ul style="list-style-type: none"> i. Bioequivalence studies (Generic products) and / or Clinical studies ii. Stability studies iii. Certificate of free sales iv. Certificate of Pharmaceutical Product (CPP) v. A copy of the Summary of Product Characteristics vi. Good Manufacturing Practice (GMP) certificate vii. Batch release certificate or certificate of origin (for blood products)
11	<p>Price Justification</p> <p>Vendor is to submit letter of justification on price increase if the same product has been previously supplied to Ministry of Health from the same supplier / distributor.</p>
12	<p>Local content & Tax Compliance Certificate</p> <p>Vendor is to provide a copy of the latest content of the company as well as the updated tax compliance certificate, if applicable.</p>
13	<p>Product Registration Number in any of the *benchmark/reference countries</p> <p>If not registered with BDMCA, priority will be given to products which are registered in any of the benchmark/reference countries.</p> <p>*The benchmark/reference countries are Australia, Canada, Malaysia, Singapore, United Kingdom, the United States of America, France, Sweden, Japan, Switzerland, Republic of Korea & European Union.</p>
14	<p>Patent Declaration</p> <ul style="list-style-type: none"> i. Vendors quoting generic products must provide an official declaration or confirmation from the Brunei’s Intellectual Property Office verifying whether the innovator product is off-patent. ii. Vendors quoting innovator products must provide information on the patent status and expiry in Brunei.

SECTION 3
TENDER FORM

To:

TENDER REFERENCE NO.: KK/17/2026/PHARM

INVITATION TO TENDER
THE SUPPLY AND DELIVERY OF MEDICINES FOR THE DEPARTMENT OF PHARMACEUTICAL SERVICES MINISTRY OF HEALTH

TENDER OF *(name of tenderer)* _____

Company/Business Registration No _____

Tender Closing Date: _____

NO.	ITEM	BRAND NAME	MANUFACTURER	PACKING/ PRESENTATION	PACK SIZE	UNIT PRICE	TOTAL PRICE
1	Dried Factor VIII injection with Von Willebrand Factor (VWF) 1000 iu per unit as Alphanate or its equivalent						

DELIVERY PERIOD:

First order 2 months, subsequent order 1 month upon receipt of purchase order

DELAY AND LIQUIDATED DAMAGES:

If the Supplier fails or is unable to deliver the Goods or any parts thereof on the Delivery Date within the time specified, the Government shall be entitled, without prejudice to claim from the Supplier by way of liquidated damages for each day of such delay, a sum of equal to one percent (1%) of the price of the Goods as stated in the relevant Purchase Order in respect of the delayed delivery, provided that the total liquidated damages shall not exceed ten percent (10%) the Purchase Order Price.

Please note that only medicinal products registered with the Ministry of Health, Brunei Darussalam will be considered unless they meet the criteria for medicinal product registration exemptions.

The following documents and/or information are required with each offer. Failure to comply with the requirement may cause unnecessary delay in processing for approval from the relevant authority.

NO.	REQUIREMENTS	VENDOR'S OFFER
1	<p>Price Validity</p> <p>Validity of offer price shall be at least 12 months from the closing date of submission of quote. Where the price validity differs from that required by the Government i.e. 12 months, the LONGER VALIDITY PERIOD will be taken as the final validity period.</p>	
2	<p>Sample</p> <p>Vendor is required to submit sample in untampered original pack including package insert and Summary of Product Characteristics (in English)</p> <p>For Controlled drugs and Psychotropics: In the event that sample cannot be submitted, photos and/or artwork are required. See 'Presentation'.</p>	
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NO.	REQUIREMENTS	VENDOR'S OFFER
4	<p>Registration with Brunei Darussalam Medicines Control Authority (BDMCA)</p> <ul style="list-style-type: none"> ▪ A copy of any of the following: ▪ Product Licence Certificate ▪ Letter of authorization from product licence holder, if applicable <p>Priority will be given to medicinal products already registered with the BDMCA.</p>	
5	<p>Manufacturer details</p> <p>Please provide manufacturer details with supporting documents. If manufacturer details are not available, please provide the following:</p> <ol style="list-style-type: none"> i. Hardcopy of declaration letter from the principal to inform any issues related to product safety, quality and efficacy as a result of a recall by the manufacturer, wholesaler or Department of Health ii. A copy of the principal's wholesaler license. 	
6	<p>Shelf life</p> <p>Please indicate the product shelf-life. Priority will be given to product with a minimum of 24 months.</p>	
7	<p>Storage condition</p> <p>The storage labelling should be in accordance with the latest guideline on registration of medicinal products in Brunei Darussalam.</p> <p>Priority is given to products with specified storage conditions. Terms such as "ambient conditions", "room temperature" or "does not require any special storage condition" should be avoided unless stability studies are provided.</p>	
8	<p>Alcohol and animal content</p> <p>Declaration of source of animal origin and/or alcohol content (if any) is to be provided.</p>	

NO.	REQUIREMENTS	VENDOR'S OFFER
9	<p>Certificate of Analysis</p> <p>A copy of the product's Certificate of Analysis (CoA) is to be submitted.</p>	
10	<p>New Product</p> <p>Where the product offered has never been supplied to the Ministry of Health, Brunei, detailed information on the product is to be submitted. The information required include, but not limited to, the following:</p> <ul style="list-style-type: none"> i. Bioequivalence studies (Generic products) and / or Clinical studies ii. Stability studies iii. Certificate of free sales iv. Certificate of Pharmaceutical Product (CPP) v. A copy of the Summary of Product Characteristics vi. Good Manufacturing Practice (GMP) certificate <p>Batch release certificate or certificate of origin (for blood products)</p>	
11	<p>Price Justification</p> <p>Vendor is to submit letter of justification on price increase if the same product has been previous supplied to Ministry of Health from the same supplier / distributor.</p>	
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13	<p>Product Registration Number in any of the *benchmark/reference countries</p> <p>If not registered with BDMCA, priority will be given to products which are registered in any of the benchmark/reference countries.</p> <p>*The benchmark/reference countries are Australia, Canada, Malaysia, Singapore, United Kingdom, the United States of America, France, Sweden, Japan, Switzerland, Republic of Korea & European Union.</p>	

NO.	REQUIREMENTS	VENDOR'S OFFER
14	<p>Patent Declaration</p> <ul style="list-style-type: none"> i. Vendors quoting generic products must provide an official declaration or confirmation from the Brunei's Intellectual Property Office verifying whether the innovator product is off-patent. ii. Vendors quoting innovator products must provide information on the patent status and expiry in Brunei. 	

1. We offer and undertake on your acceptance of our Tender to supply and deliver the above mentioned goods in accordance with your Invitation To Tender.
2. Our Tender is fully consistent with and does not contradict or derogate from anything in your Invitation To Tender. We have not qualified or changed any of the provisions of your Invitation To Tender.
3. OUR OFFER IS VALID FOR **TWELVE (12)** CALENDER MONTHS FROM THE TENDER CLOSING DATE. Where the price validity period differs from that required by the Government i.e. 12 months, the **LONGER VALIDITY PERIOD** will be taken as the final validity period.
4. When requested by you, we shall extend the validity of this offer.
5. We further undertake to give you any further information which you may require.

Dated this _____ day of _____, _____

Signature of authorised officer of Tenderer

Name:

Designation:

Tenderer's official stamp: